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Review

Use of Technology-Based Tools to Support Adolescents and Young Adults With Chronic Disease: Systematic Review and Meta-Analysis

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Abstract

Background: With the large amount of material that is readily available on the internet, there are endless opportunities for electronic health–literate patients to obtain and learn new information. Although novel, a Web- or mobile-based program can be a powerful way to engage adolescents and young adults (AYAs). The ongoing engagement of AYAs with chronic disease is vital not only to empower them but also to ensure a smooth transition from pediatric to adult health care.

Objective: This study aimed to evaluate the current evidence on Web- or mobile-based interventions designed for AYAs.

Methods: This review was registered with PROSPERO: CRD42018096487. A systematic search of MEDLINE Complete, EMBASE, and CINAHL Complete was conducted on April 10, 2019, for studies that examined the perspectives of transition-age patients about technology-based interventions, the process involved in intervention development, or the evaluation of intervention efficacy. For each study, the comprehensiveness of reporting was appraised. The Downs and Black checklist was used for intervention efficacy trials, the Standards for Reporting Qualitative Research checklist was used for qualitative work, and a 16-item tool developed by Tong et al was used for questionnaire research.

Results: The search uncovered 29 relevant studies, which included qualitative studies (n=14), intervention efficacy studies (n=7), questionnaire studies (n=4), mixed qualitative and questionnaire studies (n=2), and a mixed qualitative and pilot randomized controlled trial study (n=1). The reporting comprehensiveness score of questionnaires was rated considerably lower (n=6, 13%-57% [2/16-8/14]) than the scores of intervention efficacy trials (n=8, 48%-85% [13/27-23/27]) and qualitative research (n=17, 40%-93% [8.5/21-19.5/21]). AYAs were receptive to obtaining information via a website or mobile app. An intervention was more likely to be perceived as useful by AYAs when there was a concerted effort to involve AYAs and subject matter experts in the process of intervention design, as opposed to relying solely on the AYAs or the experts alone. The preferred medium of intervention delivery varied greatly for AYAs, ranging from static text to audiovisual materials. However, AYAs considered being concise was the most important aspect. Across different conditions, AYAs were interested in receiving information on diverse topics, such as anxiety and stress management, dealing with insurance, and having social relationships. Patients also requested for disease-specific information, such as weather forecasts and pollen levels for patients with asthma and information related to the pretransplant period for organ transplant recipients. Meta-analyses showed no significant group differences across time on quality of life, self-efficacy, and self-management.

Conclusions: Owing to the lack of intervention efficacy trials, no conclusion can be drawn if an intervention delivered via a mobile app is better than that delivered via a website. However, through this systematic review, it is confirmed that AYAs were receptive to receiving medical information electronically.

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KEYWORDS

young adult; adolescent; self-management; transition to adult care; disease management; systematic review

Introduction

Background

The number of children living with a chronic disease has grown over the past few decades [1-4]. For example, the incidence rate of childhood type 1 diabetes continues to rise by approximately 3% per annum [1,2], whereas the prevalence of cancer increases at 0.6% per annum [4]. The increase in incidence and prevalence may be attributable to medical advances that improve screening and diagnosis in addition to disease management, which altogether offer a better chance of patient survival. One such example is sickle cell disease, which had very few children surviving into adulthood in the 1970s, but 95% of those born in the recent decade will reach their 18th birthday [5]. The change in health care need is inevitable as medical advances are made. To receive age-appropriate care, young patients with pediatric-onset chronic disease need to transition from pediatric to adult health care. Transition is defined as the planned process of preparing adolescents and young adults (AYAs) as they move from caregiver-directed care in a pediatric unit to disease self-management in an adult unit [6].

Although AYAs are no longer children, they are yet to identify themselves as adults. They may be reluctant to detach from the pediatric unit, they may not feel comfortable in the adult care environment, and they may be fearful of their own future after confronting older and sicker patients in the adult unit [7]. If they are not prepared adequately, the transfer to an adult care environment can be problematic, which could cause clinic nonattendance and treatment nonadherence [8-14]. Evidence shows that outpatient clinic attendance among AYAs with chronic diseases, such as type 1 diabetes and sickle cell disease, declines significantly when comparing the pretransfer period with the posttransfer period [8-10]. A study conducted in the United Kingdom reported that 98% of 229 young people with diabetes attended a clinic appointment at least 6-monthly 2 years pretransfer but the proportion declined to 61% at 2 years posttransfer [11]. In a 2015 systematic review, Heery et al [12] reported that between 28% and 63% of adults with congenital heart disease had ≥2 years lapse in care after leaving the pediatric care in Canada, the United Kingdom, and the United States. In a retrospective study involving liver transplant recipients, immunosuppressive medication adherence significantly decreased over time from pretransfer to 2 years posttransfer [14]. These are worrying trends. Not only does patient nonadherence exacerbate symptoms and cause disease progression, but it also leads to the eventual need for more intensive monitoring and expensive treatment. However, there is evidence that an age-appropriate transition program can improve patient outcomes, which include attendance rates and medication adherence in adolescents with inflammatory bowel disease [13] and disease-specific knowledge and satisfaction with care in those with juvenile arthritis [15]. Hence, how the process of transition is managed plays a crucial role in the ongoing engagement of AYAs with the health care system.

To facilitate a successful transition, AYAs with chronic disease need to be equipped with self-management skills and be engaged with their treatment plan to maintain positive health outcomes [16]. A Cochrane review by Campbell et al [17], which was conducted in 2016, only found 4 small randomized controlled trials with sample sizes that ranged from 26 to 81. The trials covered a limited range of interventions, which included a 2-day face-to-face–delivered workshop [18], an 8-month Web-based and text-delivered disease management and skill-based intervention [19], a one-off meeting with a nurse [20], and a structured transition program involving a transition coordinator over a 12-month period [21]. No firm conclusions could be drawn from the intervention studies [17].

Objective

An emerging area that is worth exploring is the use of Web- or mobile-based materials to engage AYAs. It can be an innovative way to build their skills and prepare them for the transition process [22,23]. As parental and clinician assumptions may fall short of identifying the needs of AYA patients, it is critical to obtain knowledge of AYAs' perspectives. This knowledge will help ensure that the needs of AYA patients are addressed and that AYAs are appropriately supported through the designed intervention during their transition from pediatric to adult health care. This systematic review aimed to evaluate the current evidence on Web- or mobile-based interventions by summarizing studies that examined either the perspectives of AYAs or intervention efficacy.

Methods

Protocol and Registration

The protocol for this systematic review was registered with PROSPERO 2018: CRD42018096487 [24]. It was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines (PRISMA) [25].

Eligibility Criteria

Studies that met the following criteria were included in the review:

- There were no restrictions on the study design, provided that it was primary research exploring the perspectives of patients about a technology-based intervention; a methods paper describing the intervention development process; or primary research evaluating intervention effectiveness.
- The intervention must be freely available through a device that can be connected to the internet in the form of an app on a mobile device or on the World Wide Web; designed for patients with at least one chronic disease; and accessible by patients at any time.
- Study participants could be aged less than 18 years or adults (aged ≥18 years) who were either transitioning or had already transitioned to adult health care services.

Studies were excluded based on the following criteria:

- The only aim of the technology component of the intervention was to allow participants to engage with another party online, such as forums and social media platforms; test a serious game; test an equipment, such as a Bluetooth spirometer and blood glucose monitors; and

remotely monitor patient progress, such as patient portals and symptom reporting platform.
- Studies where pediatric group findings could not be delineated from research involving other patient groups, such as middle-aged persons and older patients.

Search Strategy

Overall, 3 electronic databases were searched: MEDLINE Complete via EBSCOhost (1967 to March 31, 2019), EMBASE (1972 to March 31, 2019), and CINAHL Complete via EBSCOhost (1978 to March 31, 2019). The search utilized terms associated with the concepts of *technology*, *transition* or *disease management*, *chronic disease*, and *adolescents* or *young adults*. An example of the search strategy is included in Multimedia Appendix 1.

Study Selection

Search results were collated in a reference manager (EndNote X8, Clarivate Analytics, 2017), duplicates were deleted, and the results were exported to a spreadsheet (Microsoft Excel, Microsoft Corporation, 2016) for initial screening of titles and abstracts. The screening was conducted independently by 2 reviewers (JKL and EM) whereby a priori inclusion and exclusion criteria were applied. The same reviewers further reviewed the full texts of articles independently to select studies for inclusion according to the eligibility criteria. Manual checks on the reference lists of retrieved reviews on the relevant topic were conducted to identify articles not found by the database searches. Discordance between reviewers was resolved through discussion.

Data Extraction and Quality Assessment

For each included study, the following items were extracted: study characteristics, participant demographics, and study design using a standardized form entered into Microsoft Excel. Data related to the design of a technology-based intervention were also extracted.

For studies using multiple methods, the comprehensiveness of reporting was appraised using checklists applicable to the major methodological approach of each study. The Downs and Black checklist (D&B) was used for intervention efficacy trials [26], the Standards for Reporting Qualitative Research (SRQR) checklist was used for qualitative research [27], and a 16-item tool developed by Tong et al [28] was used for questionnaire research. Owing to the lack of clarity on how to score item 27 in the D&B checklist (power calculation), a score of 0 or 1 was allocated to indicate whether the authors achieved their target sample size or not. If no power calculation was conducted a priori, a score of 0 was given for item 27. The same approach has been used by previous researchers [29,30]. No study was excluded based on the quality assessment.

Data Synthesis and Analysis

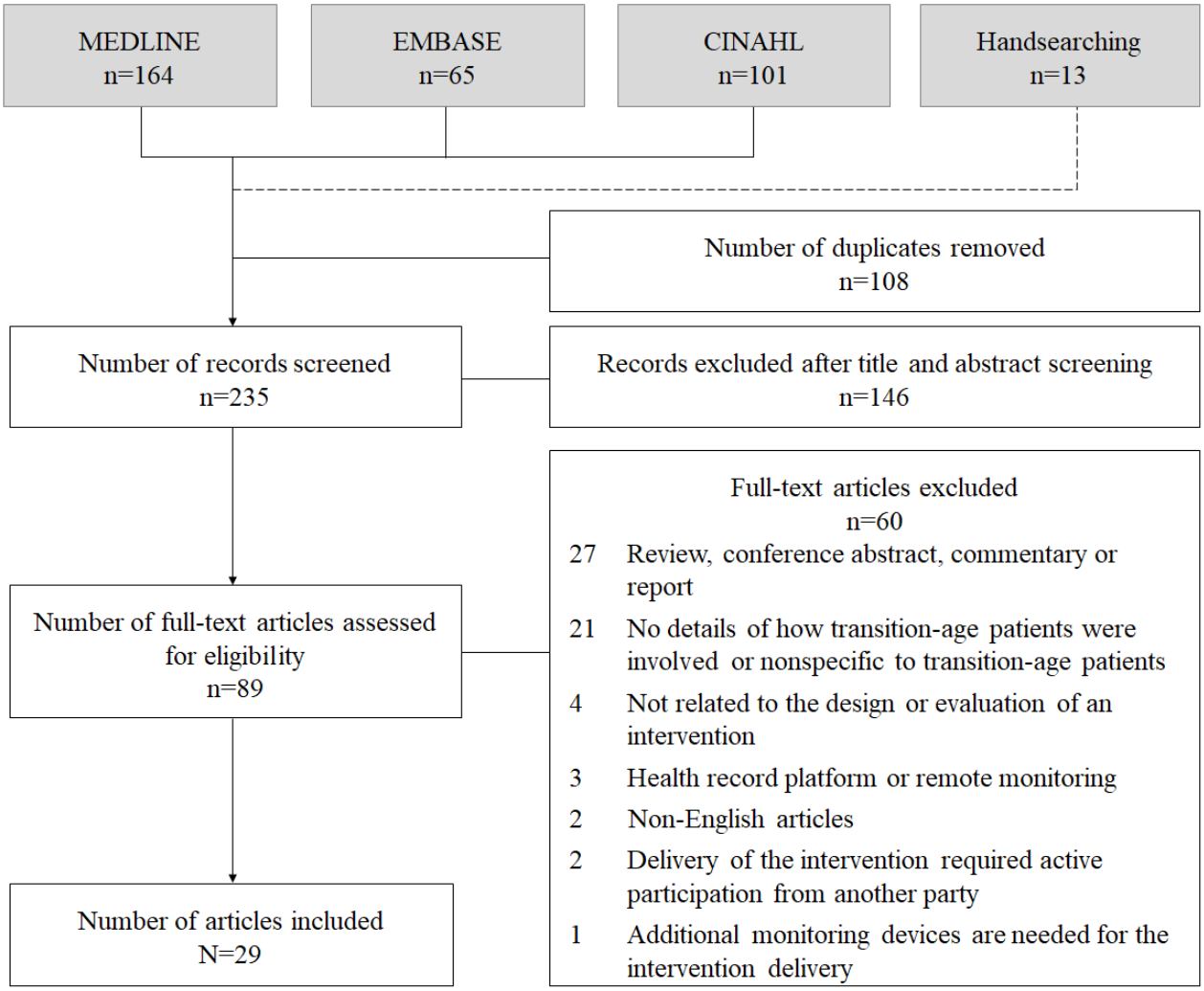
Data collected from all qualitative studies, including mixed-methods, exploratory, and feasibility studies, using interviews and focus groups in addition to open-ended responses to items in questionnaires, were extracted and organized using NVivo (version 11, QSR International Pty Ltd). Qualitative data were pooled and thematically analyzed using the method outlined by Thomas and Harden [31] by a reviewer (JKL). Quantitative data were pooled for meta-analyses using RevMan (version 5.3, The Cochrane Collaboration). Where a meta-analysis could not be conducted as a result of the small number of available studies, a descriptive synthesis of the quantitative findings was undertaken instead.

Results

Study Selection

The initial search yielded 235 records. Of these, 89 were selected for full-text review, which led to further exclusion of 60 studies because of ineligibility (Figure 1). Overall, 29 studies were included in the review [19,32-59].

Figure 1. Study flow diagram.



Study Characteristics (N=29)

All studies (N=29) were conducted in developed countries (Table 1). Diabetes was the most investigated type of chronic disease (n=9) followed by rheumatic disease (n=6), asthma (n=5), and cystic fibrosis (n=4), whereas 2 studies did not specify the type of chronic disease examined [32,35]. Participants were aged between 7 and 28 years (Table 2).

A total of 17 studies utilized a qualitative approach: 6 exploratory studies [32,39,51,53,54,57], 3 multiphase studies involving the iterative design and development of an intervention [43,47,52], 2 feasibility studies [34,45], 2 usability studies of an intervention [42,55], 1 evaluation of user experience [50], and 3 mixed-methods studies [35,38,58].

Among the included studies, 6 studies had a questionnaire component in the study design: a feasibility study [33], a cross-sectional survey to inform the development of an eHealth intervention [40], a multiphase study involving the iterative development and user evaluation of an intervention [36], an evaluation of user engagement [59], and 2 mixed-methods studies [35,38].

In addition, 8 studies included an intervention efficacy trial, of which one was a mixed-methods study [58]. The conduct of a randomized controlled trial was the most popular design (n=3) [19,41,44] followed by a pilot randomized controlled trial (n=3) [37,56,58]. The remaining intervention efficacy trials utilized a nonrandomized controlled study design [48] and a pretest -posttest design [46].

Table 1. Description of included studies (N=29).

Study identity	Country	Study design	Type of chronic disease	Quality assessment
Abraham et al [32]	United States	Exploratory qualitative design using semistructured interview	—[a]	SRQR[b]: 15.5/21
Ammerlaan et al [33]	Netherlands	Quantitative feasibility study using a Web-based questionnaire	Rheumatic disease	Tong[c]: 7/13
Ammerlaan et al [34]	Netherlands	Qualitative feasibility study using semistructured interview	Juvenile idiopathic arthritis	SRQR: 17/21
Applebaum et al [35]	United States	Mixed methodologies, cross-sectional study: questionnaire and qualitative using focus group	—	Tong: 8/14; SRQR: 9/21
Ashurst et al [36]	United Kingdom	2-stage approach: stage 1 development and stage 2 evaluation using email and a Web-based questionnaire	Diabetes	Stage 2 Tong: 6/16
Breakey et al [37]	Canada	Pilot randomized control trial	Hemophilia	D&B[d]: 19/27
Coyne et al [38]	Ireland	Four-phase participatory iterative approach using questionnaire, one-to-one interview, participatory workshop, and Google Analytics	Diabetes, cystic fibrosis, or congenital heart disease	Phase 1 Tong: 2/14; Phase 1 SRQR: 11/21
Huang et al [39]	United States	Exploratory qualitative design using a focus group	Diabetes, cystic fibrosis, or IBD[e]	SRQR: 15/21
Huang et al [19]	United States	Randomized controlled trial	Diabetes, cystic fibrosis, or IBD	D&B: 23/27
Johnson et al [40]	United States	Cross-sectional study: Web-based questionnaire	Juvenile arthritis	Tong: 7/14
Joseph et al [41]	United States	Randomized controlled trial	Asthma symptoms	D&B: 19/27
Korus et al [42]	Canada	Qualitative usability testing approach using semistructured interview	Solid organ transplant recipient	SRQR: 15/21
Lopez et al [43]	United States	Formative iterative process using semistructured interview and group interview	Congenital heart disease	SRQR: 17/21
Mulvaney et al [44]	United States	Randomized controlled trial	Diabetes	D&B: 15/27
Mulvaney et al [45]	United States	Qualitative feasibility study	Diabetes	SRQR: 11.5/21
Paul [46]	Australia	Two-phase, multimethod approach: phase 1 evaluation of intervention fidelity and phase 2 feasibility pre- to posttest	Diabetes	Phase 2 D&B: 14/27
Peters et al [47]	Australia	Multiphase, participatory user research study using participatory workshop, workbook, and user evaluation	Asthma	SRQR: 16/21
Runge et al [48]	Germany	Nonrandomized trial	Asthma	D&B: 17/27
Scal et al [49], Secor-Turner et al [60]	United States	Descriptive paper on the intervention development process	Juvenile arthritis	N/A[f]
Schneider et al [50]	United States	Qualitative evaluation of user experience using semistructured interview	Asthma	SRQR: 14/21
Schneider et al [51]	United States	Exploratory qualitative design using semistructured interview	Asthma	SRQR: 18/21
Simmons et al [52]	United States	Multiphase, iterative design and development of an intervention: environmental scan, Web-based or telephone focus group, and in-person focus group	Hemophilia	SRQR: 13.5/21
Slater et al [53]	Australia	Exploratory qualitative design using semistructured interview and focus group	Musculoskeletal pain	SRQR: 19/21
Sterling et al [54]	Canada	Exploratory qualitative design using semistructured interview	Hemophilia	SRQR: 15/21

Study identity	Country	Study design	Type of chronic disease	Quality assessment
Stinson et al [55]	Canada	Qualitative usability testing with semistructured interview	Juvenile idiopathic arthritis	SRQR: 18.5/21
Stinson et al [56]	Canada	Pilot randomized controlled trial	Juvenile idiopathic arthritis	D&B: 21/27
Stinson et al [57]	Canada	Descriptive exploratory qualitative design using focus group and interview	Chronic pain	SRQR: 19.5/21
Whittemore et al [58]	United States	Multiphase mixed-methods design: qualitative using focus group and think-aloud method, followed by a feasibility and pilot study	Diabetes	Phase 1 SRQR: 8.5/21; phase 2 D&B: 13/27
Zhao et al [59]	Australia	Pilot study using questionnaire	Diabetes, cystic fibrosis, or IBD	Tong: 2/16

[a]Not specified or not reported.

[b]SRQR: Standards for Reporting Qualitative Research.

[c]Tong: the 16-item checklist questionnaire developed by Tong et al [28].

[d]D&B: Downs and Black checklist for intervention efficacy trial.

[e]IBD: inflammatory bowel disease.

[f]N/A: not applicable.

Table 2. Description of participant demographics.

Study identity	Number of participants[a]	Mean age (SD or range)[a]	Age group (n)[a]	Gender (male), n (%)[a]
Abraham et al [32]	20	__[b]	7-11 (4), 12-14 (9), 15-17 (7)	8 (40)
Ammerlaan et al [33]	IG[c]: 10; CG[d]: 9	IG: 22.3 (17-25); CG: 20.7 (17-25)	—	IG: 1 (10); CG: (2) 22
Ammerlaan et al [34]	13	20 (17-22)	—	1 (8)
Applebaum et al [35]	Questionnaire: 35; Focus group: 20	Questionnaire: 16.9 (13-20); Focus group: —	—	Survey: 9 (26); Focus group: —
Ashurst et al [36]	Stage 1: 6; Stage 2: 83	Stage 1: 20.3 (3.3); Stage 2: 19.0 (2.6)	—	Stage 1: —; Stage 2: 37 (45)
Breakey et al [37]	29	IG: 16.0 (1.4); CG: 16.1 (1.4)	—	29 (100)
Coyne et al [38]	Phase 1 questionnaire: 207, interview: 21; phase 2 co-design group: 5, telephone interview: 4, participatory workshop: 12	—	Phase 1 questionnaire: 14-25 (207), interview participants: 14-25 (21); phase 2 co-design group: 15-25 (5), telephone interview: 15-25 (4), participatory workshop: 15-25 (12)	Phase 1 questionnaire: —, interview participants: —; phase 2 co-design group: 2 (40), telephone interview: —, participatory workshop: —
Huang et al [39]	10	20 (18-25)	—	4 (40)
Huang et al [19]	IG: 40; CG: 41	IG: 17 (12-20)[e]; CG: 17 (12-19)[e]	—	IG: 17 (43); CG: 20 (49)
Johnson et al [40]	134	High PedsQL_Psycho: 15.9 (—); low PedsQL_Psycho: 16.3 (—)	—	High PedsQL_Psycho: 10 (15); low PedsQL_Psycho: 12 (18)
Joseph et al [41]	314	15.3 (1.0)	—	115 (37)
Korus et al [42]	21	—	12-14 (7), 15-17 (13), 18 (1)	14 (67)
Lopez et al [43]	Phase 2 expert panel: 6	Phase 2 expert panel: 16 (15-19)[e]	—	Phase 2 expert panel: 2 (33)
Mulvaney et al [44]	IG: 48; CG: 24	IG: 15.1 (1.5); CG: 15.1 (1.3)	—	IG: 25 (52); CG: 15 (62)
Mulvaney et al [45]	41	IG only: 15.1 (1.5)	—	IG only: 21 (51)
Paul [46]	Phase 1: —; phase 2: 5 (*Only 3 participants completed phase 2)*	—	Phase 1: —; phase 2: 14 (1), 15 (3), 17 (1)	Phase 1: —; phase 2: 3 (60)
Peters et al [47]	20	17.8 (15-24)	—	8 (40)
Runge et al [48]	178	IG1: 11.1 (2.4); IG2: 11.0 (2.2); CG: 11.5 (2.9)	—	IG1: 47 (55); IG2: 29 (66); CG: 38 (79)
Scal et al [49], Secor-Turner et al [60]	Youth: 5; Young adults: 5	Youth:16.2 (14-21)[f]; Young adults: 25.4 (22-28)[f]	—	Youth: 2 (40)[f]; young adults: 1 (20)[f]
Schneider et al [50]	16	—	13-18 (16)	—
Schneider et al [51]	20	14.4 (1.6)	—	9 (45)
Simmons et al [52]	Web-based focus group: 40; In-person message testing focus group: 19	—	Web-based focus group: 16-17 (24), 18-19 years (16); In-person message testing focus group: 16-17 (12), 18-19 (7)	—
Slater et al [53]	23	20.8 (2.4)	—	3 (13)
Sterling et al [54]	11	16.3 (12.8-18.3)	—	11 (100)
Stinson et al [55]	19	15.7 (1.5)	—	5 (26)
Stinson et al [56]	IG: 22; CG: 24	IG: 14.4 (1.3); CG: 14.8 (1.7)	—	IG: 7 (32); CG: 8 (33)
Stinson et al [57]	23	—	14-18 (23)	5 (22)

Study identity	Number of participants[a]	Mean age (SD or range)[a]	Age group (n)[a]	Gender (male), n (%)[a]
Whittemore et al [58]	Phase 1 intervention development: 3; Phase 2 randomized pilot trial: 12; program evaluation: 10	Phase 1 intervention development: —; phase 2 randomized pilot trial: 14.4 (0.9); program evaluation: 14.0 (1.2)	—	Phase 1 intervention development: —; phase 2 randomized pilot trial: 5 (42); Program evaluation: 6 (60)
Zhao et al [59]	10	20.2 (—)	—	3 (30)

[a]Characteristics of parent, health care professional, or healthy participants are not included.

[b]Not specified or not reported.

[c]IG: intervention group.

[d]CG: comparison group.

[e]Median years (minimum-maximum).

[f]Information was obtained from a related, secondary source.

Comprehensiveness of Reporting

An evaluation of the comprehensiveness of reporting was conducted for all studies, except for Scal et al [49] as the authors did not present any qualitative or quantitative data, and it merely provided a description of the intervention development process. All mixed-methods studies were assessed using 2 separate checklists [35,38,58]. One study, which was identified by the authors as a mixed-methods approach, was actually a study involving multiple methods including a literature review, Web-based or telephone focus group, and in-person focus group [52]. Overall, the reporting of questionnaires was rated considerably lower (n=6, scores from the questionnaire developed by Tong et al [28]: 13%-57% [2/16-8/14]) than the intervention efficacy trials (n=8, D&B scores: 48%-85% [13/27-23/27]) and qualitative research (n=17, SRQR scores: 40% -93% [8.5/21-19.5/21]).

Of the 17 qualitative research papers, 4 were missing at least 40% of the items considered important on the SRQR checklist (Multimedia Appendix 2). Most studies were lacking in detail on the data processing of participants' responses before data analysis, such as the procedure to ensure anonymity and rigor (n=14), an indicative title containing information that it was a qualitative study (n=13), the characteristics of the data collector that may influence the research such as qualification and relationship with participants (n=12), and the context from where participants were recruited (n=12).

All 6 studies that included a questionnaire were missing at least 40% of the items considered important on the Tong et al [28] 16-item checklist for reporting questionnaire studies (Multimedia Appendix 3). None of the 6 studies included details on participants' response rate, characteristics of refusals, if follow-up reminder was provided, and whether the questionnaire was piloted.

Of the 8 studies that reported an intervention efficacy trial, 3 were missing at least 40% of the items considered important on the D&B checklist (Multimedia Appendix 4). All the studies did not detail how the sample size was estimated, a majority did not detail if blinding of participants and data collectors occurred (n=7) and if there were any adverse events as a result of the intervention or the lack of it (n=7). In 5 studies, the reporting of the results was not ideal [19,37,41,44,58]. For example, 3 studies reported within-group comparisons, whereas the reporting of between-group comparisons across time was lacking in detail [19,37,44]. One study reported having the intervention group showing trends for "better diabetes self-efficacy, better general treatment and less perceived stress" [58, p.7] than the control group; however, the reported *P* values were .20, thereby, demonstrating a lack of statistical significance.

Summary of Interventions (n=22)

Of the 22 studies which provided a description of the intervention (Multimedia Appendix 5), 8 were evaluated in an efficacy trial. All of the 8 evaluations were conducted on Web-based interventions [19,37,41,44,48,56,58].

Most interventions were delivered via a website (n=13) [19,34,37,38,41,42,44,46,48,49,52,55,56,58]. Other modes of delivery included a mobile app (n=4) [47,50,57,59] and a choice of 3 websites and 3 mobile apps developed by peers (n=1) [36]. In addition, 8 interventions were based upon theories, such as Social Cognitive Theory, Self-Determination Theory, Self-Efficacy Theory, and Social Learning Theory [19,33,44,46,47,49,57,58].

Adolescents and Young Adults' Perceived Usefulness or Acceptability (n=16)

Perceived usefulness or acceptability was explored in 14 interventions across 16 studies because 2 of the interventions, *Challenge your arthritis* [33,34] and *Teens Taking Charge: Managing Arthritis Online* [55,56] were evaluated twice (Multimedia Appendix 6). Most of the interventions (n=11) received a positive reaction from the participants [33,34,37,42,44,46,47,51,52,55-58]. Of the 3 interventions that received a neutral response, 2 did not involve pediatric patients in the intervention development [50,59], whereas one fully relied on AYAs without the involvement of a health care professional or content expert [36].

Adolescents and Young Adults' Preferred Intervention Design

The use of preexisting technology, such as a mobile app, not designed specifically for AYAs was not appealing to them [50]. As indicated by 91% of AYAs in the study conducted by Ashurst et al [36], AYAs' input was important to ensure that the intervention was tailored to their needs.

Preferred Delivery Method

AYAs' preferred delivery method ranged from concise text to interactive content [50,53,58]. Placement of the information was important, whereby one study reported that AYAs wanted the most important information on each page at the top of the page [55]. Adolescents suggested incorporating visually appealing features, such as pictures and graphics [55], and games or audiovisual medium to create an engaging website [42,43,51,54]. Learning about medications through interactive games on a tablet or watching educational videos at a kiosk was also preferred [32]. Quizzes were considered more engaging than the sole use of text [54]. In addition, visual aids that allowed patients to view the severity level of their condition based on their symptoms were found be useful [50].

The main advantage of a Web- or mobile-based intervention was that it was readily accessible and it could be browsed at any time at the AYA's preferred pace [38,39]. To optimize uptake, AYAs suggested that a mobile app should be affordable and be made available on major mobile platforms whilst a website should be mobile-optimized [53]. Furthermore, an app that could perform offline would further optimize usage [51].

Short videos were very appealing to AYAs, especially those that provide support on the medical, lifestyle, and psychological aspects of living with a chronic disease [50,52]. Video testimonial by young people was deemed as an important way for AYAs to realize that they were not alone in their struggles [38]. In those interventions that incorporated videos or life stories, AYAs were able to understand the content easily and enjoyed watching the videos because they recognized themselves in the stories relayed [34,42,52].

Information Needs

AYAs suggested using peers with chronic disease to comment on topics such as disease management tips, transition experiences [39], and disease experiences [54]. In addition, AYAs would like to receive disease-specific news or research updates [39,54]. In preparation for their transition to adult care, AYAs sought to obtain practical information, such as the differences between child and adult health care, the clinic's location, and key staff members [38].

Across different conditions, mental health support was found to be an appreciated feature by AYAs [34,39,47]. Huang et al [39] reported that young adults wanted to learn how to manage anxiety and stress, intimate relationships, alcohol and drug situations, and health insurance regardless of their condition. Similarly, Ammerlaan et al [34] reported that the most appealing topics were on how to deal with pain, fatigue and emotions, physical exercise, holidays, study, and work. Hence, rather than emphasizing health care and medical information, AYAs preferred to learn about challenges at school, work, and social settings and the emotional burden that they would be experiencing [49].

Suggestions to include disease-specific information were mentioned by AYAs. For example, patients with asthma mentioned about incorporating real-time reports concerning environmental conditions, such as pollen levels and weather forecasts, within an app [50]. They wanted a mobile app that could be customized to include their own profile with a personal medical history and treatment summary, reminders, a symptom tracker, access to emergency information even in the absence of an internet connection, and motivational feedback [47,51]. Conversely, young adults with juvenile idiopathic arthritis wanted reliable sources of medication information to be accessible via the website [34]. For organ transplant recipients, they wanted to have information relevant to the pretransplant period, details about medical emergencies or complications, and a section for parents [42]. Patients with hemophilia sought to learn about the pathology and severity of hemophilia, first aid, emergency services, and activity limitations [54].

Support From Peers or Health Care Professionals

Compared with face-to-face interactions, AYAs preferred an online support group [40,54]. One study reported that AYAs were wary of using chat rooms and existing social media sites to talk to strangers because of privacy concerns [35]. However, 7 other studies reported that AYAs would like to have the opportunity to network with their peers [34,39,42,43,53-55], which could help to ease feelings of isolation. Online discussion forums [34,42,54] or *question and answer* forums or use of a platform to share achievements [47] were suggested by AYAs as ways that they could feel connected with others diagnosed with the same condition. Although they might not post to the forum, 96% of AYAs revealed that reading comments posted by others was useful [45]. Some AYAs liked being able to contact or share information with their health care providers [35,47,50,51].

Synthesis of Quantitative Data (n=8)

A total of 8 studies included an intervention efficacy trial, and all evaluations were conducted on Web-based interventions; none included a mobile app (Multimedia Appendix 7). For one study that had 3 groups of participants, the evaluation of intervention efficacy was reported based on the comparison between the "standardized patient management program (SPMP)" group and the "internet-based education program plus standardized patient management program (IEP+SPMP)" group as opposed to the "usual care" group [48]. Meta-analysis did not include studies that had no control group [46] and those that did not report standard deviation [48,58] as group comparisons could not be conducted. Information requests were sent but there was no response from the corresponding authors [48,58].

The most frequently measured outcomes were quality of life, self-efficacy, and self-management. The combined data for meta-analysis showed that there was no statistically significant group difference in quality of life (n=3, standardized mean difference −0.15, 95% CI −0.52 to 0.22; P=.43), self-efficacy (n=3, standardized mean difference 0.15, 95% CI −0.17 to 0.47; P=.23), and self-management (n=3, standardized mean difference 0.11, 95% CI −0.18 to 0.40; P=.44).

Discussion

Principal Findings

This systematic review examined 29 articles, which were published between 2006 and 2019, and included primary

research articles discussing Web- and mobile-based interventions.

Using the qualitative data, this systematic review revealed that AYAs were very receptive to obtaining information electronically. AYAs were more likely to perceive an intervention as useful when there was a concerted effort of involving AYAs and experts in the process of intervention design as opposed to relying solely on AYAs or experts alone. However, engaging AYAs in research could be difficult. Ashurst et al [36] reported that many AYAs cited study commitment as a reason for nonparticipation or withdrawal although the project was conducted at a time that coincided with school holidays. Similarly, Simmons et al [52] faced difficulties in recruiting participants although an extensive strategy was used, and a cash incentive was offered. With the growing consensus about the crucial role that patients play in improving the value of health care research, there is a clear need to identify the best methods to achieve engagement, which is currently lacking [61]. To engage AYAs, research suggests that the most effective recruitment approach may be one that is initiated by AYAs' own health care providers combined with social media outreach and frequent contact [62].

Although AYAs had different preferred styles of message delivery, ranging from static text to audiovisual materials, being concise was the most important part to keeping them engaged. The findings of this systematic review revealed approaches that can be undertaken to design an intervention for AYAs; however, it also contains suggestions suitable for young school-aged children. The use of engaging technology can be a fun and easy way to captivate patients' attention and to encourage learning [32,35,53]. For example, young school-aged children can benefit from an intervention with audiovisual content about self-management and their condition. However, depending on the age group that the intervention is targeting, there is a need to use age-appropriate language.

Using the combined quantitative data, the meta-analysis showed that efficacy of the interventions on quality of life, self-efficacy, and self-management skills could not be found. With only 3 sets of data available for each outcome, the insignificant findings could be because of the study heterogeneity (I^2 score ranged from 27% for self-management to 50% for quality of life). A conclusion cannot be drawn on the overall effect of a Web-based intervention in preparing AYAs to self-manage their condition and to become independent adults in comparison with usual care. As there was no intervention efficacy trial on a mobile app, no conclusion can be drawn if a mobile app is a better tool for AYAs than a website. There was also a lack of high-quality randomized controlled trials as only 3 intervention efficacy trials obtained a D&B score of ≥20 out of a possible 27 items. The omission of information in intervention efficacy reports made it hard to assess if there were biases that could have influenced the findings. In particular, the reports did not detail the characteristics of participants who were lost to follow-up, and if blinding of participant and data collector was achieved. Similarly, studies that utilized a questionnaire failed to detail response rates and if the questionnaire used was piloted before distribution. The methodological shortcomings make it difficult for future investigators to adopt or refine the strategies used in designing or refining an intervention.

To date, systematic reviews have been conducted to examine the use of technology-based interventions in young people, such as the prevention and treatment of pediatric obesity [63] and suicide prevention [64]. Like the findings of this systematic review, other researchers found that there is a paucity of current evidence for technology-based interventions to improve patient outcomes [63,64]. The use of a Web- or mobile-based intervention is a relatively new area. As evidenced in this systematic review, the oldest study retrieved was published in 2006. There is a rise in the number of research studies undertaken given that most studies (n=17, 61%) were published between 2015 and 2019. Although there are many trials exploring AYAs' perspectives, quality randomized controlled trials assessing the efficacy of an intervention are lacking.

Limitations

The findings of this systematic review and meta-analysis should be interpreted with caution because of several methodological limitations. First, in the hope of uncovering replicable and inexpensive interventions, this systematic review focused on interventions that did not require extra resources, such as a device or a third party. However, it was found that AYAs wanted to obtain support from their peers or health professionals online. The extent of how this support enhanced the effectiveness and the reach of an intervention could not be concluded from this systematic review. Second, the included studies consisted of qualitative, quantitative, and mixed-methods studies, making it difficult to compare the quality of the studies. The different study designs also meant that the data were so varied that it was difficult to ascertain the effects of the interventions on overall AYAs' transition readiness. Nonetheless, the findings provided information on AYAs' preferred intervention design for future work. Finally, although there were no language restrictions when searching the major medical databases, it was acknowledged that a search including foreign language databases may reveal additional studies published in languages other than English in developed and developing countries.

Conclusions

This systematic review revealed that AYAs were receptive to receiving information through a website or mobile app, which is a first step to engaging them in their own care. Although no conclusion can be drawn on an effective intervention design because of the lack of intervention efficacy trials, this systematic review contained information about AYAs' preferred intervention. In designing an AYA-focused intervention, the best approach would be to first identify AYAs' disease-specific needs. This is to be coupled with or followed by obtaining suggestions from health professionals caring for AYAs. Finally, it is essential to obtain AYAs' feedback on the style and content of the designed intervention. Such a systematic iterative process will ensure that the designed intervention is accepted by AYAs, in the hope that it will improve patient engagement during the transition process and, thus, patient outcomes. Providing AYAs an age-appropriate, reliable condition-specific resource, which can be accessed anywhere, is the very first step in supporting

them to becoming resourceful independent adults managing their own care.

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Authors' Contributions

JKL and EM were responsible for the idea conception, protocol refinement, and data analysis. JKL contributed to the drafting, whereas EM contributed to the revision of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Search strategy.

[PDF File (Adobe PDF File), 302KB - mhealth_v7i7e12042_app1.pdf]

Multimedia Appendix 2

Quality appraisal of the qualitative component of the studies.

[PDF File (Adobe PDF File), 303KB - mhealth_v7i7e12042_app2.pdf]

Multimedia Appendix 3

Quality appraisal of the questionnaire component of the studies.

[PDF File (Adobe PDF File), 336KB - mhealth_v7i7e12042_app3.pdf]

Multimedia Appendix 4

Quality appraisal of intervention efficacy trials.

[PDF File (Adobe PDF File), 351KB - mhealth_v7i7e12042_app4.pdf]

Multimedia Appendix 5

Characteristics of included interventions.

[PDF File (Adobe PDF File), 132KB - mhealth_v7i7e12042_app5.pdf]

Multimedia Appendix 6

A summary of feasibility study or users' perceived acceptance of theintervention (n=16).

[PDF File (Adobe PDF File), 458KB - mhealth_v7i7e12042_app6.pdf]

Multimedia Appendix 7

A summary of intervention efficacy evaluations (n=8).

[PDF File (Adobe PDF File), 762KB - mhealth_v7i7e12042_app7.pdf]

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Abbreviations

AYAs: adolescents and young adults

D&B: Downs and Black checklist
SRQR: Standards for Reporting Qualitative Research

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Original Paper

What Patients Want in a Smartphone App That Supports Colonoscopy Preparation: Qualitative Study to Inform a User-Centered Smartphone App

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Abstract

Background: The preparation for colonoscopy is elaborate and complex. In the context of colorectal cancer screening, up to 11% of patients do not keep their colonoscopy appointments and up to 33% of those attending their appointments have inadequately cleansed bowels that can delay cancer diagnosis and treatment. A smartphone app may be an acceptable and wide-reaching tool to improve patient adherence to colonoscopy.

Objective: The aim of this qualitative study was to employ a user-centered approach to design the content and features of a smartphone app called *colonAPPscopy* to support individuals preparing for their colonoscopy appointments.

Methods: We conducted 2 focus group discussions (FGDs) with gastroenterology patients treated at the McGill University Health Centre in Montreal, Canada. Patients were aged 50 to 75 years, were English- or French-speaking, and had undergone outpatient colonoscopy in the previous 3 months; they did not have inflammatory bowel disease or colorectal cancer. FGDs were 75 to 90 min, conducted by a trained facilitator, and audiotaped. Participants discussed the electronic health support tools they might use to help them prepare for the colonoscopy, the content needed for colonoscopy preparation, and the features that would make the smartphone app useful. Recordings of FGDs were transcribed and analyzed using thematic analysis to identify key user-defined content and features to inform the design of *colonAPPscopy*.

Results: A total of 9 patients (7 male and 2 female) participated in one of 2 FGDs. Main content areas focused on bowel preparation instructions, medication restrictions, appointment logistics, communication, and postcolonoscopy expectations. Design features to make the app useful and engaging included minimization of data input, reminders and alerts for up to 7 days precolonoscopy, and visual aids. Participants wanted a smartphone app that comes from a trusted source, sends timely and tailored messages, provides reassurance, provides clear instructions, and is simple to use.

Conclusions: Participants identified the need for postcolonoscopy information as well as reminders and alerts in the week before colonoscopy, novel content, and features that had not been included in previous smartphone-based strategies for colonoscopy preparation. The ability to tailor instructions made the smartphone app preferable to other modes of delivery. Study findings recognize the importance of including potential users in the development phase of building a smartphone app.

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KEYWORDS

colonoscopy; early detection of cancer; mobile health technology; qualitative research; smartphone; user-centered

Introduction

Colorectal cancer screening has been recommended by the Canadian Task Force on Preventive Health Care for individuals aged 50 to 75 years since 2001 [1,2]. Colorectal cancer screening is a preventive health behavior that typically increases the chance of survival by detecting and treating precancerous polyps (growths) and asymptomatic colorectal cancer. Colonoscopy is the recommended follow-up examination for individuals who screen positive to stool testing for colorectal cancer and are at high-risk for colorectal polyps and cancer. However, colonoscopy is an invasive procedure that requires complex and elaborate preparation including consumption of a laxative, restriction of food and liquids, and cessation of certain medications in the week leading up to the colonoscopy appointment. Studies show that up to 11% of individuals do not keep their colonoscopy appointments [3,4] and up to 33% of those attending colonoscopy have inadequately cleansed bowels that can impair colonic visualization [5-11]. Nonadherence to colonoscopy follow-up can delay cancer diagnosis and treatment and waste health care resources in terms of the financial costs for rescheduled and repeat colonoscopies. This is noteworthy because, in Canada, colorectal cancer is the second most commonly diagnosed cancer and the second and third leading causes of cancer deaths in men and women, respectively [12].

Patient educational strategies have been used to improve patient adherence to colonoscopy follow-up. Tools including booklets, cartoons, and short message service (SMS) text messaging have been shown to boost rates of colonoscopy follow-up compared with usual care [13]. More recently, smartphone-based strategies have been developed to help patients prepare for colonoscopy [14-24]. Studies of smartphone-based strategies supporting colonoscopy preparation most often show better outcomes (eg, higher bowel cleansing quality scores) in the intervention groups compared with usual care control groups [14-17,22-24]. However, there was no evidence that the designs of these smartphone-based tools were informed by input from intended end-user groups [14-17,22-24], limiting their utility. Involvement of potential users in the early stages of app development is likely to optimize usage by aligning the app content and features with user-elicited preferences [25,26]. User-centered models involve understanding the environment of intended end users, often through focus group discussions (FGDs) [27]. In fact, one Canadian provincial colorectal cancer screening program that sought to increase screening uptake conducted FGDs to optimize the content and features of its mailed invitations [28]. Feedback obtained from intended users was then used to guide the redesign of the mailed invitations [28].

Mobile health apps have been created following a qualitative user-centered approach in which FGD methodology was used in the design phase to provide insights into end-user needs [29-31]. Previous apps addressed enduring or modifiable health behaviors, such as sun protection, diet, and physical activity [29-31], and their features may not be relevant to screening colonoscopy, a preventive health behavior that occurs once every 10 years according to Canadian guidelines [1,2]. To date, little is known about user-elicited preferences for an app that supports colonoscopy screening.

In this study, we employed a user-centered approach to design a smartphone app called *colonAPPScopy* to support the needs of patients preparing for colonoscopy in the context of colorectal cancer screening. We conducted FGDs to elicit user preferences to inform the content and features of our smartphone app.

Methods

Study Design

We conducted FGDs with individuals who recently underwent colonoscopy as they would be knowledgeable about user needs and preferences during colonoscopy preparation. Focus groups were considered the most appropriate method to collect data as group interactions enable the exploration of a broader range of views and prompt group members to frame and clarify individual and shared views [32,33]. The aims of the FGDs were to determine the content (*what*) and features (*how*) of the smartphone app.

Participants and Recruitment

Gastroenterology outpatients at the McGill University Health Centre in Montreal, Canada, were eligible for participation if they were aged 50 to 75 years, were fluent in English or French, and had undergone colonoscopy in the context of screening within the past 3 months. We excluded patients with inflammatory bowel disease or colorectal cancer as these patients routinely undergo colonoscopy. Given their frequent experiences with colonoscopy preparation, we assumed their needs would be different than the needs of our intended end users who have a screening indication for colonoscopy.

Participants were recruited through purposive sampling. At their colonoscopy appointments, eligible patients were asked by their gastroenterologist if they were interested in participating in a study to build a smartphone app to support patients preparing for colonoscopy. The study research assistant subsequently phoned them to provide further information about the study and invited them to participate in an FGD. Potential participants were made aware of the topic of the focus group at the time they were invited to join, which gave them time to consider what they wanted and did not want to discuss. Participants were remunerated Can $25 for parking or transportation, and a lottery for Can $25 was implemented to encourage participation.

Data Collection

The FGDs took place in the small conference room of the Division of Clinical Epidemiology at the McGill University Health Centre in April and May 2015. Both FGDs were conducted by the same trained female facilitator. At the beginning of each FGD, the facilitator made participants aware that she was not a part of the clinical care team to reduce the potential for social desirability bias. The facilitator led the FGDs using the focus group guide that was created for the purpose of this study, with the first author (MJS), who was also not a member of the clinical care team, taking field notes.

Textbox 1. Focus group guide.

Icebreaker questions:

- Do you use the internet to get information on health or health care?
- How helpful is the information you get from the internet?

Key questions:

- When you think about getting health information from the internet, what features do you find attractive/unattractive?
- What information contained in the app would you like to be available to you before you undergo colonoscopy?
- How would you like this information to be available? Prompts: cartoons, figures, web links.
- Are there specific features/tools that would help you follow doctors' orders for preparing for your colonoscopy?

Discussion topics focused on patients' experience with using electronic health support tools, the information needed to prepare for colonoscopy, and the preferred format for communicating the information. The focus group questions are presented in Textbox 1. Discussions were 75 to 90 min in duration and audiotaped.

Data Analysis

Audiotapes of the FGDs were transcribed verbatim by the focus group facilitator. A total of 2 reviewers analyzed the transcripts using thematic analysis, a flexible method for identifying, analyzing, and reporting patterns within data that is not tied to a specific theoretical perspective [34]. The analysis was data driven; the 2 reviewers independently read all transcripts to familiarize themselves with the data and manually recorded their initial codes. Each reviewer then organized and combined recurrent codes into broader themes. Data triangulation was achieved by cross-checking data sources and involving 2 reviewers in the study to discuss discrepancies before agreeing on a final set of themes [35].

Ethics

Ethics approval was obtained from the Research Ethics Board of the McGill University Hospital Centre (14-084-PSY-T). Written informed consent was obtained from participants at the focus group meetings before beginning the discussions. Audio recordings and transcripts were stored according to policies of the McGill University Hospital Centre.

Results

Overview

In total, 12 gastroenterology patients (8 male and 4 female) agreed to join the FGDs. A minimum of 5 participants per focus group was arranged to ensure adequate breadth and depth of discussions [32]. However, on the day of the FGDs, 3 participants did not show; thus, 9 participants (7 male and 2 female) attended one of 2 FGDs. Participants included 4 male and 2 female participants in the first focus group (1 male no-show) and 3 male participants in the second focus group (2 female no-shows). Data saturation was achieved after 2 FGDs.

When participants were asked to discuss the informational or educational content that could be included in the app, 5 content areas emerged: (1) information and instructions for bowel preparation (laxative, diet, and clear liquids), (2) medication restrictions, (3) appointment logistics, (4) communication with endoscopy staff, and (5) what to expect postcolonoscopy. Minimization of data input, reminders and alerts up to 7 days precolonoscopy, and visual aids were identified as possible features of the smartphone app. Discussions were organized into 5 main themes to qualify the content (*what*) and features (*how*) of what users wanted in a smartphone app that supports colonoscopy preparation.

Trusted Source

As an icebreaker question, participants were asked about the internet, another electronic health tool used frequently by older adults and the colonoscopy screening population. All participants owned smartphones and had used the internet to obtain health-related information. Participants used the internet to obtain health information on colonoscopy and felt there was *no judgement* owing to the anonymity of the internet. However, the anonymity of both users and sources of information as well as the abundance of information on the internet might create a lack of trust:

> *The internet is dramatic...not possible to tell who to trust.* [FGD 1, P1]
>
> *The internet has too many sources, too much information...exaggerated...what do you trust?* [FGD 2, P1]

Some participants suggested that the information on the internet was exaggerated, conflicting, and fear-inducing. Accordingly, participants expressed the importance of including the name of the sponsoring institution in the smartphone app to increase user confidence that it comes from a trusted source:

> *The (name of our institution) should be in the app...to allay fear and find (easily) on searches.* [FGD 1, P3]

Timely and Tailored Messages

Some participants needed to stop medications before the colonoscopy appointment but were confused about when and which medications to stop. Participants suggested that the smartphone app should automatically send reminders if someone was taking these medications. Reminders and alerts that are tailored to each patient based on the date and time of the colonoscopy appointment were discussed as an essential feature to the app, as colonoscopy appointments are often scheduled months in advance. Priority alerts included purchasing of the laxative, timing of laxative consumption, timing of medication

restrictions, and timing of food and liquid restrictions. Alerts to initiate behaviors were felt to be most effective if accompanied by acoustic signals (eg, beeping for when to purchase the laxative and when to begin the laxative):

> *...need reminders or you can miss doing the right thing...like stop eating nuts 1 week before.* [FGD 2, P1]

> *The app would provide reassurance and confidence that things are done correctly, on time and at the right time.* [FGD 1, P3]

Moreover, participants indicated that the ability of the smartphone app to tailor messages to individual users made it preferable to other modes of information delivery (eg, paper, Web-based and SMS text messaging) that are less tailored to the user:

> *Although the internet can provide the same information as the smartphone app, the app may be more helpful because (tailored) alerts can remove fear and (make sure) you take the right thing at the right time.* [FGD 2, P3]

When prompted for a wish list of features, 1 participant suggested implementing a real-time report on the wait time to colonoscopy that facilitates timing of the drive to the appointment; another participant suggested implementing a real-time report in the endoscopy waiting room.

Reassurance

When asked to discuss the informational or educational content that could be included in the app, participants emphasized the importance of having an introduction that described the colonoscopy and its purpose. A smartphone app for colonoscopy preparation had the potential to reassure patients that they were doing the right thing at the right time:

> *I need reassurance I am doing it correctly...had to review the paper (instructions) every hour to be sure I was following instructions.* [FGD 2, P3]

Some participants noted feeling anxious about administrative and logistical arrangements for their colonoscopy appointments. Noting that hospital cards may have expired by the time of their colonoscopy appointments, participants wanted the smartphone app to provide the location of the office where new cards are issued and provide a message to allow sufficient time to get a new card. Similarly, participants felt the app should provide logistical information for the day of the appointment such as directions to the hospital and the location of the endoscopy unit:

> *The hardest thing in the day is (knowing) how to get there.* [FGD 2, P2]

> *Directions on how to get there (the endoscopy unit) would help relieve stress.* [FGD 1, P1]

Communication with endoscopy staff through the smartphone app was thought to be important. Participants expressed wanting to speak with a knowledgeable person to ease their concerns regarding their colonoscopy and, more specifically, about adverse events and what to do in case of emergencies:

> *I'd like to have (had) a contact number for possible complications to know if it's serious.* [FGD 1, P2]

> *Doc or staff should be available for adverse events.* [FGD 2, P1]

First-time colonoscopy attenders explained that they did not know what to expect or do after the colonoscopy, such as what foods to eat or avoid postcolonoscopy. Some participants wanted information on possible adverse events or complications. They thought the smartphone app could provide the relevant details for users to distinguish minor from serious postcolonoscopy adverse events that required a visit to the hospital. But others thought it was not wise to present this information to all users:

> *It's not good to tell anxious people about adverse events...creates fear.* [FGD 2, P1]

A total of 2 participants suggested the smartphone app could include videos of a colonoscopy being performed as well as testimonials from former patients, but these ideas were not widely endorsed by the group.

Clear Instructions

Participants wanted information presented in a clear manner at all steps of colonoscopy preparation. Many participants recalled being confused about the consumption of the laxative during the colonoscopy preparation. One participant remembered being confused about the timing of the laxative and had gone shopping before the laxative took effect:

> *I made a mistake of getting up too quickly and went shopping.* [FGD 2, P3]

Participants discussed including visual aids (ie, photos) of the different laxatives for easy identification at the time of purchase:

> *...include photos what to buy (the laxative)...not sure what I was supposed get...photo would help.* [FGD 1, P4]

Similarly, participants mentioned using colors to signal warnings or restrictions (ie, red) and what was permitted (ie, green) during the colonoscopy preparation:

> *Warnings should come in a different color...different colored warnings would help to know what and what not to eat or drink.* [FGD 1, P1]

Simple to Use

Participants suggested minimizing the amount of data to enter into the app by using check boxes and drop-down menus. These features would also reduce errors and increase user friendliness. Complicated data input (eg, entering the name of a medication) was described as frustrating and time-consuming:

> *Keep it simple...enter the date of the colonoscopy and the app does the rest.* [FGD 1, P4]

> *Make life easy, to help you do the right thing at the right time...just enter the data and the app does the rest.* [FGD 1, P2]

Participants discussed design features that might complicate and thereby negatively impact the use of the app. These features included cartoons that are demeaning and screens that contain visuals that detract from the message:

Not too busy, not too dark, not too many visuals, not too colorful. [FGD 1, P2]

Discussion

Principal Findings

Participants used the internet to search for information on colonoscopy preparation but were not satisfied with the colonoscopy information found online, saying it was exaggerated, conflicting, and fear-inducing. Having the information come from a trusted and reliable source such as the user's health care institution would reassure patients of correctly following the bowel preparation instructions as well as the numerous other behaviors involved in preparing for the colonoscopy appointment. Smartphone apps have the potential to tailor messages and makes them preferable to paper, online, and SMS text messaging modes of information delivery. Participants wanted an app that comes from a trusted source, sends timely and tailored messages, reassures users about all steps in preparing for the colonoscopy appointment, has clear instructions, and is simple to use.

Comparison With Previous Smartphone-Based Strategies

Our findings are similar to those of other qualitative studies that used focus groups to inform the development of mobile health apps, in that participants wanted the apps to contain clear and concise messages tailored to users [29,31], and for the apps to facilitate communication with clinicians [30]. Our findings are also similar to those of a Canadian study that sought patient input to inform the design of a mailed invitation letter for stool-based testing for colorectal cancer screening, in which key themes were that invitation letters come from a trusted source (patient's own family physician) and that messages be brief and succinct [28].

In this study, focus group participants identified the same content areas of previously developed smartphone-based strategies for colonoscopy preparation, such as instructions on laxative consumption and restrictions on food, fluid, and medication [14-17,22-24]. However, compared with the general instructions of previously developed colonoscopy apps, participants wanted to input personal data to create automated tailored messages and for the instructions to be clear and simple to follow. Participants also recognized that colonoscopy requires the completion of multiple complex steps in the week leading to the colonoscopy appointment; they wanted the app to send timely reminders to reassure users. Such reminders included alerts for purchasing and ingesting laxatives, medication restrictions tailored to individuals, and administrative and logistical preparation such as renewing hospital cards. Some of these instructions may have been provided at the time of colonoscopy scheduling but are likely to be forgotten when the colonoscopy preparation begins, as the mean wait time from scheduling to undergoing colonoscopy in Canada is 79 (SD 101) days [36]. Reminders may be essential to the effectiveness of a colonoscopy smartphone app; 1 randomized controlled trial found the same quality of bowel cleanliness in the app and control groups when the app was not enabled to send reminders [21].

Personalized reminders and alerts have been shown to increase the uptake of electronic health technologies in modifying various health behaviors [37]. Although SMS text messaging is already well-known and useful for concise time-sensitive information, SMS text messages can contain only 160 characters, limiting the amount of information that can be communicated and personalized to the user. In contrast to SMS text messaging, the content of smartphone app notifications (eg, reminders and alerts) can be more flexible to tailor messages that meet the needs and preferences of the user. Moreover, once the app is set up, notifications are functional without an internet connection, whereas SMS text messaging requires a medically secure server that is expensive and at risk of being hacked. Future studies will determine whether individuals are willing to download an app for single occasion use.

In our study, postcolonoscopy expectations was another content area that was not addressed by previous smartphone apps. Understandably, patients are concerned about food restrictions and adverse events after their colonoscopies. About 25% of patients experience a minor adverse event within 48 hours of a colonoscopy and 0.5% experience a serious adverse event within 30 days [38]. Given the high frequency of adverse events, providing details on the common adverse events and their degrees of severity in the app could result in fewer consultations with health care providers for complications that are self-limited [39]. To reduce arousing fear and anxiety, information on adverse events could be available but not imposed as an app feature.

Strengths and Limitations

To our knowledge, this is the first study of a smartphone-based strategy for colonoscopy preparation to include potential users at the design phase. We employed a user-centered approach to understand the needs and preferences of patients who had recently undergone colonoscopy in the Canadian context of colorectal cancer screening that begins with stool testing. A second strength was that the 2 focus groups were conducted by the same focus group moderator, under the same conditions, and in the same physical setting to reduce variability in responses owing to environmental factors.

Participants in our study did not represent all patients who undergo colonoscopy; the lack of representativeness is a limitation of all qualitative studies [32]. Focus group participants had undergone colonoscopy and their opinions may not reflect individuals who opted not to have the procedure. Findings may not reflect the needs and preferences of patients who are not fluent in English or French. Further study is needed to determine if the app encourages a larger proportion of individuals to follow through with colonoscopy. Study participation may have been motivated by the desire to make improvements to the delivery of colonoscopy services or by the chance to win the Can $25 lottery. Although the sample size was small, data saturation was reached with both focus groups discussing overlapping topics except for inclusion of videos in the app and for wanting the app to provide real-time updates on time to the next colonoscopy. A recent methodology paper found that greater than 80% of all themes are discoverable within 2 to 3 FGDs [40].

Development of colonAPPscopy

Our smartphone app, *colonAPPscopy,* has recently been developed, incorporating the insights gained from these FGDs, which identified novel content and features to meet users' informational and support needs. When designing the content and features of our smartphone app, we attempted to capture the qualities revealed in our FGDs: trusted source, timely and tailored messages, reassurance, clear instructions, and simple to use.

The title screen of *colonAPPscopy* includes the name of our institution (Figure 1). Content areas include the following: (1) colonoscopy description and purpose, (2) food, liquid, and medication restrictions, (3) logistics of preparation for the colonoscopy appointment, (4) clear liquid diet and laxative explanations and instructions, and (5) what to expect postcolonoscopy including when to seek medical help. Features include the following: (1) check boxes or drop-down menus for simple data input. Data refer to the colonoscopy appointment (eg, appointment time, date, hospital, and gastroenterologist) and to the user's medical history (medications and diseases); (2) daily tailored reminders and alerts beginning 7 days before colonoscopy for behaviors such as stopping medications, foods, and liquids, beginning the laxative, checking hospital cards are up-to-date, and finding someone to accompany them to the appointment; (3) disability considerations (eg, ability to resize content for users with visual impairments, good color contrast to assist users with cognitive impairments, the appearance of a bell image to indicate notifications for users with hearing impairments, other cues such as capital letters and high contrast for headings, red and green colored letters for important alerts, and blue buttons to immediately gain access to specified information; Figure 2); and (4) safety considerations (each medication that needs to be stopped is accompanied by a red alert instructing the user to consult their physician about the number of days before the colonoscopy that it needs to be stopped, which the user enters into the app, allowing tailored messages to be sent to the user). Features not included in the app prototype are videos owing to budgetary constraints and communications with the endoscopy unit staff owing to firewalls, but direct phone numbers are provided.

Development of *colonAPPscopy* was informed by user-elicited preferences as well as by endoscopist knowledge and experience, and by the core constructs of the Health Belief Model, which was developed specifically to explain preventive health behavior (perceived susceptibility and severity; perceived benefits and barriers; cues to action; and self-efficacy) [41]. Beta testing for comprehension of the English version of the prototype was conducted with 20 patients and then the text was translated into French. We are currently pretesting the bilingual *colonAPPscopy* prototype with users for acceptability and feasibility in a single institution, continuing with the next step of the user-centered design process. For safety reasons, patients are always given both usual care and access to *colonAPPscopy* [42]. Privacy of notifications depends on users securing their smartphones with passwords.

Figure 1. Screenshot of title page of colonAPPscopy.

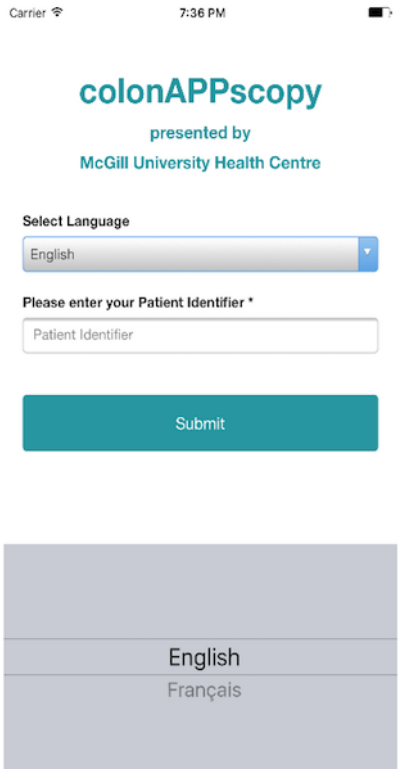
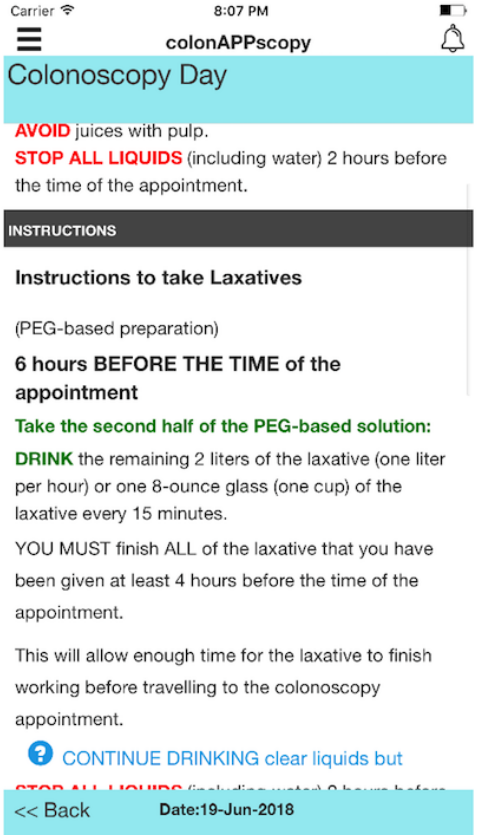


Figure 2. Screenshot of the colonoscopy day in colonAPPscopy.



Conclusions

Findings from this qualitative study were used to guide the development of *colonAPPscopy*, a smartphone app for colonoscopy appointment preparation. Potential end users wanted an app that comes from a trusted source, is capable of sending timely and tailored messages, provides reassurance, has clear instructions, and is simple to use. Including users at the design stage resulted in the identification of content and features not considered in previous similar colonoscopy smartphone apps that were not informed by user perspectives. Our user-centered smartphone app, *colonAPPscopy*, has the potential to be more relevant to the broader patient community and to result in greater uptake, better patient adherence, and improved patient health outcomes.

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Conflicts of Interest

None declared.

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Abbreviations

FGD: focus group discussion
SMS: short message service

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Review

Patients' Perceptions of mHealth Apps: Meta-Ethnographic Review of Qualitative Studies

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Abstract

Background: Mobile phones and tablets are being increasingly integrated into the daily lives of many people worldwide. Mobile health (mHealth) apps have promising possibilities for optimizing health systems, improving care and health, and reducing health disparities. However, health care apps often seem to be underused after being downloaded.

Objective: The aim of this paper is to reach a better understanding of people's perceptions, beliefs, and experience of mHealth apps as well as to determine how highly they appreciate these tools.

Methods: A systematic review was carried out on qualitative studies published in English, on patients' perception of mHealth apps between January 2013 and June 2018. Data extracted from these articles were synthesized using a meta-ethnographic approach and an interpretative method.

Results: A total of 356 articles were selected for screening, and 43 of them met the inclusion criteria. Most of the articles included populations inhabiting developed countries and were published during the last 2 years, and most of the apps on which they focused were designed to help patients with chronic diseases. In this review, we present the strengths and weaknesses of using mHealth apps from the patients' point of view. The strengths can be categorized into two main aspects: engaging patients in their own health care and increasing patient empowerment. The weaknesses pointed out by the participants focus on four main topics: trustworthiness, appropriateness, personalization, and accessibility of these tools.

Conclusions: Although many of the patients included in the studies reviewed considered mHealth apps as a useful complementary tool, some major problems arise in their optimal use, including the need for more closely tailored designs, the cost of these apps, the validity of the information delivered, and security and privacy issues. Many of these issues could be resolved with more support from health providers. In addition, it would be worth developing standards to ensure that these apps provide patients accurate evidence-based information.

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KEYWORDS

mHealth; apps; mobile apps; qualitative studies; systematic review; mobile phone

Introduction

Mobile health (mHealth) technology has been widely adopted in many countries worldwide. Since smartphones are already being used by many people, the latest technological innovations could improve access to health care, its delivery, and outcomes while decreasing the cost of health care by introducing evidence-based medical practices at the point of care and

facilitating people's access to medical information and data [1]. The health care industry should make use of these advantages by creating mHealth apps to improve patient care, as mentioned in the World Health Organization's 2011 report [2]. The International Telecommunication Union estimates that by the end of 2018, there will be 107 mobile phone subscriptions per 100 inhabitants [3]. In addition to owning a mobile device, one-third of American smartphone users had downloaded health- and fitness-related apps onto their phones [4]. There are currently more than 100,000 health-related apps on the mobile phone app market, and according to the World Health Organization, 112 countries have reported the existence of at least one mHealth initiative [2].

mHealth apps are health apps available on a mobile device (a smartphone, tablet, or phablet), which can be used by both patients and their health care providers [5]. In a recent classification of mHealth apps, six main reasons were defined for using these apps: consulting medical information and references, communicating and/or sharing information, fulfilling a contextual need, obtaining educational tools, managing health professionals' activities, and facilitating health-related management of patients [6]. It was reported that the introduction of mHealth technology in the health care industry was a slow process but that it is capable of revolutionizing health care, especially in developing countries [7]. However, health care apps seem to be frequently underused after being downloaded [8].

Since mobile phones and tablets are being increasingly integrated into the everyday lives of many people worldwide, mHealth apps provide some appealing possibilities for optimizing health systems, improving care and promoting health, and reducing health disparities. mHealth apps can provide patients with medical and health-related information (both general and personalized information) and education, improve patients' compliance with treatment, and help them manage their own health (by conducting monitoring and diagnostic activities and improving their knowledge about their state of health or their illness). These promises explain why mHealth apps are frequently presented in the medical and public health literature as means of empowering patients [9].

Social scientists are more critical about the promise of increasing empowerment via mHealth. They have pointed out the existence of several moral and ethical issues associated with the emergence of these tools, such as the idea that the users of these technologies are ideal subjects who are responsible, self-disciplined, and motivated to improve their own health and mHealth's intrusion into users' private lives to record, survey, monitor, and discipline people [9]. Those taking a critical approach generally question whether mHealth practices may not be based on a rather consumerist vision of medicine in which patients' relationship with care may tend to be based on the consumption of services, and patient-consumer satisfaction becomes the main issue [10].

Therefore, given the fast development and integration of mHealth apps, it has become imperative to document people's perceptions, beliefs, and experience of mHealth apps as well as to determine how highly they appreciate them. Several academic papers have addressed the relevance of mHealth apps and solutions for dealing with a specific disease or state [5,11-14]. Other studies have addressed the implementation of electronic health (eHealth) from the physician's perspective [15] or reviewed the evidence favoring the use of mobile technology by community health workers [16]. Based on a review of the quantitative surveys available in the literature, Azhar and Dhillon have modelled factors influencing the effective use of mHealth apps for self-care purposes [17]. However, since very little information is available on the patients' perspective, the aim of this study was to review the latest findings on how patients perceive mHealth apps in order to establish whether they agree that the idea of prescribing apps more widely is potentially feasible and desirable.

Methods

Search Strategy

Using relevant electronic databases (PubMed and Web of Science), a systematic search was performed on the literature. Key concepts such as perception and experience of mHealth were used to search the databases. The search was completed using a Medical Subject Heading keyword combination (eg, "telemedicine" AND "qualitative study") and other relevant keywords (Textbox 1).

The studies included in this review were related to mHealth or similar concepts (ie, telehealth apps, eHealth, or digital devices). Other terms and keywords used for this purpose were mobile health application(s) (or apps), eHealth app(s), telehealth devices, telehealth systems, and digital devices. Other keywords related to perception included in the search were experience, views, perspective, perception, feasibility, usability, review, utility, acceptability, evaluation, quantified self, and self-assessment. Keywords used to describe these apps were mHealth, mobile health, eHealth, telecare technologies, apps, mobile health, health technology, mobile applications, smartphones, digital health, telemedicine, and mobile apps. We restricted our focus to one main population of users, consisting of patients and potential patients. In order to determine what patients believe and how they perceive mHealth apps, we were particularly interested in original studies using a qualitative approach. Qualitative methods are potentially useful for understanding the individual needs of patients, their experiences, and their perception of mHealth apps [18]. Combinations of keywords including the term "qualitative study" were also used. In addition to the results obtained by searching databases and journals, other references to relevant articles were retrieved by performing a manual search. The studies included had to be in English and had to have been published within the last 5 years (from January 2013 to June 2018). The use of smartphones, especially iPhones and Androids, increased sharply to over 55% in 2013, along with the use of smartphone apps [19]. We therefore decided to focus on articles published within the last 5 years.

Textbox 1. Concept and keywords used in the search strategy.

Device related:

- Digital devices
- Medical app(s)
- mHealth
- mHealth app(s)
- Mobile health
- Smartphone app(s)
- Telecare technologies
- Telemedicine

Perception/value/belief related:

- Acceptability
- Evaluation
- Experience
- Feasibility
- Perception
- Perspectives
- Review
- Usability
- Utility

Type of study:

- Qualitative
- Qualitative study
- Literature review

User:

- Patients
- Physicians
- Providers

Inclusion and Exclusion Criteria and Quality Assessment

Since this research project focused on how mHealth apps can be used to improve patients' health care, any apps designed for the sole purpose of surveillance, location tracking, consultation, changing health behavior or health styles, or monitoring patient activity were excluded from the study. Since the focus was also restricted to patients, any studies focusing only on caregivers and other members of patients' social networks (such as spouses and parents) were excluded. Lastly, papers only reviewing an app's user interface and usability were not included unless they contributed to understanding patients' perception of mHealth app usage.

In view of the fast progress of technology, papers related solely to the use of short message service were not included because information, reminders, and other data are communicated via mHealth apps themselves. Studies on the wide range of digital and other technological tools that are in development, such as FitBits, eHealth, telemonitoring devices, and telehealth systems, were also excluded in order to focus on mobile phone apps alone.

Since this review examines studies with qualitative designs, all relevant articles were finally double checked to make sure that they were in line with the Consolidated Criteria for Reporting Qualitative Research, after which no further studies were excluded.

Data Extraction and Analysis

The titles and abstracts were scanned to retrieve the keywords and combinations of keywords mentioned above in order to identify relevant articles and exclude those that were not within the scope of this review. The Methods section of each article was reviewed extensively to ensure that each study was based on a qualitative design. Full texts of relevant articles were retrieved and further reviewed to ensure that they matched the

objectives of this study, and any incomplete studies and studies in progress were excluded. To list the information presented in each paper, a table was drawn up on an Excel file, in which the following details were recorded: author, country involved in the study, study population and demographics, methods, disease/condition of interest, type and purpose of the app, results, themes, and time scheme.

Data were extracted from the articles included in this review using the meta-ethnographic framework and the corresponding interpretative method, which was designed for developing new interpretations via comparisons rather than aggregate findings [20]. The first step consisted of arranging these studies in chronological order and extracting the themes from the Results and Discussion sections. While continuing to analyze other articles, we continued to keep an eye out for any emerging themes and include them in the ongoing analysis.

Results

Study Selection Procedure

The search conducted on the literature yielded 356 articles, 43 of which met the inclusion criteria (Figure 1). Three of these articles were included as the result of a manual search, while the other 40 articles were found by consulting databases. The reference numbers, the authors' names, the year of publication, the countries in which the studies were conducted, data on participants and their disease/condition, the methods used, the purpose of the app/device, and the most significant findings obtained in the studies selected are all presented in Table 1.

Figure 1. Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow diagram of study selection.

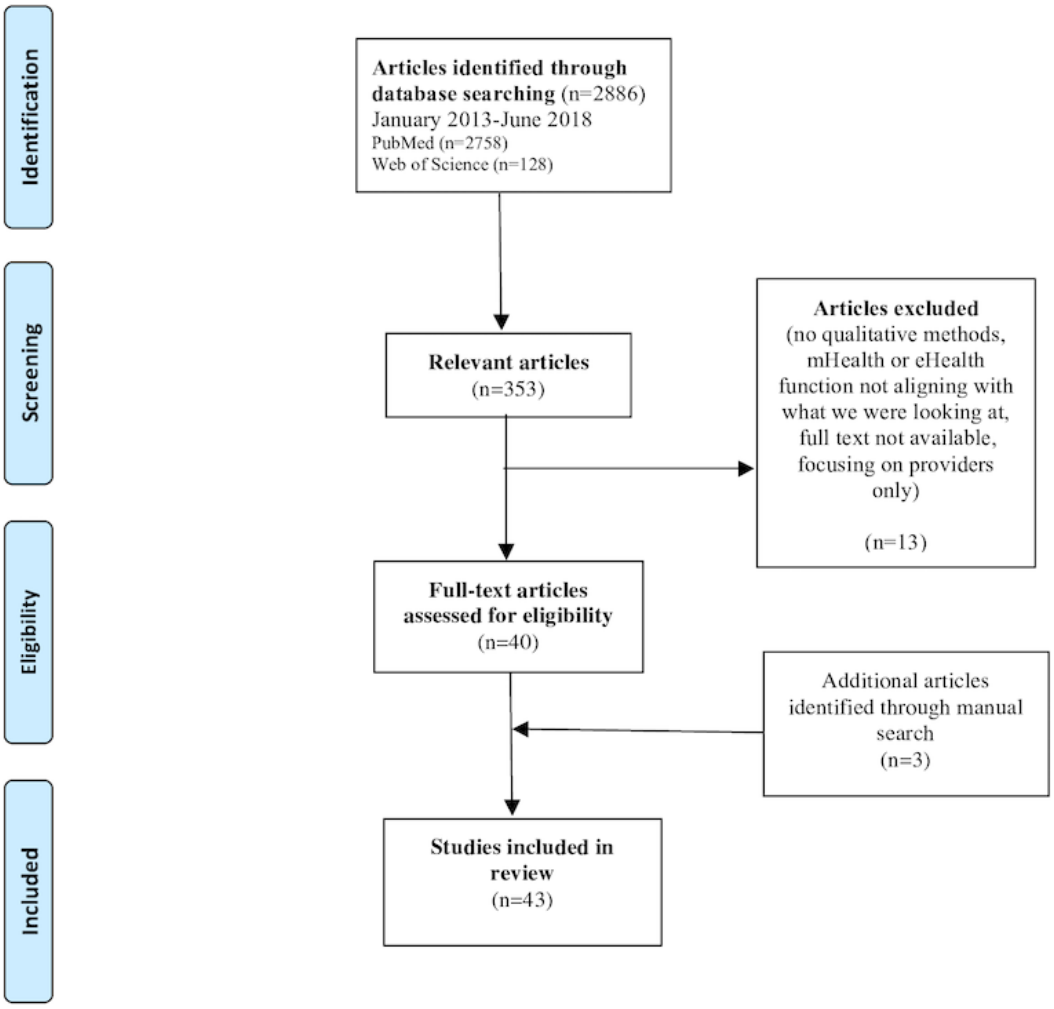

Table 1. Characteristics of the selected studies.

Study	Country	Methods and participants	Disease/condition	Type of device/app	Purpose of device/app	Evaluation or expectation of app	Results
Hilliard et al, 2014 [21]	US	Questionnaires and telephone interviews; patients (n=16)	Cystic fibrosis	mHealth[a] app	Treatment adherence, disease management	Evaluation after use of app	Benefits: access to information, socialization with the cystic fibrosis community, enhance communication with the health care team, support prescription refills Critiques: apps need to support those with cystic fibrosis, so they must be customized
Lubberding et al, 2015 [22]	The Netherlands	Face-to-face interviews; patients (n=30)	Head and neck, breast cancer	eHealth[b] app	Monitors quality of life, gives advice/feedback and referrals	Expectation of eHealth app	Survivors determined that the eHealth app could be valuable for follow-up of cancer care by enabling them to monitor quality of life, personalized advice, and supportive care
Schnall et al, 2015 [23]	US	Focus groups; patients (n=50)	HIV	mHealth app	Management and prevention of HIV (via adherence and retention of HIV medication)	Evaluation after use of app	Benefits: empowers with the sense of autonomy and helped patients in their decision making, increases competency in self-management and sense of belonging and attachment
Schnall et al, 2015 [24]	US	Focus groups; providers (n=30) and patients (n=50)	HIV	mHealth app	Monitoring and managing health of people living with HIV/AIDS, communication with providers	Evaluation after use of app	Benefits: potentially useful, can facilitate delivery of care, and helps self-manage Critiques: security and privacy of app, need an app that is simple and easy to understand
Martinez, 2015 [25]	US	Focus groups; patients (n=27)	Chronic disease	mHealth app	Patient attitudes toward mHealth technology to best tailor interventions to the needs of high-risk adults patients living with chronic disease	Expectation of eHealth app	Benefits: quick communication with health care providers, self-monitoring, self-management Critiques: confidentiality, security, expenses, customizability, depersonalized interactions with medical community
Egsgaard et al, 2016 [26]	Denmark	Questionnaires and face-to-face interviews; patients (n=82)	Chronic pain	Tablet app	Identifying location of pain	Evaluation after use of app	App helped patients accurately describe and locate pain
Israni et al, 2016 [27]	US	Face-to-face interviews; patients (n=16)	Kidney	mHealth app	Medication adherence	Expectation of app	Kidney transplant recipients responded positively on the potential app specifically for their condition Critiques: concern about technical details, need to include a few features for their condition

Study	Country	Methods and participants	Disease/condition	Type of device/app	Purpose of device/app	Evaluation or expectation of app	Results
Knight et al, 2016 [28]	Australia	Focus groups; patients (n=7)	Diabetes	mHealth app	Diabetes bolus calculator for medication	Evaluation after use of app	Benefits: useful self-management tool, improves usability Critiques: low health literacy
Lupton, 2016 [29]	Australia	Focus groups; patients (n=36)	Pregnancy	mHealth app	Access to information on pregnancy	Evaluation after use of app	Benefits: detailed and immediate information, entertainment, facilitates communication and socialization, reassuring
Puszkiewicz et al, 2016 [30]	UK	Questionnaires and telephone interviews; patients (n=11)	Cancer	mHealth app	Promotion and management of physical activity in cancer survivors	Evaluation after use of app	Benefits: helpful exercise instructions, did not cause any injuries or specific problems Critiques: need to be personalized for cancer survivors in terms of lifestyle and fitness needs, add in feature on socialization
Rosen et al, 2016 [31]	US	Focus groups; patients (n=22)	HIV	mHealth app	Management for medication adherence and CD4/viral load counts	Evaluation after use of app	Benefits: assists in adhering to drug regimen Critiques: notifications are too frequent, privacy and security, requests too much information
Simons et al, 2016 [32]	UK	Focus groups; providers (n=31), parents (n=9), and patients (n=19)	Attention deficit hyperactivity disorder	mHealth app	Collection of physiological/health-related data	Evaluation after use of app	Benefits: improved and supported management of attention deficit hyperactivity disorder in between appointments, improved quality of appointments, supported self-management Critiques: burden on clinics, privacy and confidentiality issues of data, credibility and validity of sources
Young-Afat et al, 2016 [33]	The Netherlands	Face-to-face interviews; providers (n=10) and patients (n=15)	Breast cancer	mHealth app	Collection of patient-reported outcomes of breast cancer patients	Evaluation after use of app	Benefits: potentially be in more control of health Critiques: does not provide anything more than medical team and internet
Bendixen et al, 2017 [34]	US	Focus groups; providers (n=11) and patients (n=16)	Brain and spinal cord anomalies	mHealth app	Self-management	Evaluation after use of app	Benefits: engaging, add value to daily life, accessible information, relevant to health needs Critiques: add feature for socialization and make it customizable
Cai et al, 2017 [35]	UK	Face-to-face interviews and focus groups; providers (n=21), parents (n=7), and patients (n=29)	Juvenile idiopathic arthritis	mHealth app	Monitor symptoms and facilitate engagement with providers and patients	Evaluation after use of app	Benefits: high levels of acceptability and usability, can improve health care and outcomes

Study	Country	Methods and participants	Disease/condition	Type of device/app	Purpose of device/app	Evaluation or expectation of app	Results
Fleming et al, 2017 [36]	US	Face-to-face interviews; patients (n=9)	Mental health	mHealth app	Management of anxiety and depressive symptoms	Evaluation after use of app	Benefits: facilitate engagement with patient and provider Critiques: app needs to be culturally tailored for young sexual minority men
Goetz et al, 2017 [37]	Germany	Face-to-face interviews; patients (n=30)	Pregnancy	eHealth and mHealth app	Patient engagement of clinical routine care/pregnancy care	Evaluation after use of app	Benefits: facilitates socialization with other mothers and providers, easy and quick access to information, overall positive attitude toward using eHealth app Critiques: need for personalization, lack of scientifically validated sources, add feature for immediate feedback, data security
Hälleberg Nyman et al, 2017 [38]	Sweden	Face-to-face interviews; patients (n=28)	Prostate cancer	mHealth app	Management, reporting of symptoms during radiotherapy for patients with prostate cancer, symptom and risk assessment, alerts via SMS[c]	Evaluation after use of app	Benefits: facilitates conversation between patient and provider
Huerta-Ramos et al, 2017 [39]	Spain	Focus group and face-to-face interviews; providers (n=13), family members (n=9), and patients (n=14)	Schizophrenia	mHealth app	Empowerment, individualizing treatment and improving understanding of the illness	Evaluation after use of app	Benefits: access to reliable information regarding disease and support, improved contact with clinicians, support of self-management of daily tasks and appointments Critiques: wanted more human contact with clinicians
Langius-Eklöf et al, 2017 [40]	Sweden	Face-to-face interviews; patients (n=66)	Prostate cancer	mHealth app	Manage symptoms from radiotherapy for prostate cancer patients, risk assessment, alerts via SMS to providers, access to information	Evaluation after use of app	Benefits: app is easy and efficient to use, increased security and well-being, improved self-management
Mistler et al, 2017 [41]	US	Questionnaire and face-to-face interviews; patients (n=13)	Mental health	mHealth app	Self-management of and treatment	Evaluation after use of app	Benefits: app is easy to use, relieved anxiety, sleep, and boredom
Nightingale et al, 2017 [42]	UK	Face-to-face interviews and focus groups; providers (n=7), parents (n=12), and patients (n=12)	Chronic kidney disease	mHealth app	Management of treatment and dietary regiments, treatment adherence	Evaluation after use of app	Expectation: accessible information, engaging/interactive and developmentally appropriate care-management app, endorsement from renal professionals, supplementary to professionals
Sebern et al, 2017 [43]	US	Focus groups; providers (n=7) and patients (n=8)	Heart failure	mHealth app	Education and self-management, monitor symptoms and physical activity for patients of heart failure	Evaluation after use of app	Benefits: facilitates self-management and communication Critiques: cost, overwhelming

Study	Country	Methods and participants	Disease/condition	Type of device/app	Purpose of device/app	Evaluation or expectation of app	Results
Velu et al, 2017 [44]	The Netherlands	Focus groups; providers (n=12) and patients (n=2)	Obstetric care	mHealth app	Assess health risk of working pregnant women	Evaluation after use of app	Benefits: accessible to practical and understandable information Critiques: extensive battery and memory use, notifications too frequent
Westergaard et al, 2017 [45]	US	Face-to-face interviews; patients (n=19)	HIV	mHealth app	Medication adherence/management, monitor risk behaviors of patients with substance use and HIV	Evaluation after use of app	Benefits: manage HIV care when busy or stressed, empowered them to support others, socialization
Webb et al, 2017 [46]	Australia	Questionnaires and phone interviews; patients (n=14)	Mental health	mHealth app	Health and lifestyle screening tool	Evaluation after use of app	Benefits: using app allowed participants to easily disclose sensitive issues raised in their consultation, participants felt more prepared and in control
Bauer et al, 2018 [47]	US	Questionnaires and face-to-face interviews; patients (n=17)	Mental health	mHealth app	Symptom monitoring, self-management of mental health, connect with collaborative care program	Evaluation after use of app	Benefits: facilitated discussion, supported relationship between patient and providers Critiques: lack of personalization, privacy and data security
Cordova et al, 2018 [48]	US	Questionnaires and face-to-face interviews and focus groups; patients (n=30)	HIV	mHealth app	HIV intervention app	Evaluation after use of app	Benefits: facilitate adolescent-clinician communication, engaging and informative, interesting (culturally fitting to adolescents) Critiques: Confidentiality of risk assessment
Dahlberg et al, 2018 [49]	Sweden	Face-to-face interviews; patients (n=18)	Postoperative recovery	eHealth app	Assess and follow-up on postoperative recovery day after surgery	Evaluation after use of app	Benefits: supportive, informative, facilitates communication, socialization
Desveaux et al, 2018 [50]	Canada	Telephone interviews; patients (n=16)	Type II diabetes	mHealth app	Management and adherence to insulin for patients with type II diabetes	Evaluation after use of app	Benefits: supports self-management, increase awareness Critiques needs specific feedback, includes feature that acknowledges and recognizes successes, time consuming
Floch et al, 2018 [51]	European countries	Face-to-face interviews and netnography; providers (n=33), parents (n=17), and patients (n=24)	Cystic fibrosis	mHealth app	Access to information, manage treatment and follow-up	Expectation before use of the app and evaluation after use of the app	Critiques: needs an app that is easy to use, customizable, and will support self-management; takes into account the needs of individuals with cystic fibrosis and their busy personal life

Study	Country	Methods and participants	Disease/condition	Type of device/app	Purpose of device/app	Evaluation or expectation of app	Results
Giunti et al, 2018 [52]	Switzerland	Questionnaires, focus group, and face-to-face interviews; providers (n=12) and patients (n=12)	Multiple sclerosis	mHealth app	Health promotion	Evaluation after use of app	Benefits: realistic and positive feedback, minimize usability burdens Critiques: design, validity of information, need to emphasize that app is secondary to provider, need to be more engaging (eg, games), personalization, health literacy, privacy and data ownership, socialization
Grist et al, 2018 [53]	UK	Face-to-face interviews; patients (n=40)	Self-harm/mental health	mHealth app	Management of those who self-injure by tracking moods, promoting mood changing activities, etc	Evaluation after use of app	Benefits: helpful in managing their condition, privacy and discreetness of app, easy to use, Critiques: poor personalization
Hirschey et al, 2018 [54]	US	Questionnaire and face-to-face interviews; patients (n=12)	Atrial fibrillation	mHealth app	Self-care and treatment adherence for patients with atrial fibrillation who are prescribed NOACs[d]	Evaluation after use of app	Benefits: easy to use, supported self-care and treatment adherence, information accessible
Husted et al, 2018 [55]	Denmark	Face-to-face interviews; patients (n=20)	Type 1 diabetes mellitus	mHealth	Management/adherence	Evaluation after use of app	Benefits: socialization, sense of competence safety, empowered to ask for help Critiques: lack of motivation for long-term app use
Jibb et al, 2018 [56]	Canada	Telephone interviews; patients (n=20)	Cancer	mHealth app	Pain management support	Evaluation after use of app	Benefits: supported self-management, engaging, facilitates discussion with provider Critiques: notifications too frequent, technical problems
Morrissey et al, 2018 [57]	Ireland	Focus groups; patients (n=24)	Hypertension	mHealth app	Medication adherence, management of hypertension	Evaluation after use of app	Benefits: motivates engagement with physician and self-management Critiques: using an app meant acknowledgment of the disease/condition or failure of memory, app is too challenging to use, app should include medical care in case of emergency, data regulation, cost of tools that is needed to use the app, burden of reminders
Riis et al, 2018 [58]	Denmark	Questionnaires and face-to-face interviews; patients (n=15)	Lower back pain	eHealth app	Access to information and advice for those with lower back pain	Evaluation after use of app	Benefits: self-management, informative Critiques: difficult to navigate, people prefer to speak to provide, need support from providers to use app, information should be presented comprehensively and succinctly, customization

Study	Country	Methods and participants	Disease/condition	Type of device/app	Purpose of device/app	Evaluation or expectation of app	Results
Shorey et al, 2018 [59]	Singapore	Face-to-face interviews; patients (n=17)	Pregnancy	mHealth app	Access to health care information for postnatal care	Evaluation after use of app	Benefits: convenient, empowering, made providers more accessible, socialization, emotionally supported Critiques: technical issues, extend duration of use, provide more information
Switsers et al, 2018 [60]	Belgium	Focus groups; patients (n=16)	Bipolar disorder	mHealth app	Self-management of bipolar disorder	Perception of mobile health apps prior to usage	Benefits: self-management, informative, socialization Critiques: customization, frequency of feedbacks
Waite-Jones et al, 2018 [61]	UK	Focus group and face-to-face interviews; providers (n=8), parents (n=8), and patients (n=9)	Juvenile arthritis	mHealth app	Self-management of juvenile arthritis, access to information and self-management strategies	Evaluation after use of app	Benefits: facilitates self-management, informative Critiques: customization, security, add more functions to app (notifications, mindfulness/relaxation techniques, gamification), provide age/gender relevant information, security, cost
Anstey Watkins et al, 2018 [62]	South Africa	Face-to-face interviews; providers (n=43) and patients (n=113)	Chronic diseases	mHealth app	Information and service regarding chronic disease, pregnancy	Expectations prior to app use	Benefits: facilitated management of treatment, accessible information Critiques: limited functions on their phones, cost
Zhu et al, 2018 [63]	China	Face-to-face interviews; patients (n=13)	Breast cancer	mHealth app	Access to education/information on breast cancer, facilitating communication with peers and providers, symptom management	Evaluation after use of app	Benefits: accessible information, facilitates management of condition, empowering in confidence and emotional well-being, easy and convenient to use Critiques: technical difficulties, make language succinct and comprehensible, information app provides should be updated regularly, quick feedback

[a]mHealth: mobile health.

[b]eHealth: electronic health.

[c]SMS: short message service.

[d]NOAC: Nonvitamin K antagonist oral anticoagulant.

In 31 studies, the participants were all patients, whereas in 12 studies, the participants included both patients and providers. All 43 articles discussed patients' opinions about including patient-centered mHealth apps or eHealth apps in their mobile phones. The aim of 37 of the 43 articles was to report patients' assessment of an app, while 5 articles included either patients' expectations or their perception of an app prior to its use, and one study included both their expectations and assessments.

Most of the articles reviewed included populations inhabiting developed countries, apart from one that focused on a developing country (South Africa). Most of these qualitative studies focused on the United States [21,23-25,27,31,34,36,41,43,45,47,48,54] and the United Kingdom [30,32,35,42,53,61]. Other countries included were the Netherlands [22,33,44], Denmark [26,55,58], Sweden [38,40,49], Australia [28,29,46], Canada [50,56], South Africa [62], Singapore [59], China [63], Germany [37], Ireland [57], Belgium [60], Spain [39], and Switzerland [52]. One paper included populations originating from seven European countries [51]. Although all the articles selected had been published during the last 5 years, about 70% of them were published more recently, during the last 2 years (2018: n=17; 2017: n=12). In addition, 8 articles were published in 2016, 4 articles were published in 2015, and 1 article was published in 2014.

Most of the apps under consideration were tailored to deal with chronic diseases: cancer [22,30,33,38,40,56,63]; HIV [23,24,31,45,48]; diabetes [28,50,55]; hypertension and cardiovascular diseases [43,54,57]; chronic kidney disease

[27,42]; cystic fibrosis [21,51]; chronic pain [26,58]; juvenile arthritis [35,61]; brain and spinal cord anomalies [34]; multiple sclerosis [52]; chronic illnesses, in general [25,62]; and mental health disorders [32,36,39,41,46,47,53,60]. Other apps were specific to pregnancy/obstetric care [29,37,44,59], and one was for postoperative care [49]. Since almost all the studies' objectives focused on chronic diseases/conditions, the views and expectations of patient users were related to apps designed for the purpose of providing support, including giving access to information, promoting interventions, promoting compliance with treatment, assisting with the management of treatment or disease, and facilitating discussions.

This article discusses the main strengths and weaknesses of using mHealth apps from the patients' point of view. The strengths mentioned can be categorized into two main aspects: patients' engagement and their empowerment. The four main weaknesses to which the subjects objected were the apps' lack of trustworthiness, appropriateness, personalization, and accessibility (Textbox 2).

Increasing Patient Engagement

Improving the Accessibility to Information

Apps are frequently used to make information accessible to users. In many cases, the apps under consideration here included information about a specific disease or condition or the medication available, to help patients handle their situation. Other apps were designed to assist patients by explaining their medication and medical treatment regimens. For the more educational apps, patients expressed their appreciation of the possibility of increasing their knowledge about health topics related to their disease or condition. However, some patients, such as cancer survivors, do not want more information and advice than they have already received at the hospital, because receiving more information might increase their anxiety [22].

Facilitating Two-Way Communication With Health Care Providers

Patients described mHealth apps as tools facilitating discussions with their providers. Making it possible to communicate easily with providers seems to be one of the great promises of mHealth [25]; some tools include a function that enables patients to contact their providers to ask questions or express concerns. For example, young individuals with diabetes who were interviewed by Husted et al [55] said they had experienced greater continuity in their patient-health care provider relationships and were more highly motivated to improve their self-management of diabetes, since their health care providers immediately responded to the questions they asked in the chat room. Some of the patients who were able to use a mobile phone app efficiently stated that these tools enhanced their experience of the health care services [38]. One patient reported that they made it possible to personalize their messages to their provider or health care professional and receive useful responses. The mobile phone device was described as a tool for patients to have a "two-way dialogue" with their health care professionals, making it "a security line and […] a link to someone who was caring for you and being in control of the situation" [38].

Textbox 2. Summary of the emerging themes.

Strengths mentioned by patients:

- Engaging patients more strongly
  - Improving the accessibility of information
  - Facilitating two-way communication with health care providers
  - Peer support
- Increasing patient empowerment
  - Facilitating self-management
  - Gaining greater control and autonomy

Weaknesses mentioned by patients:

- Concerns of trustworthiness
  - Scientific validity
  - Technical validity
- Appropriateness as an essential quality
  - Relevance to specific diseases and conditions
  - Cultural and user appropriateness
- The need for greater personalization
- Accessibility issues

Patients also mentioned that these tools make for pleasant participation on the part of both users and health care professionals. They also described it as "passive receipt of care," which was readily accepted by patients. With this type of care, they were able to accept and "resign themselves to receiving care without taking up the possibility to engage in active participation" [38].

Patients also felt that with the knowledge they had acquired, they were able to address topics they previously thought to be unimportant or irrelevant. The new information they received about what to bring into discussions with providers may enhance patients' engagement with their providers. For example, patients using an app to describe their pain found that this helped them collaborate and interact with their physicians more effectively than using verbal descriptions and physical gestures. In addition, patients prefer gender-specific 3D body charts giving a "detail[ed] and realistic representation of the body" [26]. Patients described this body chart app as a "tool to facilitate communication of pain," which is likely to "lead to improvements in pain communication, and thus facilitate clinical reasoning and treatment strategies" [26]. This will therefore help providers make more accurate assessments and more appropriate treatment plans for their patients.

However, it is worth noting that although the patients interviewed felt they had become more engaged in self-management owing to the use of these apps, they stressed the fact that apps should be used only as a complementary tool. Although mHealth apps can change the dynamics of patient-provider relationships by providing relevant information for making assessments, diagnoses, prescribing treatment, and so forth, patients prefer to use them simply as tools for facilitating these relationships and not for replacing them. Users believe apps to be a positive addition to the clinical process only, as one participant in the study by Simons et al [32] said, it "adds to what's there already...not if it's used as an excuse to see people less." Apps could also be used to fill the gap between two doctors' follow-up sessions [59]. On the other hand, some elderly patients fear that mHealth may lead to more depersonalized interactions with their doctors [25].

Peer Support

Not only were patients able to engage with their providers more effectively, but they also stated that some apps facilitated conversation with other people who had undergone similar experiences, via forums or chat rooms. Some apps also enabled patients to interact more easily with caregivers and other members of their social network. By facilitating exchanges between patients and other individuals, these apps enhance patient socialization by alleviating their social isolation and providing social support. Providing peer-to-peer support by sharing feelings, practical knowledge, and experience was found to be the main benefit of apps with a chat room for young people with diabetes [55]. It has been stressed that the process of socialization achieved by chatting with other people who are experiencing a similar situation is one of the most helpful aspects of an educational app for new parents during the postnatal period [59]. The users of this app were parents of newborn infants who found it comforting that they were able to link up with other new parents who were "linkable" and "going through the same things," which results in parents providing answers that are directly relevant to the question [59]. However, not everyone is comfortable chatting on social networks. Some patients, especially those with cystic fibrosis, fear that comparing oneself with other people may lead to negative feelings or discouragement [21]. On the whole, mHealth apps can play a social role by improving patient self-management of their disease-related and other health-related issues [23].

Increasing Patient Empowerment

Facilitating Self-Management

Many patients approve of apps that can be used for self-monitoring and self-management of their health [25]. In addition, it is worth noting that patients who were high engagers in self-management described the use of mHealth apps as beneficial and not a barrier or an interference. High engagers were "interested in using mobile technology to improve their health and enthusiastically engaged with the app immediately and consistently thereafter" [50]. Among moderate users, these tools were perceived as useful means of increasing their awareness of their actions and keeping track of the details in the management of their disease, whereas those who had little to no self-involvement in the management of their health were skeptical about using mHealth apps as a means of self-management. The level of engagement of the members of this group was found to be minimal to low. They were not able to integrate these apps successfully into their daily routine and stated that they were a burden. Overall, the perceived value of these apps and their integration as well as patients' engagement with the tool depend on how self-reliant the patients are.

Gaining Greater Control and Autonomy

Patients provided with a tool that gave them access to useful supplementary information and helped them engage with their providers declared that they felt more empowered and in control of their condition, disease, or regimen. When the information provided in the app is succinct, comprehensible, and easily accessible, patients feel that they can improve their knowledge about their disease or condition, symptoms, and medication. One participant noted that one of the apps had too much content, and she felt "overwhelmed by the information each time [she] opened it. [She did] not have the patience to read all of [it]..." [63]. Therefore, in order to ensure that patients will engage fully with an app, the information provided must be clearly and concisely presented in laymen's terms [58].

In addition to the supplementary information provided by these apps, the possibility of recording treatment-related conversations with physicians or their medical team gives patients a sense of control, especially when they are distressed [33]. Patients also mentioned that it would be beneficial to be able to edit and share the files recorded. However, recordings of meetings and consultations would have to be hashed out in detail to make sure that patients' identity and data are protected.

Apps provide young people with chronic conditions a sense of autonomy and help develop skills such as problem-solving and decision-making skills and the ability to use resources and build

relationships with professionals [61]. Having a tool equipped with these functions provided them with a "secure and supportive environment" [61]. Young patients often stated that having an interactive app with which they were in control provided them with information, a means of monitoring symptoms, and social support [61]. Patients found self-monitoring apps to be especially helpful for managing their symptoms or their mood in the case of bipolar disorders, by providing personalized feedback [32,60]. With self-monitoring apps, patients are able to gain control over their own health and health care and feel more empowered when consulting a doctor. They are usually enthusiastic about apps and willing to engage with them. However, some other patients tend to feel that apps are too demanding, which leads them to give up on using them regularly [57]. Apps should not have too many push notifications, as they can overwhelm or burden the users.

In short, with their newly acquired knowledge, patients felt they were well equipped to manage their own disease or condition, symptoms, medication, health-related behavior, and test results, thus facilitating the decision-making process and making them feel reassured and empowered.

Concerns of Trustworthiness

Scientific Validity

Most of the patients interviewed said they were in agreement with the concerns sometimes expressed about the validity of the information provided on mHealth apps. Although patients found mHealth apps informative and supportive, they also expressed worry about how reliable the information may be. Patients mentioned that without the basic support they received from their providers, they would be much less inclined to trust the information provided by apps. Patients are sometimes rather skeptical of their apps because there is no proof that the information provided is evidence based or obtained from a reliable source. They suggested that it would be better if providers were able to back up the information conveyed by apps. They suggested that app designers should use evidence-based information and cite the sources of the information conveyed in order to confirm its validity. As mentioned in Goetz's study [37], pregnant women, in particular, specified the need for scientifically valid data. Many of the users of these apps objected that the quality of the information they provide is questionable. Patients even explicitly stated that if their provider recommended an app, "it would make a difference" [58]. Having an app recommended by a physician familiar with evidence-based information is one of the most important criteria according to the users.

Technical Validity

The main issues mentioned by users in connection with these apps were those of privacy and security. Many of these apps ask users for sensitive information to achieve optimum performances. Some apps also allow providers to send patients personal data and findings via the app. Patients were concerned about the security of the apps, how many parties were able to view their data, and whether a data breach might occur. They wanted to know what the consequences of a situation of this kind might be and how it could be dealt with.

Concerns about privacy and data ownership were voiced in Giunti's study [52], in which patients said they were not happy about having a third party, such as pharmaceutical or insurance companies, having access to their data. One patient put this point quite clearly: "If everyone could see my data, I wouldn't give [the app] a chance" [52]. Similar findings were obtained in connection with an app that was tailored for HIV patients [24]. Patients expressed great concern about the privacy of their information, how much personal information they were willing to contribute, and the risk of being tracked [24,31]. Participants in the study by Martinez [25] mentioned "hackers" and "big brother" "to express their mistrust regarding the current state of digital information security" [25].

Appropriateness as an Essential Quality

Relevance to Specific Diseases and Conditions

Several articles reviewed reported that many patients interviewed reported that these apps should be designed more closely in line with their condition or their disease, keeping individual users' lifestyles and needs in mind. For example, since patients with cystic fibrosis have to follow a very strict multidrug treatment regimen, using an mHealth app could help them comply with it [51]. However, many patients find that the apps designed to promote compliance with drug treatment for cystic fibrosis did not take into account the busy lives these patients lead. Frequent alarms and notifications to take their medication may be annoying and consume their phone battery. Patients would prefer apps to be customizable to suit the user and tailored to meet individual preferences [25]. For example, there should be a "snooze" option if the medication cannot be taken immediately, or it should be possible to personalize the function so that their multiple-drug intake can be recorded in their schedule [21].

Cultural and User Appropriateness

Patients also stressed the need for apps to understand their users. It is essential for app developers to know who their end users are going to be and to ensure that the products are appropriate for them. For example, an HIV management app tailored for young men who have sex with other young men should be tailored to the specificities of this population. In this particular case, the author of the study mentioned that these young male patients would like to have an app that is colorful, bright, and visually appealing [36]. Developers need to keep the users and users' culture in mind in order to ensure their engagement [48]. Young people usually prefer youth-friendly language and designs [35,46,61].

Patients expressed the need for specific information, which plays an important role in their sociocultural groups, such as information about diet in the case of Chinese women with breast cancer [63]. Culturally tailored help with some specific characteristics of the disease could be added to improve the content of these apps. For instance, apps could help improve people's perception of stigmatized diseases (such as cancer in some countries) and thus strengthen their engagement with their apps [63].

The Need for Greater Personalization

One of the most critical factors stressed upon by many participants in these studies was the need to personalize the content of mHealth apps to a greater extent. Patients believed that since mHealth apps were created for their use, they should be able to personalize the apps to meet their own needs. From the patients' point of view, using personalized apps could be as simple as changing the text size. It can be more complex to, for instance, make a drug regimen notification more flexible, give users the choice of adding personal information and receiving advice, or program a self-management app acting like a virtual personal coach [22,32,44,60]. Users wanted to be able to adjust the timing of their prompts, the number of symptoms reported, the frequency of health tips, and so forth [47]. Users also suggested that personalization of the app could also include the language used on the app: Some of them felt that the language used was rather patronizing, and they wanted to be able to change the type of language used to suit their tastes [47].

Greater personalization of apps could also make users feel more interactive with them. One user suggested, for example, that in order to meet health-related goals, they could have avatars that change, mature, and develop as the users learn more, achieve more goals, and become more independent by improving their self-management skills [34]. On the whole, patients value apps that are customized and tailored to meet their needs [25]. With more complex diseases such as cystic fibrosis, personalization is an essential requirement for users. With some diseases and conditions, management or treatment of the disease can vary from one patient to another, and patients may therefore have different routines to follow [51]. It would be best if these apps included "diverse functions" that enable patients to personalize and tailor them to meet their needs

Accessibility Issues

In addition to the trustworthiness of the information and the appropriateness of the app, patients were also worried about a few issues related to their access to apps, such as the connectivity and cost. Some patients found that they had problems with their connection to these apps and other user interface issues. The frustration of not being able to connect with the apps was found to be particularly prevalent among older adults and the elderly, who frequently have poor eyesight and a lower level of digital literacy than other age groups [25,43,57,62]. The elderly patients included in the studies reviewed consisted of two groups: those wanting to acquire digital skills in order to be able to engage with these apps and those having no desire to improve their digital skills for this purpose [57]. Some expressed the feeling that placing greater reliance on technology meant that they were "admitting that the memory isn't as good as it used to be," which is distressing and prevented them from wanting to engage with their app [57]. Those with high-to-moderate levels of familiarity with computer technology were more likely to want to use apps, while those who were less familiar with computers and mobile phones were less likely to do so. People's preferences for the use of apps varied, depending on their familiarity with this form of technology and their wish to become digitally competent. In addition to their digital incompetence, some patients have physical barriers that have to be to overcome to be able to use these apps. Elderly patients have described poor eyesight as one of the main barriers to using apps because they are not able to see their phone screens clearly [25,62].

Other accessibility challenges cited by patients are the extensive battery and memory requirements of smartphones [44]. For example, the mHealth app designed for pregnancy care used a lot of battery and memory space, which set patients problems. Patients had to ask themselves "what kind of apps do you delete?…[apps that use] lots of memory, lots of power, apps that are very active, [but] in that case your battery goes down…" [44]. Instead of being able to use their app to manage their care seamlessly, patients were bothered with having to think about whether an app was worth keeping.

Another issue patients faced was the cost of these apps [25], especially in developing countries where some patients cannot afford them [62]. In addition, some patients were worried about purchasing data to use the app when they were not living in an area with available Wi-Fi [62]. Not being able to use apps consistently because of data issues deterred some patients from engaging with them for long. An additional cost-related barrier was the fact that some apps charge patients a fee for obtaining full access to the app and for being advertisement-free [41,58]. Some patients would have to pay for using the full app, since some free versions provided only a few functions. The financial issues arising therefore prevented some potential app users from fully optimizing the use of an app and engaging with it.

Discussion

Principal Findings

To our knowledge, this is the first review of qualitative studies available in the literature that provides an overall picture of patients' perceptions, beliefs, and experiences of mHealth apps. This study completes the model identifying the factors involved in the effective use of mHealth Apps for self-care purposes developed by Azhar and Dhillon [17]. In this model, the behavioral intention to use mHealth for self-care purposes is influenced by perceived usefulness, perceived ease of use, performance expectancy, social influence, self-efficacy, potential lack of privacy, and hedonic motives.

Our interpretation of qualitative findings shows how mHealth can strengthen patients' engagement and sheds light on the dynamics of patients' engagement and ways to make patients feel more empowered by using mHealth apps. As defined by Carman, the concept of patient engagement develops "as patients...and health professionals [work] in active partnership at various levels across the health care system - direct care, organizational design and governance, and policy making - to improve health and health care" [64]. Some authors have portrayed eHealth (internet and related technologies) as an important means of achieving patient engagement [65], especially in the case of isolated people and those who are hard to reach or have difficulty in remaining engaged in care [16]. Even when patients are not physically in a health care setting, health care advice and guidance are within easy reach at all times. From the patients' point of view, mHealth could facilitate

communication with health care providers and other patients, encourage them to be more participative during clinical encounters, and promote the use of coping techniques to manage their illness. However, some studies based on other methods have shown that some patients are reluctant to use mHealth apps, which is paradoxically the case with adolescent patients because they want to separate their feelings of being a patient from those of being a teenager and make their illnesses and diseases invisible [66]. In addition, they find apps, especially those with push notifications, annoying, intrusive, and time consuming [66]. Patients also stated that although these technical health innovations have supported them in many different respects, they still view their providers as the first point of contact to be consulted for discussing the options available. Health apps serve only as back-up consultations when they are really needed; apps are simply available to support physician-patient relationships and do not replace a physician in any way. mHealth is therefore not a substitute for care but simply a complementary tool [67].

Most of the studies included in this review suggest that patients feel empowered by the information provided by mHealth. WHO defines empowerment for health as: "…a process through which people gain greater control over decisions and actions affecting their life" [68]. According to the World Health Organization, adequate and understandable information is a necessary prerequisite for patient empowerment. Health care policymakers, politicians, and the media share the widespread idea that digital health technologies empower patients [9]. However, when faced with too much overwhelming information, users tend to feel more confused and possibly disempowered, which decreases the effectiveness of discussions with their physicians [67]. Users have also mentioned that the possible lack of validity of the information provided by apps makes it difficult to trust this information, which may make empowerment ambivalent. However, as mentioned above, if apps presented valid information more clearly and concisely, they could possibly incite users to engage more strongly with them as well as with users' providers, caretakers, and support networks. Some authors have also reported that patients described themselves as reluctant, resistant, and anxious when using digital devices because they feel "disempowered" owing to the surveillance performed by some digital devices, which restricts their autonomy and reminds them that they are ill [69].

The results presented here suggest that despite the many advantages of mHealth apps, barriers to their successful adoption persist. Patients are still reluctant to rely solely on these tools for reasons related to privacy and security and the validity of the information provided. Other barriers to the optimal usage of apps are a lack of accessibility (the cost and absence of access to Wi-Fi) and issues concerning the technical and scientific validity of these tools. Many of the challenges could be met if there was more support on the part of health providers. In addition, standards could be developed and implemented to ensure that these apps provide patients with accurate evidence-based information. These standards could also address the security and privacy issues that many patients are concerned about as well as the compatibility of mobile apps with the technology with which existing health care systems are equipped. There is also a need for inexpensive quality apps and updates (possibly financed by health insurance funds or other agencies) that patients can easily afford.

The levels of engagement and empowerment resulting from the use of mobile phone apps and tools have been found to depend on the users. For example, one study showed that older adults were faced with barriers to adopting these tools because they were not as familiar with smartphones and tablets as younger people and had difficulty in using these technologies [70], whereas those who were digitally literate preferred to receive health information via tablets and electronic devices [70]. Patients' requirements should be taken into account by those designing mobile health apps in order to alleviate some of the burden [71]. In addition, preference for the use of mobile devices can differ in some contexts. Female participants in Ghana spoke, for example, about how they did not comply voluntarily with health messages "because they didn't see the point or because it went against their own experience or local knowledge" [72]. Users often expressed the feeling that automatic generic health messages seemed "depersonalized," which may have resulted in "the opposite effects from those expected by the promoters of mHealth: Reduce caregiver-patient interactions and loosen the link with the health system" [72]. When developers create apps and tools of this kind for users, they should keep their users in mind and remember how their personal identity may influence users' integration and engagement with the apps in order to facilitate adoption of the apps and the perpetuation of their use.

Although most authors focusing on developing countries discussed how mHealth apps help community health workers, few of them discussed the perspectives of patients using these apps. As the infrastructures with which the large cities in developing countries are improving, their inhabitants are gaining greater access to mobile data and Wi-Fi [73]. However, although the rates of penetration of mobile data and Wi-Fi have reached approximately 50% in these places, rural and underdeveloped regions still have no access at all to these services. It may be necessary to improve the infrastructure in developing countries' rural and underdeveloped regions in order to be able to promote the use of mHealth apps [74].

Limitations

Since only full-text articles available in English on PubMed were included in this review, many other studies have not been included because they were not written in English or were still in progress at the time of publication. The papers included here deal mainly with developed countries and less with developing countries, which limits the general validity of the results presented here. Since the rates of smartphone ownership in developing countries increased from 21% to 37% in 2015 and the active mobile phone subscription rates reached 53.6% in 2017, the uptake of mHealth apps may be different in these countries from the situation in more industrialized countries [3,75]. mHealth integration may have considerable implications in developing countries [76]. It is therefore worth noting the perceptions of individuals inhabiting developing countries in order to establish how this technological advancement is liable to improve or limit their access to health care [77].

Conclusions

In this review, a meta-ethnographic approach was used to summarize the data published in 43 qualitative studies on patients' perceptions of mHealth. Although mHealth apps were considered a useful complementary tool by many of the patients studied, some major issues emerged with regard to the optimal use of mHealth technologies, such as the need for more highly tailored designs, their cost, the validity of the information they provide, and issues such as privacy and security. Lastly, there is definitely a need for apps to be more personalized in order to meet the needs of individual users and their particular disease or condition, by designing apps that are easier to use, for example, by those who are not as digitally literate as others.

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Conflicts of Interest

None declared.

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Abbreviations

eHealth: electronic health
mHealth: mobile health
NOAC: Nonvitamin K antagonist oral anticoagulant
SMS: short message service

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Original Paper

Development and Pilot Testing of Text Messages to Help Reduce Sugar-Sweetened Beverage Intake Among Rural Caregivers and Adolescents: Mixed Methods Study

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Abstract

Background: A high consumption of sugar-sweetened beverages (SSBs) poses significant health concerns, particularly for rural adults and adolescents. A manner in which the health of both caregivers and adolescents can be improved is by developing innovative strategies that target caregivers as the agents of change. Sending text messages through mobile phones has been cited as an effective way to improve behavioral outcomes, although little research has been conducted in rural areas, particularly focusing on SSB intake.

Objective: By targeting rural caregivers, this 2-phase study aimed to (1) understand caregivers' perceptions and language preferences for SSB-related text messages to inform and refine message development and delivery and (2) evaluate the acceptability of text messages for SSB intake behavior change and examine short-term effects on SSB intake behavior.

Methods: A convergent mixed methods design was used to systematically develop and pilot-test text messages with caregivers in Southwest Virginia. In phase 1, 5 focus groups that included a card-sorting activity were conducted to explore advantages/disadvantages, language preferences (ie, tone of voice, audience, and phrase preferences), and perceived use of text messages. In phase 2, caregivers participated in a 5-week text message pilot trial that included weekly educational and personalized strategy messages and SSB intake assessments at baseline and follow-up. Before the focus groups and after completing the pilot trial, caregivers also completed a pre-post survey that assessed SSB intake, SSB home availability, and caregivers' SSB-related practices. Caregivers also completed individual follow-up telephone interviews following the pilot trial.

Results: In phase 1, caregivers (N=33) reported that text messages were convenient, accessible, and easy to read. In addition, they preferred messages with empathetic and authoritative tones that provided useful strategies and stayed away from using absolute words (eg, always and never). In the phase 2 pilot trial (N=30), 87% of caregivers completed baseline and 77% completed follow-up assessment, suggesting a high utilization rate. Other ways in which caregivers reported benefiting from the text messages included sharing messages with family members and friends (80%), making mental notes (57%), and looking back at messages as reminders (50%). Caregivers reported significant improvements in home environment, parenting practices, and rulemaking around SSB (P=.003, P=.02, and P=.04, respectively). In addition, the frequency of SSB intake among caregivers and adolescents significantly decreased (P=.003 and P=.005, respectively).

Conclusions: Spending time in the formative phases of text message development helped understand the unique perspectives and language preferences of the target population. Furthermore, delivering an intervention through text messages has the potential to improve caregiver behaviors and reduce SSB intake among rural caregivers and adolescents. Findings from this study were used to develop a larger bank of text messages, which would be used in a future study, testing the effectiveness of a text message intervention targeting SSB intake–related caregiver behaviors.

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KEYWORDS

sugar-sweetened beverages; rural health; text message; mixed-methods; caregivers; adolescents

Introduction

Background

Sugar-sweetened beverages (SSBs) pose significant health concerns because of the excessive amounts consumed across the United States [1]. Several systematic reviews and meta-analyses have identified health risks associated with increased SSB consumption, including obesity, cardiovascular disease, and obesity-related cancers [2-4]. High consumption is even more concerning for populations in which these diseases are known to be disproportionately high, such as rural adults and adolescents [5-8]. The rurality status has been associated with an increased likelihood of drinking more than 3 cans of SSBs per day [9,10]. Developing strategies to reduce SSB intake that target caregivers as the agents of change in the home could be a promising way to improve SSB intake behaviors within families.

Many studies have found that caregivers are significant influencers of adolescents' dietary habits through their role modeling of behaviors, parenting practices, and management of the home environment [11,12]. In rural areas, multilevel interventions targeting adolescent SSB consumption, which also address caregivers' influence, are substantially lacking [13]. Possible reasons for this are the multitude of barriers faced by rural residents, such as lack of transportation, geographical dispersion, and reduced health services that make it difficult to access disease prevention programming [14]. Consequently, there is a need to develop and test scalable strategies that overcome these barriers while reaching and engaging rural caregivers.

One such strategy that is gaining momentum is the use of text messaging for behavior change. Mobile phone and text message use are rising rapidly in the United States, with 95% of the adult population owning a mobile phone with text message capabilities [15,16]. In rural areas, 91% of adults have text messaging–capable phones, and 65% of these are smartphones, which can go beyond simple text messages [16]. Furthermore, text message use is high in low socioeconomic populations and those with poorer health, thus making text message a prime modality for health interventions in rural areas [17].

Importantly, systematic reviews have found that text message–delivered interventions are effective in producing positive behavioral outcomes [17,18]. Specifically, preliminary studies indicated that text messages had promise in delivering SSB strategies [19,20]. A small study that used text messages to modify SSB intake behaviors found that attrition rates were lower and adherence to self-monitoring was significantly higher when compared with control groups that did not receive text messages [19]. Although this study shows promise, it did not find significant changes in SSB intake behaviors and has limited generalizability to rural areas. In fact, there are no known published studies that use text messages targeted at rural caregivers to reduce SSB intake among both caregivers and adolescents.

Theoretical Rationale

Although interventions using text messages for health behavior change are on the rise, few have documented theoretical rationales [18]. Similar to any intervention, it is important to ground the content of text messages in behavioral theory, such as the Theory of Planned Behavior, to optimize the likelihood of promoting behavior change [21,22]. With the brief nature of text messages, it may also be important to consider a language theory in the development of these short messages. Linguistic theory can provide insight into how the language and *paralanguage* (ie, the nonlexical features) of the messages play a role in the overall meaning and effect [23]. These features of the messages are elements such as the tone of voice and message phrasing [23]. These issues become increasingly important when delivering health education messages that are limited in characters, such as the 160-character limit for text messages. A study by Pollard et al explored the tone of voice and content of text messages aimed at changing dietary behaviors in young adults and found that offering substitutes and empathetic tones were most likely to motivate behavior change [24]. As suggested by linguistic theory, spending time in formative phases to understand these features specific to the target population might increase the effectiveness of the text messages to change SSB intake behaviors [25].

Objectives of This Study

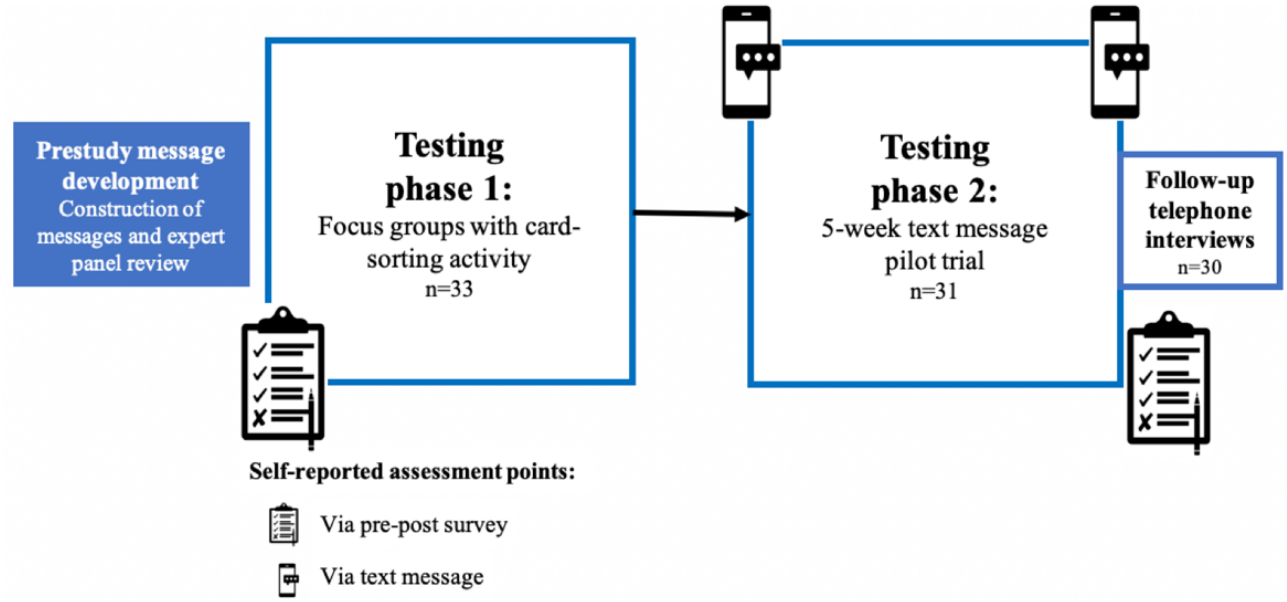
Targeting rural caregivers, the objectives of this 2-phase study were to (1) understand caregivers' perceptions and language preferences for SSB-related text messages to inform and refine message development and delivery and (2) evaluate the acceptability of text messages for SSB intake behavior change and examine short-term effects on SSB intake behaviors. In phase 1, this study explored advantages/disadvantages, language preferences (ie, tone of voice, like and disliked words, and target audience), and perceived use of text messages through focus groups and card-sorting activity. In phase 2, a text message pilot trial was conducted to further assess acceptability and examine the effects of a text message pilot trial on SSB intake and behaviors of caregivers and their adolescents. Findings from this study will inform the development of a larger scale multilevel intervention targeting SSB intake among adolescents and their caregivers.

Methods

Design

This formative study took place from August 2017 to August 2018. A convergent mixed methods design [26] was used to systematically develop and pilot-test text messages with caregivers (Figure 1). The 2 phases of testing included focus groups with a card-sorting activity and a 5-week text message pilot trial. A pre-post survey was conducted at the beginning of the focus group and the end of the pilot trial. In addition, individual follow-up telephone interviews were conducted with caregivers following the pilot trial.

Figure 1. Study overview.



This study was approved by the Institutional Review Board at the University of Virginia. Caregivers reviewed and signed an informed consent before participating in any study activities. Caregivers received a US $25 gift following the focus group and another US $25 gift card after completing the follow-up telephone interview.

Participants

To be eligible, caregivers had to be aged at least 18 years, have a child in grades 5 through 8, speak English, and own a mobile phone with text messaging capabilities. Recruitment took place in 3 counties across Southwest Virginia, part of central Appalachia: Tazewell, Wise, and Montgomery. These counties have a rurality status of 7, 5, and 3, respectively, on the rural-urban continuum codes (ie, 1=metro/urban, 9=nonmetro/very rural) [27,28]. A total of 49 caregivers were screened and eligible. Of these, 16 caregivers were either unable to be reached or had a conflict during the time the focus group was held. Overall, 33 caregivers were reached and agreed to attend the focus group. Most of the caregivers were female (85%), white (97%), and had an income >US $55,000 per year (76%). Around 49% were college graduates, 30% had completed graduate school, 12% had completed some college, and 9% had completed high school only. Of these 33 caregivers, 31 (31/33, 94%) participated in the pilot trial and 30 (30/33, 91%) were reached for the follow-up interview.

Text Message Development

In the development process, the research team crafted a sample set of text messages by adapting content used in a previous trial grounded in the Theory of Planned Behavior that aimed to reduce SSB consumption in rural adults [29]. For this study, the adapted messages comprised 2 types, educational and strategy messages, both of which aimed to reduce SSB intake. Educational messages contained facts about SSBs, such as what is considered an SSB and health risks of excessive SSB intake. Strategy messages included tips caregivers could use to help reduce SSB intake. In total, the research team developed 7 messages: 4 educational messages and 3 strategy messages. Each message was written in 3 different tones of voice adapted from Pollard et al (ie, authoritative, empathetic, and catchy) [24] and targeted toward 3 different audiences (ie, caregiver, adolescent, and family) for a total of 9 different versions of each message (n=63). The length of each message was kept to 160 characters to stay within the maximum amount of text that can be sent to most mobile telephones. See Table 1 for definitions and example messages.

Table 1. Example educational and strategy messages by varying tones of voice and target audience used in testing phases (these messages are the revised versions modified after face validity testing by the expert panel).

Message type and target audience	Authoritative tone: tone conveys a commanding, all-knowing voice and gives the readers information to act on	Empathetic tone: tone conveys that the readers' struggles are understood, and then asks the readers to act on the information	Catchy tone: tone uses pleasing, rhyming, and easy to remember words to give the readers information to act on
Educational message: recommendations for sugary drinks			
Caregiver-focused	Research says adults should only drink less than 8 oz or 1 small cup of sugary drinks/day, and kids should have 0 oz! Think about where you can cut back.	We know it's hard to cut back & most people drink too much sugar. Adults should drink <8 oz & kids should have 0 so start by figuring out how much you drink.	Drink less, live more, throw sugar out the door! Limiting sugary drinks to 8 oz for adults can lead to a long and healthy life!
Adolescent-focused	Research says adults should only drink less than 8 oz or 1 small cup of sugary drinks/day, and kids should have 0 oz! Think about where your child can cut back.	We know it's hard for your kid to cut back their sugary drinks. Adults should drink <8 oz & kids should have 0. Start by figuring out how much they drink.	Drink less, live more, throw sugar out the door! Helping your kids stop drinking sugary drinks can lead to a long and healthy life for them.
Family-focused	Research says adults should only drink less than 8 oz or 1 small cup of sugary drinks/day, and kids should have 0 oz! Think about where your family can cut back.	We know it's hard for your family to cut back their sugary drinks. Adults should drink <8 oz & kids should have 0. Start by figuring out how much they drink.	Drink less, live more, throw sugar out the door! Limiting sugary drinks to 8 oz for adults, and 0 for kids can lead to a long and healthy life for the whole fam.
Strategy message: bringing alternatives on the go			
Caregiver-focused	Stay on track when you're on the go. Sugary drinks are everywhere, so always remember to pack your favorite non-sugary drink so you don't slip up.	We know it's hard to stay on track when you're on the go. There may be sugary drinks where you go. Pack your favorite non-sugary drink so you don't slip up!	Don't slip on your trip! Make sure to carry your favorite non-sugary drink when you leave the house to help stay on track.
Adolescent-focused	Make sure your child stays on track when on the go. Sugary drinks are everywhere. Always pack their favorite non-sugary drink so they don't slip up.	We know it's hard to stay on track when on the go. There may be sugary drinks where your child goes. Pack their favorite non-sugary drink so they don't slip up!	Don't let your child slip on their trip! Make sure they carry their favorite non-sugary drink when they leave the house to help keep them on track.
Family-focused	Make sure your family stays on track when on the go. Sugary drinks are everywhere. Always pack their favorite non-sugary drink so they don't slip up.	We know it's hard to stay on track when on the go. There may be sugary drinks where your family goes. Pack their favorite non-sugary drink so they don't slip up!	Don't let your family slip on their trip! Make sure they carry their favorite non-sugary drinks when they leave the house to help keep them on track.

Next, the research team sent the messages to an expert panel (n=15) comprising registered dietitians, PhD, and/or graduate level behavioral health researchers to assess the face validity of the messages (ie, intended tone of voice conveyed by messages). The expert panel categorized text messages correctly 67% of the time and provided qualitative feedback regarding areas for improved clarity. The prominent finding that emerged from this panel was to create more distinction between authoritative and empathetic tones. These modifications were made to improve face validity of messages before starting the study.

Caregiver Pre-Post Survey

Caregivers completed a pre-post survey that assessed demographics, SSB intake, SSB home availability, and caregiver SSB-related practices twice: at the beginning of phase 1 during the focus group and after phase 2.

Demographics

Participants reported gender, year of birth, race/ethnicity, education, and income. Race was reported across 5 categories and ethnic background was categorized as Hispanic or non-Hispanic. Education was reported across 6 categories ranging from completion of grades 0 to 8 to graduate school. Income level was reported on 12 categories ranging from <US $5000 to >US $55,000.

Caregivers' Sugar-Sweetened Beverage Intake

An abbreviated version of the validated 15-item beverage intake questionnaire (BEVQ-15) was used to assess SSB intake [30]. The BEVQ-15 includes questions that assess frequency and amount of individual SSBs, including sweetened fruit drinks, soda, sweetened tea, sports and energy drinks, and coffee with cream and/or sugar. Using standardized scoring procedures, the frequency was recoded to ounces per day and calories per day for each SSB.

Home Availability of Sugar-Sweetened Beverages

Caregivers reported home availability of individual SSBs on a 5-point Likert scale from *all the time* to *never*, taken from the instrument developed by van de Gaar et al [31]. Responses were reverse coded so that *0* would reflect *never* and *5* would reflect

all the time and were recoded onto a continuous scale. Availability of each type of SSB was then averaged to obtain availability of all SSBs reported.

Caregivers' Sugar-Sweetened Beverage–Related Practices

Items involving caregivers' SSB-related practices were obtained from the instrument developed by van de Gaar et al [31]. These included parenting practices toward the adolescent's SSB intake (4 items), rules at home around the adolescent's SSB intake (2 items), and role modeling of the caregivers' SSB intake behaviors (1 item). The items around parenting practices included questions about how often the caregivers monitor the adolescent's intake, if the adolescent is allowed to drink SSBs whenever he/she wants, if the adolescent receives an SSB when he/she asks for it, and if the caregivers buy the adolescent SSBs when he/she asks for it. The role modeling item asked 1 question around how often the caregivers drink SSBs with the adolescent and how often they drink SSBs in total. Items were assessed on a 5-point Likert scale, with the exception of the 2 items around rules at home with their adolescent, which was reported as yes or no [31]. All Likert-type responses were recoded onto a continuous scale for analysis.

Phase 1: Focus Groups With Card-Sorting Activity

In the first phase of testing, a trained moderator and comoderator led 5 focus groups using established methods [32]. Each focus group lasted approximately 2 hours, comprised 4 to 9 caregivers, and was audio recorded. At the start of the focus group, caregivers completed a survey (caregiver pre-post survey described above). Then, using a semistructured focus group guide, the moderator elicited caregivers' thoughts around text message advantages/disadvantages, language preference, and perceived use of text messages for changing SSB intake behaviors.

Participants also completed a card-sorting activity [33] to understand specific language preferences: (1) tone of voice preferences, (2) audience preferences, and (3) liked and disliked words and phrases. Each caregiver was given 3 sets of message cards: 2 educational and 1 strategy message (n=27), a sorting mat, and a pink and green highlighter. Participants were first instructed to sort the cards into 3 piles: liked, disliked, and neutral. Next, caregivers went through their separated piles and used a green highlighter to highlight words and phrases liked and pink highlighter for those disliked. Participants were given the option to write comments on the cards and/or write new text messages. Within the focus groups, message sets (n=7, each set had 9 versions of the same message) were randomly distributed, so that each educational and strategy message set was tested at least once. Afterward, message sets were randomly repeated as needed until thematic saturation was met after 5 focus groups.

Phase 1: Data Analysis

Notes and transcriptions were qualitatively analyzed using an inductive approach [34]. First, the primary moderator reviewed the transcripts and took notes to summarize the focus groups. These notes were used to develop the codebook by identifying broad categories (eg, advantages to text messages) and codes within the categories (eg, timing and accessibility). Second, 2 additional coders independently reviewed notes and transcripts and identified meaning units that corresponded to the codes. Categories and codes were reviewed to allow for additions, merging overlap, and removal, as needed. Finally, the 3 reviewers met to resolve discrepancies and gain consensus.

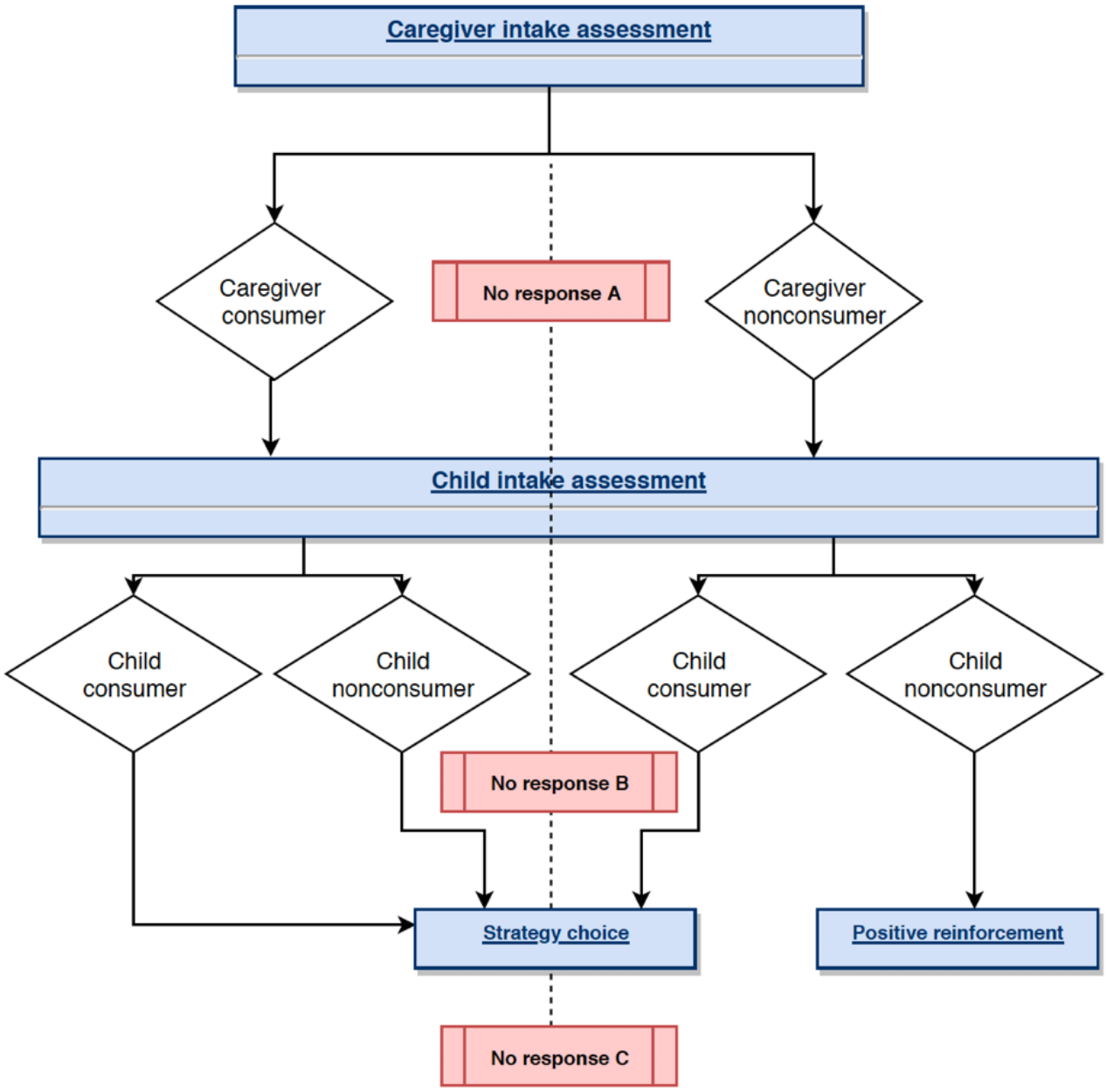
Frequency statistics were used to understand preferences for the tone of voice, audience, and liked and disliked phrases. The card-sorting activity was analyzed in 3 steps. First, the cards were coded with unique identifiers that represented the tone of voice and target audience for each message (eg, a catchy tone geared toward the family would have the code *CaF*). Second, the research team used these codes to tally how many cards fell into the liked, disliked, and neutral categories. For example, if a participant sorted a *CaF* card into a *liked* pile, 1 tally would be marked for the catchy tone and another one for the family audience, within their respective liked column. Educational and strategy messages were analyzed separately to account for preference differences by the type of content. Finally, to analyze liked and disliked words and phrases, the research team used the highlighting on the cards, which was completed after the sorting portion of the activity. Regardless of how the cards/messages were initially sorted into *liked*, *disliked*, or *neutral* piles, participants could still use highlighters (liked and disliked words and phrases) on all cards in each pile. Findings from Phase 1 informed text messages used in the phase 2 pilot trial.

Phase 2: 5-Week Text Message Pilot Trial

In the second phase of testing, caregivers from the focus groups participated in a 5-week text message pilot trial (see Multimedia Appendix 1 for user experience). The first week of this trial introduced the program, reminded caregivers what counted as an SSB, and delivered the baseline self-reported assessment point via text message. This baseline text message assessment first assessed caregivers' intake and then adolescents' intake using a 1-item question adapted from the BEVQ-15 to quickly assess the frequency of all SSB intake for caregiver and adolescent over the past week [30]. Caregivers reported from 7 categories: less than 1 time, 1 time, 2 to 3 times, 4 to 6 times, every day, 2 per day, or 3 or more per day. Responses were recoded to a continuous scale by dividing each response by 7 to reflect a frequency per day.

Following this, the text message software used caregiver and adolescent intake data to separate caregivers into 4 categories based on SSB consumption patterns (see Figure 2). The consumption category impacted the content of the third message of the assessment. If either were an SSB consumer, the third assessment question was an option to select a personalized strategy (ie, tasty alternatives, breaking your habit, home and shopping tips, and parenting tips). If neither the caregivers nor the adolescents were SSB consumers, caregivers received positive reinforcement (eg, *Congrats on drinking little to no sugary drinks! Keep up the good work.*) Or were given the opportunity to respond with strategies they used with their own families (ie, *Other families could use your help! What types of things do you do as a parent to help your child drink less (or no) sugary drinks?*).

Figure 2. Decision tree for the caregiver text message–based assessment.



Over the next 3 weeks, caregivers were sent 2 text messages per week: an educational message and a random strategy message from the category chosen (or positive reinforcement). The last week, caregivers received an educational message followed by the final self-reported assessment point via text message. At this last assessment, caregivers were able to choose 1 last strategy message based on consumption patterns. This message was then displayed immediately after they made their strategy selection. The research team collected process data on text message–based assessment response rates, changes in consumer type, and changes in strategy selection from baseline to final assessment.

Phase 2: Data Analysis

Quantitative analyses were performed using SPSS statistical analysis software (version 25.0). For data obtained from text messages, frequencies were used to analyze assessment response, consumer category, and personalized strategy choice rates. For both data obtained from text messages and pre-post surveys, descriptive statistics, including means and standard deviations, and paired t tests were used to assess changes in SSB intake, home availability, parenting practices, and role modeling behaviors. Cohen d effect sizes for paired samples were calculated. A McNemar test was used to assess the difference in the proportion of caregivers reporting yes versus no to making rules around SSBs and phi effect sizes were calculated for these 2 items.

Follow-Up Telephone Interviews and Data Analysis

Following the text message pilot trial, caregivers also received a follow-up phone call. Research staff trained in qualitative methods conducted the phone calls using semistructured,

open-ended questions with probes to reevaluate language preference, perceptions, and overall acceptability of the text messages. The interviews were audio recorded and the interviewer also took notes during these phone calls. Each call lasted between 15 and 20 min. For qualitative findings from the postinterviews, interviewer's notes were qualitatively analyzed using an inductive approach and quantified across the caregivers [34]. Although the postinterviews were audio recorded, detailed notes of the interviewer provided sufficient information for coding. Only representative quotes were transcribed from audio recordings.

Results

Phase 1: Focus Groups With Card-Sorting Activity

Semistructured Discussion

Main categories that emerged from the focus groups were advantages and disadvantages of using text messages for SSB intake behavior change, liked and disliked language and features of text messages, and thoughts around best practices to increase text message use among caregivers (eg, personalization, completing assessment via text message, and timing and frequency). Multimedia Appendix 2 illustrates the categories and codes that emerged from the focus groups and sample quotations that represent the codes.

Some of the common advantages identified included that text messages were convenient because of the timing, more accessible than other means of communication, such as fliers or emails, short and easy to read and understand, and are supported by most cellular plans in this region. On the contrary, caregivers felt that some of the disadvantages to text messages were some people might not have text message–capable devices, poor coverage or service areas, and some may be using temporary phones or phone numbers.

Regarding liked and disliked language and features of text messages, some of the top liked responses included messages that contained memorable phrases, used a family approach or sparked discussion with family, provided useful information and solutions to drinking less SSBs, and were phrased encouragingly. Some of the top disliked features included messages that told them what to do without providing any useful strategies, made caregivers feel judged as a parent/caregiver, used symbols that may be hard to interpret, used condescending and demeaning tones, made assumptions about their drinking habits, or used absolute words, such as never, always, or only.

Participants also identified best practices to increase text message use among caregivers. Some caregivers felt that personalizing with the caregiver and/or adolescent name might grab attention, but some others also felt personalization was unnecessary and would not make a difference in their behavior. Participants also felt that doing assessments to check in on caregivers' and adolescents' SSB intake would be helpful in reaching their goals; however, the response quality might be poor. Most caregivers preferred or felt that most caregivers would benefit the most from the text messages delivered at a time when they were with the adolescent, such as after school. Some others felt that delivering messages at the start of the day, week, or month would be preferred because that was when most people set goals. Finally, most caregivers agreed that 1 to 2 times per week was a good frequency to receive text messages.

Card-Sorting Activity

Data analyses revealed that there was no strong preference for messages framed for a particular target audience (Figure 3). Preference for caregiver-, child-, and family-focused messages were relatively evenly distributed at 29% to 35%. However, some tone of voice preferences emerged (Figure 4). Of all educational messages that were liked, 37% were empathetic, 34% were catchy, and 30% were authoritative. Of all personalized strategy messages that were liked, 43% were empathetic, 41% were authoritative, and 16% were catchy (Figure 4). Some common words disliked included absolute words, such as only, always, and never, and commanding words and phrases, such as stop or don't be tricked. Liked words included positive actions, such as practice and help. Changes were made to messages based on recommendations from semistructured discussions and card-sorting activity before moving into the pilot trial.

Figure 3. Caregivers' target audience preferences for educational and personalized strategy text messages related to changing sugar-sweetened beverage intake behaviors.

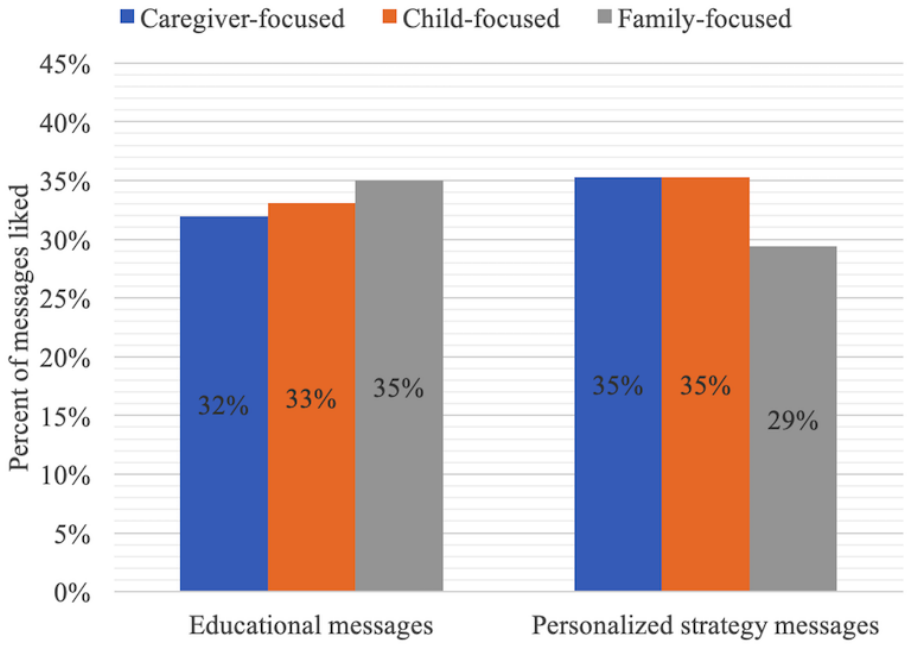
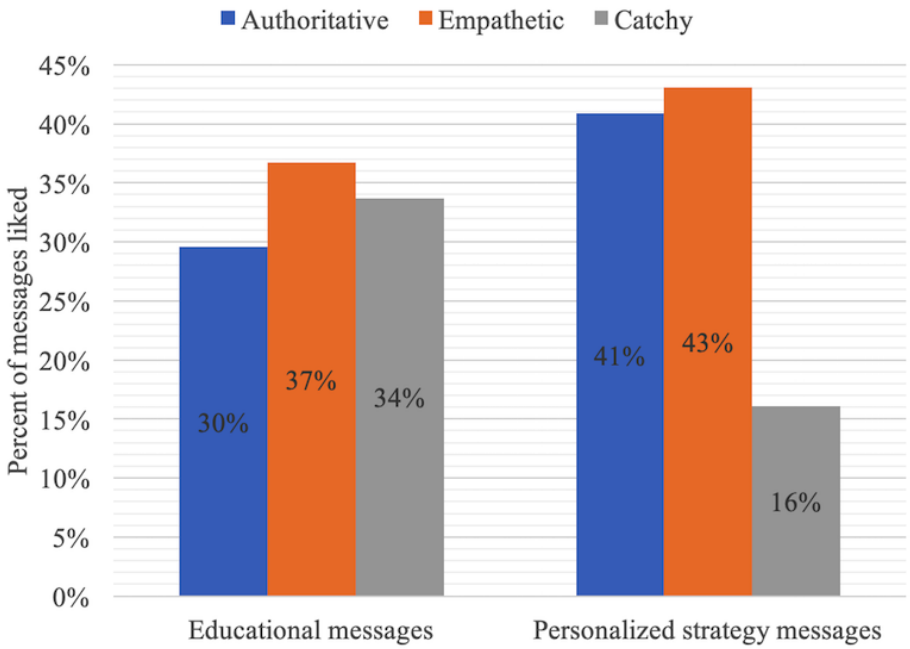


Figure 4. Caregivers' tone of voice preferences for educational and personalized strategy text messages related to changing sugar-sweetened beverage intake behaviors.



Phase 2: 5-Week Text Message Pilot Trial

Text Message Process Data

Of the 31 caregivers, 27 (27/31, 87%) fully completed the text delivered baseline assessment (ie, answered all 3 text message questions on caregivers' SSB intake, adolescents' SSB intake, and personalized strategy choice; Table 2). There were also 3 partial completers and 1 nonresponder at baseline. At follow-up, 24 of 31 (24/31, 77%) caregivers fully completed the 3 text message assessment questions and there were 2 partial completers and 5 nonresponders.

At baseline, 19 of 27 (19/27, 70%) caregivers started in the caregiver consumer/adolescent consumer category, but at follow-up, only 8 of 27 (8/27, 33%) were categorized into this group. At follow-up, most caregivers were categorized into the caregiver nonconsumer/adolescent consumer bucket (11/24, 46%). When given the choice of strategy, home and shopping tips was the top choice at both baseline and follow-up (about 45%). The other strategies chosen were relatively evenly distributed, ranging from 8% to 17%. Also, 65% (15/23) of the caregivers changed their strategy from baseline to follow-up (Table 3).

Table 2. Text message–based assessment process data: changes in the sugar-sweetened beverage consumption category and changes in personalized strategy choices.

Process data variable	Participants at baseline (n=27)[a], n (%)	Participants at follow-up (n=24)[a], n (%)
Caregiver and adolescent sugar-sweetened beverage intake category[b]		
Caregiver consumer/adolescent consumer	19 (70)	8 (33)
Caregiver consumer/adolescent nonconsumer	1 (4)	1 (4)
Caregiver nonconsumer/adolescent consumer	3 (11)	11 (46)
Caregiver nonconsumer/adolescent nonconsumer	4 (15)	4 (17)
Chosen personalized strategy[c]		
Home and shopping strategies	12 (44)	11 (46)
Parenting strategies	4 (15)	3 (12)
Strategies to find tasty alternatives	3 (11)	2 (8)
Strategies to break habit	4 (15)	4 (17)
Positive reinforcement or qualitative response	4 (15)	4 (17)

[a]Only considers caregivers that fully completed both baseline and follow-up assessments. At baseline, there were 3 partial completers and 1 nonresponder. At follow-up, there were 2 partial completers and 5 nonresponders. Participants were considered partial completer if they did not respond to all 3 assessment questions and if missing data were not considered in the calculations for changes in consumption category and personalized strategy choice.

[b]Categories were assigned based on responses to assessment. Caregivers and adolescents were considered consumers if SSB intake was ≥2 to 3 times per week.

[c]Caregivers who were consumers or had an adolescent that was a consumer were given the choice between strategies. Nonconsumers received positive reinforcement messages or were asked for some tips they would give other families.

Table 3. Sugar-sweetened beverage intake and behavior change from text message–based assessment and pre-post survey (n=29[a]).

Variable	Baseline	Follow-up	Effect size, Cohen *d*	Test statistic, paired *t* tests	*P* value
Text message–based assessment: caregiver and adolescent intake[b], mean (SD)					
Caregiver SSB[c] intake frequency (times/day)	0.60 (0.53)	0.22 (0.40)	0.82	3.241	.003
Adolescent SSB intake frequency (times/day)	0.77 (0.70)	0.46 (0.41)	0.54	3.103	.005
Pre-post survey: caregiver intake only[b], mean (SD)					
SSB intake frequency (times/day)	1.26 (1.25)	0.85 (0.88)	0.38	2.435	.02
SSB intake (fl oz/day)	17.70 (28.73)	9.60 (9.64)	0.38	1.633	.12
SSB intake (kcal/day)	184.42 (252.53)	105.83 (110.71)	0.40	1.813	.08
Pre-post survey: SSB availability in the home[d], mean (SD)					
Total SSBs	1.90 (0.70)	1.47 (0.74)	0.60	3.266	.003
Coffee w/cream and/or sugar	1.86 (1.33)	1.21 (1.26)	0.50	3.732	.001
Soda	2.25 (1.43)	1.71 (1.36)	0.39	2.737	.01
Sweetened tea	1.46 (1.23)	1.07 (1.21)	0.32	2.499	.02
Sports/energy drinks	1.57 (1.60)	1.18 (1.72)	0.24	1.036	.31
Sweetened fruit drinks	2.40 (1.17)	2.27 (1.15)	0.11	0.486	.63
Pre-post survey: caregiver SSB-related practices[e]					
Parenting practices, mean (SD)	3.20 (0.8)	3.45 (0.54)	0.37	−2.519	.02
Role modeling, mean (SD)	2.98 (0.7)	3.17 (0.54)	0.30	−1.516	.14
Rules[f], n (%)					
Are there rules in your home about how many sugary drinks your child can drink?	17 (58.62)	24 (82.76)	0.36[g]	4.000[h]	.04
Are there rules in your home about when your child can drink sugary drinks?	20 (68.97)	23 (79.31)	0.39[g]	0.571[h]	.45

[a]A total of 29 responses were analyzed; however, sample sizes fluctuated between variables because of missing responses.

[b]SSB intake was reported on a 7-point scale from <1 time to 3 or more per day. Responses were recoded to a continuous scale by dividing each response by 7 to reflect a frequency per day. Using standardized scoring procedures, the frequency was recoded to ounces per day and calories per day for each SSB.

[c]SSB: sugar-sweetened beverage.

[d]Reported on a 5-point scale and coded so that 0=never available and 4=available all the time.

[e]Reported on a 5-point scale and coded so that a higher number represents a more positive behavior that would lead to reduced adolescent SSB intake.

[f]Caregivers reported as yes/no. Reported in table as percentage that reported yes so that a higher number represents a more positive behavior.

[g]Effect sizes for the 2 rule making variables are reported as phi.

[h]Changes analyzed for the 2 rule making variables were analyzed using McNemar test.

Text Message–Based Assessment

Paired t test analyses of the caregiver-reported text message–based assessments found that both caregivers (*P*=.003) and adolescents (*P*=.005) significantly reduced their frequency of SSB intake per day and effect sizes were medium to large (Table 3).

Caregiver Pre-Post Survey

As further illustrated in Table 3, pre-post survey data found that caregivers significantly reduced their frequency of SSB intake per day (*P*=.02). Caregiver changes in SSB calories and fluid ounces per day were not significant. Availability of total SSBs in the home also significantly decreased (*P*=.003). When analyzed by individual SSBs, home availability of coffee with cream and/or sugar (*P*=.001), soda (*P*=.01), and sweet tea (*P*=.02) also each significantly decreased, yet sports drinks and sweetened fruit drinks did not change. Caregiver's parenting practices significantly improved toward encouraging adolescent behaviors that promote reduced SSB intake (*P*=.02). Role modeling, however, was not significant. Related to parenting rules on SSB intake, rules for when adolescents can have sugary drinks significantly increased (*P*=.04), yet rules for how many sugary drinks an adolescent can have did not significantly change. As shown, effect sizes varied across variables.

Follow-Up Telephone Interview

After completing the pilot trial, the majority of the caregivers (25/30, 83%) reported liking all the messages and stated high acceptability of receiving an SSB intervention through text messages. Some statements made by caregivers about the acceptability of the trial included:

> *It was encouraging and informative,*
>
> *I didn't realize how much I drank until I joined your program,*

and

> *It was a good way for me to start thinking about a plan.*

Most caregivers (28/30, 93%) reported that the number of messages sent was a good amount and would have accepted more than 2 messages per week. A stronger preference for receiving messages in the evening time also emerged after the pilot trial. Some of the ways that caregivers used the messages included making mental notes (17/30, 57%), sharing messages with family members, friends, and coworkers (24/30, 80%), and looking back at messages as reminders (15/30, 50%).

All 30 caregivers who completed the follow-up interview reported that the messages were beneficial to their family. Caregivers stated benefits, such as "It gave me more ammunition as a parent," and "It's now at a point where we are discussing the issue and consciously thinking about our choices." Of these, 87% (26/30) reported making actual changes around SSB intake behaviors, such as changing parenting practices (eg, made rules around when and how many SSBs their adolescent can have, increasing the adolescent's access to water and healthy alternatives), decreasing home availability of SSBs, increasing communication around making healthy drink choices, reducing SSB intake for both the caregiver and adolescent, and creating a general, constant awareness of their intake. The 2 caregivers that reported no changes were made, stated that they were either maintaining their intake or are now planning to make some changes.

Discussion

Principal Findings

This is the first known study to evaluate text messages targeted to caregivers to reduce SSB intake in both caregivers and adolescents in a rural setting. Findings from this multiphase mixed methods approach suggest that texting is an acceptable way to deliver educational, strategy, and assessment messages to change SSB intake behaviors in rural populations. In addition, there are unique linguistic perspectives of rural caregivers to take into consideration when designing behavior change messages that may help improve SSB intake behaviors. These include tone of voice with attention to the words, phrases, and other language and features preferred by the target population. This formative study provides a framework for future research involving the development and testing of text messages targeted at SSB intake and other health behaviors.

Advantages and Disadvantages

Text messaging has several advantages that make it an appealing modality for health promotion and intervention delivery in rural areas. These advantages include low implementation cost, convenience of accessing messages, and increasing reach to those who would otherwise be unable to attend an in-person intervention [17]. Encouragingly, these advantages were also emphasized by caregivers in this study. Although most caregivers felt that the text messages were acceptable and beneficial, one of the top disadvantages mentioned in the focus group was that some caregivers might not have text messaging–capable devices. This perception is inconsistent with a recent report from 2018 that found 91% of rural residents had access to mobile phones [16]. This discrepancy may be because of the fact that mobile phone ownership has risen dramatically in the past few years [16], and the caregivers in this study may not fully understand the rates of cell phone ownership in their communities. Other disadvantages mentioned included poor coverage in very rural areas and the use of temporary phones. Despite these disadvantages, caregivers felt text messages could be effective and beneficial in their respective communities. Collectively, the text message advantages accentuated in the focus groups outweighed the disadvantages. Given the potential continued increase in the use of text messaging technology in rural populations and the benefits it provides to overcoming barriers to accessing evidence-based programs, this is an optimal time to develop and test text message–based interventions.

Language Preferences

As technology for delivering health behavior interventions advances, theoretical approaches must continue to be utilized. Few studies have documented the development and testing process

for text messages using theory-based approaches [17], particularly those that focus on the features of language. Linguistic theory postulates that word choice and underlying tones can help the target audience identify with the messages and, in conjunction with behavior change theories, can produce desired health outcomes [25]. Furthermore, theorists have stated that considering cultural perspectives of the targeted population when developing health education messages could lead to not only an appreciation of the messages but ultimately effectiveness and adoption of the desired intervention [35].

Results from the focus groups revealed several important language considerations for the targeted rural caregiver population and are also supported by a study by Denham et al around health messaging for Appalachian residents [36]. Overall catchy type tones were disliked because of the use of slang and trendy words that some caregivers found unappealing, yet the memorable aspect of these messages was liked. Authoritative tones were preferred, as long as the messages were providing useful strategies and stayed away from absolute words (ie, always, never, and only). Empathetic tones were also liked, as long as the messages were not making assumptions about the caregivers' SSB intake behaviors or using condescending tones. Finally, although no audience preferences emerged from the card-sorting activity, the benefit of a family-based approach was a prominent theme that emerged from focus group

discussions and post interviews. Importantly, Denham et al found similar results when conducting focus groups around health messaging to decrease underage drinking and tobacco use, though not exclusive to text messages. Their study suggests that messages should be based on fact, have a polite tone, and present information in a nonjudgmental way; findings that align with the results presented here. Furthermore, this same study found the importance of family-based approach, particularly among women who felt they were the gatekeepers to their family's health [36]. Together these results suggest that preferences for message language and framing is consistent between delivery modalities and health behaviors and provide a strong foundation of evidence for future health messaging development in rural and Appalachian areas.

Text Message Use and Preliminary Effectiveness

During the text message pilot trial, caregivers interacted with the messages by responding to assessments, making mental notes, and sharing messages with family and friends. The high rate with which caregivers utilized the text messages in this study indicates that this may be an effective modality for caregivers to receive SSB intake–related behavior change strategies. This finding is supported by several studies that have found greater adherence to self-monitoring practices and higher intervention completion rates through text message use [19,37]. Not only does text messaging have the potential to increase self-monitoring adherence, results in this study suggest that text messages delivered to caregivers may also be an effective method to improve caregiver SSB intake–related behaviors and reduce SSB intake of both caregivers and adolescents. Studies have found that parenting practices, home environment, and parental role modeling have significant influence over adolescent SSB intake [31,38], but few studies have studied this using text messages. A study by Grutzmacher et al found that delivering a nutrition and physical activity intervention through text messages to low-income parents of school-aged children significantly improved home environment, parent behaviors and intake, and child intake around fruit and vegetable consumption [39]. Findings from Grutamzcher et al reinforce this study's preliminary results and emphasize the potential for text messages delivered to caregivers to change caregiver and child health behaviors.

Limitations

The results of this study should be interpreted in the context of several limitations. The recruitment methods may have resulted in a more motivated and informed sample of caregivers. Caregivers who are less motivated to change their SSB intake may have had different reactions to the language and content of the messages. However, during the focus group elicitation process, caregivers were asked to think about themselves and their whole community. Also, this study was over representative of females, high income, high education, and lower SSB intake. SSB intake in this study sample was lower than what has been found in previous research with representative samples [40]. These factors may limit the generalizability of the results.

In addition, there are several limitations in interpreting behavior change results. First, although validated measures were used, self-reported behaviors by the caregiver and may have introduced bias or human error. Second, it is important to distinguish that the tested text message strategy was not a stand-alone intervention. The pilot trial was preceded by a focus group, so caregivers naturally received some education and face-to-face discussion around SSBs before receiving messages. This makes it difficult to tease out the isolated effects of the pilot trial. Finally, this pilot study did not compare behavior change to a control group and the pre-post changes should be interpreted somewhat cautiously because of the small sample size. Despite these limitations, the effect sizes provide general estimates to inform fully powered future studies and a framework for future study with text message–based health interventions in rural areas.

Conclusions and Future Directions

This study aimed to develop and test relevant text messages to reduce the high consumption of SSBs in rural areas, which may be contributing to the widespread health disparities. Spending time in the formative phases of text message development helped understand the unique perspectives and language preferences of the target population. This study also found that delivering an intervention through text messages had the potential to reduce SSB intake in rural caregivers and adolescents, where SSB intake is a prevalent problem [9,40]. This is promising because text message has many benefits, such as being low-cost, easily accessible, and asynchronous, which may help overcome some of the current barriers to programming faced by rural populations.

This text message–based intervention to reduce SSB consumption in caregiver and adolescents shows promise, yet there are important considerations for future study. Fully powered studies are needed to determine engagement, adherence, and effects of a text message intervention targeting SSBs. Future text message studies in rural areas should aim to incorporate the ability to choose the frequency and timing of the delivery of messages to fit the needs of various caregivers' work schedules and general preferences for increased adherence and response rates. In addition, future studies should explore incorporating tailored feedback, as studies have shown that they improve behavioral outcomes [20,41]. Finally, studies should be conducted to understand how text messages can be used or incorporated into interventions that target multiple levels of influence on caregiver and adolescent SSB intake behaviors [42].

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Authors' Contributions

MY implemented the study, managed the text message software, analyzed and interpreted results, and drafted the manuscript. KJP and D-JPB assisted in co-moderating focus groups, analyzing and interpreting data, and provided feedback on the manuscript. AL and BAM assisted in analyzing qualitative data and provided feedback on the manuscript. JMZ was involved in conceptualizing the study, analyzing, and interpreting data and providing feedback on all drafts of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

A short video demonstrating how caregivers received and interacted with the text message intervention.

[MP4 File (MP4 Video), 15MB - mhealth_v7i7e14785_app1.mp4]

Multimedia Appendix 2

Results from semistructured focus group discussion with representative quotes around using text messages for sugar-sweetened beverage behavior change.

[PDF File (Adobe PDF File), 102KB - mhealth_v7i7e14785_app2.pdf]

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Abbreviations

BEVQ-15: 15-item beverage intake questionnaire
NIH: National Institutes of Health
SSB: sugar-sweetened beverage

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Original Paper

A Smart and Multifaceted Mobile Health System for Delivering Evidence-Based Secondary Prevention of Stroke in Rural China: Design, Development, and Feasibility Study

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Abstract

Background: Mobile health (mHealth) technologies hold great promise in improving the delivery of high-quality health care services. Yet, there has been little research so far applying mHealth technologies in the context of delivering stroke care in resource-limited rural regions.

Objective: This study aimed to introduce the design and development of an mHealth system targeting primary health care providers and to ascertain its feasibility in supporting the delivery of a System-Integrated techNology-Enabled Model of cAre (SINEMA) service for strengthening secondary prevention of stroke in rural China.

Methods: The SINEMA mHealth system was designed by a multidisciplinary team comprising public health researchers, neurologists, and information and communication technology experts. The iterative co-design and development of the mHealth system involved the following 5 steps: (1) assessing the needs of relevant end users through in-depth interviews of stakeholders, (2) designing the functional modules and evidence-based care content, (3) designing and building the system and user interface, (4) improving and enhancing the system through a 3-month pilot test in 4 villages, and (5) finalizing the system and deploying it in field trial, and finally, evaluating its feasibility through a survey of the dominant user group.

Results: From the in-depth interviews of 49 relevant stakeholders, we found that village doctors had limited capacity in caring for village-dwelling stroke patients in rural areas. Primary health care workers demonstrated real needs in receiving appropriate training and support from the mHealth system as well as great interests in using the mHealth technologies and tools. Using these findings, we designed a multifaceted mHealth system with 7 functional modules by following the iterative user-centered design and software development approach. The mHealth system, aimed at 3 different types of users (village doctors, town physicians, and county managers), was developed and utilized in a cluster-randomized controlled trial by 25 village doctors in a resource-limited county in rural China to manage 637 stroke patients between July 2017 and July 2018. In the end, a survey on the usability and functions of the mHealth system among village doctors (the dominant group of users, response rate=96%, 24/25) revealed that most of them were satisfied with the essential functions provided (71%) and were keen to continue using it (92%) after the study.

Conclusions: The mHealth system was feasible for assisting primary health care providers in rural China in delivering the SINEMA service on the secondary prevention of stroke. Further research and initiatives in scaling up the SINEMA approach and this mHealth system to other resource-limited regions in China and beyond will likely enhance the quality and accessibility of essential secondary prevention among stroke patients.

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KEYWORDS

stroke; secondary prevention; rural health services; mobile application; software design; China

Introduction

Stroke in Rural China

China bears the largest stroke burden in the world. Every year, there are about 2.5 million new stroke cases, and 1 million deaths due to stroke [1]. According to recent estimates, the age-standardized prevalence of stroke in China was 1114.8 per 100,000 people, whereas the rate is significantly higher in rural areas where the prevalence has tripled in the past three decades [2]. Stroke prevention has become a national priority in China since 2009, and significant efforts have been made in establishing stroke registers, improving acute stage treatment, and screening high-risk populations [3]. However, accessibility and quality of secondary prevention of stroke is still a major public health challenge.

Currently, preventive care for stroke patients is suboptimal in rural China, and there is no clear strategy for improving secondary prevention of stroke in resource-limited settings in China and around the world [4]. The current lack of quality essential care provided by the health care system and the insufficient awareness on self-management among stroke survivors contribute to the high prevalence of stroke recurrence and stroke-related mortality in rural China. Village doctors and physicians in township hospitals, who undertake both the basic public health services and clinical services in rural settings, are primary care providers for delivering preventive care and health education for rural residents [5]. Most of them receive less than 5 years of professional medical training and are often unable to provide guideline-based high-quality health care services for stroke patients [6,7]. In addition, stroke patients generally lack awareness and education on secondary prevention, and previous studies found that adherence to medications for secondary prevention was poor among community-dwelling individuals after their discharge from the hospital [8]. To address these challenges, effective strategies for empowering the existing health workforce with the ability to deliver and promote secondary prevention of stroke are needed.

Potential of Mobile Health

Owing to the rapid popularization of ubiquitous network connectivity and mobile phones, mobile health (mHealth) technology has emerged as a potential solution for improving both the accessibility and quality of health care, especially in resource-limited settings. There is an increasing body of evidence demonstrating that mHealth-based programs could improve health care service delivery and quality of care among people with chronic conditions [9-12]. However, there are still many challenging issues that remain to be addressed. First, most of these studies focused on health care providers who deliver clinical services at secondary or tertiary hospitals, so evidence is still very limited for mHealth programs designed for a primary health care context in resource-limited settings [10,13]. Second, although some recent research investigated factors related to adopting and using an mHealth system [14,15], most published programs appear to have relatively little input from the targeted end users [16,17]. Poor involvement of end users in the design stage likely leads to poor adoption of the new mHealth system and suboptimal usability and engagement in using the mHealth programs, which further limits the effectiveness of digital health interventions. Finally, the available mHealth programs usually provide care tools for one care role only rather than for a coordinated team of providers with multifaceted roles. Previous literature reviews revealed that except for individual factors, external factors, such as supporting the relationship with their coworkers and collaboration efforts at the organizational level, also facilitated the adoption of an mHealth system among health care providers, which is especially important for mHealth programs in developing countries [14,15].

Study Objectives

To address these multiple determinants, we have designed an mHealth system for improving stroke care in rural China. This technology was used in the *System-Integrated techNology-Enabled Model of cAre* (the SINEMA project) for secondary prevention of stroke in rural China. The protocol of the SINEMA study has been published earlier [18]. In this paper, we will describe the design process of the SINEMA mHealth system as well as report the findings from the contextual research supporting the user-centered design, the iterative design and implementation of the SINEMA mHealth system, and the results from the users' survey after a yearlong trial. The clinical effectiveness of the SINEMA intervention model is beyond the scope of this paper and will be discussed in a separate paper.

Methods

Study Site

The SINEMA study was undertaken in a region in China—Nanhe County, Hebei Province. This province, together with 8 other provincial regions, constitutes a high incidence *Stroke Belt* scattered from the north to west of China, which has a stroke incidence of 205.1 to 550 per 10,000 population, doubling that of the national average [19]. This study aimed to design, implement, and evaluate an mHealth model of care for secondary prevention of stroke. It was anticipated that the care approach would be generally applicable to other resource-limited settings in the country. Nanhe County is listed in the provincial government's record as a *poverty-stricken county* with an annual disposable income per capita less than half of the national average of 11,030 RMB [20]. In Nanhe County, there are 2 county-level hospitals, 8 township hospitals (one for each

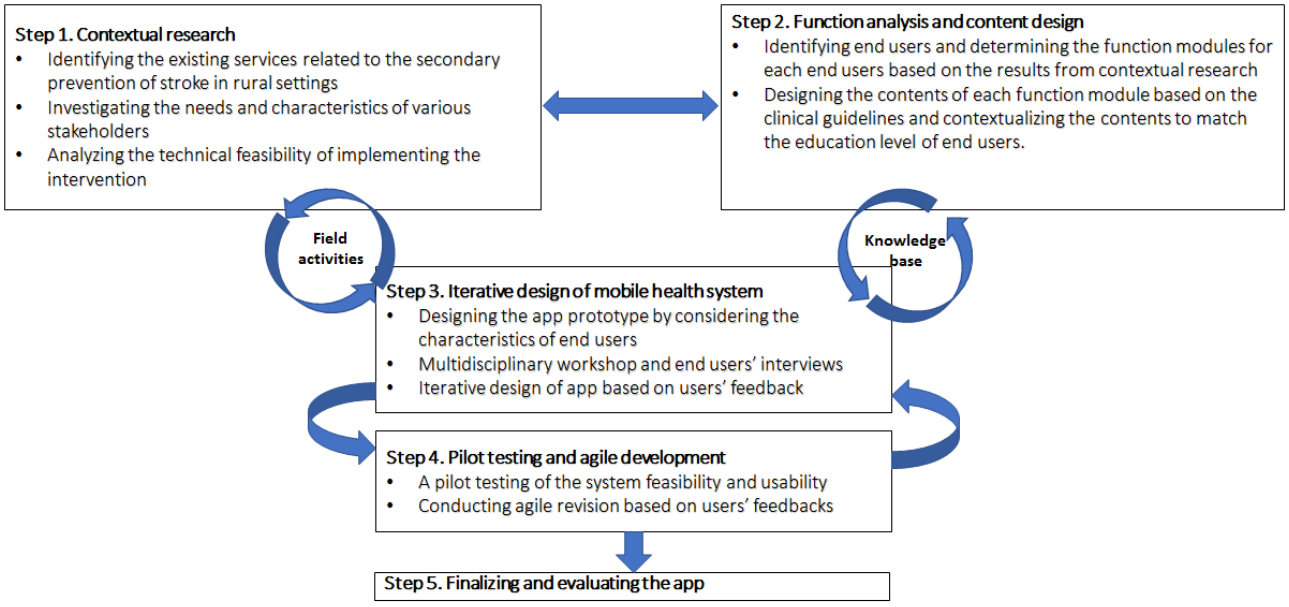
township), and 218 village clinics (one for each village). Overall, 4 typical villages within the area were selected for contextual research and the pilot study.

Design Framework of the System-Integrated Technology-Enabled Model of Care Mobile Health System

In line with the user-centered design principles, our design framework consisted of 5 key steps, including (1) assessing the needs of relevant end users through in-depth interviews with stakeholders; (2) designing the functional modules and evidence-based contents based on end users' needs; (3) iteratively designing and building the mHealth system structure and the app user interface based on end users' roles and characteristics; (4) improving and enhancing the system through pilot testing and agile development based on end users' feedback; and (5) finalizing the mHealth system, deploying it in field trial, and evaluating its feasibility through a survey of the dominant user group (summarized in Figure 1).

To successfully complete all these steps and tasks, we assembled a multidisciplinary team of researchers who have diverse expertise in public health, medical anthropology, behavioral science, stroke treatment, care transition, software design and development, and user interface design.

Figure 1. Steps involved in the design of the system-integrated technology-enabled model of care mobile health system.



Step 1: Contextual Research and Needs Assessment

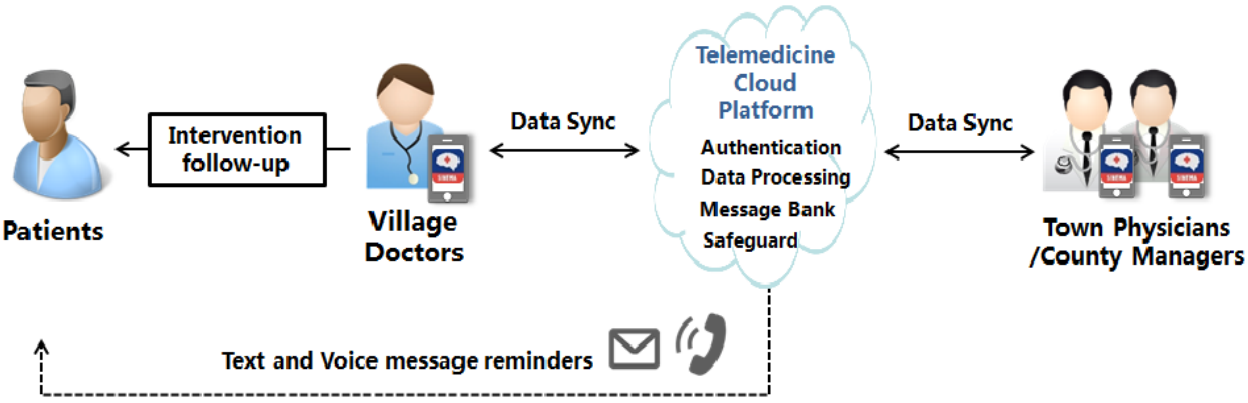
To design an effective system that caters to the needs of both health care providers and patients on secondary prevention of stroke, we first carried out contextual research in 4 villages in Nanhe County to identify existing health care services available and accessible in the villages and assessed the needs of relevant end users.

Considering the concerns from patients and families in discussing and sharing their experience with other people in the village, and participants' geographically dispersed locations, we adopted face-to-face in-depth interviews as the most feasible method to collect data. Participants included stroke patients, family caregivers, village doctors, and health care providers in township hospitals. Participant recruitment occurred in collaboration with local health facilities, and stroke patients and their caregivers were referred by village doctors. The number of participants interviewed was decided based on a saturation point of obtaining a comprehensive understanding where no new substantive information was being acquired. The interviews were conducted by experienced researchers. Interviews followed preprepared semistructure interview guides, which were developed after discussions among the multidisciplinary research team (see Multimedia Appendix 1 for interview guides). Separate guides were used for different group of participants. Interviews were conducted in a private room (either in a private room in the clinics for health care providers or in the patients' own house) to ensure the confidentiality of the information. All interviews were audio-recorded and transcribed verbatim in Mandarin Chinese.

Step 2: Functional Analysis and Content Design

Based on of the results obtained from contextual research and the SINEMA intervention model design, the research team chose to design the mHealth system (Figure 2) in 2 parts, ie, an app and a cloud platform that is linked with a patient-oriented message dispatch system. The research team drafted a requirement document. In the document, types of end users were identified, including village doctors, township physicians, and county managers, with the latter two also assuming management roles. The overall aims of the mHealth system—empowering primary health care providers to perform guideline-based care for stroke patients and supporting them in delivering the SINEMA intervention method—were also clearly stated.

Figure 2. A schematic diagram of the system-integrated technology-enabled model of care mobile health system.



In this requirement document, the key functions and contents of the system modules were also drafted. The content of the modules was developed based on the Chinese clinical guideline for the secondary prevention of stroke in primary health care settings [21]. The guideline emphasizes on early diagnosis of stroke-related symptoms and risk factor management through lifestyle modification and a combination of medical therapies. On the basis of the guideline, stroke specialists proposed the structure of the follow-up visits, taking full consideration of the different types of strokes. Then a team of researchers translated the information from the guideline into a series of questions, following a standard logic flow, for village doctors' follow-up visit. In line with the guideline, they also prepared training materials with videos, graphs, and texts, and a list of essential medicines to assist village doctors' decision making on medication prescription. Behavior change techniques such as goals and planning, feedback and monitoring, and social support were applied to promote the actual behavior changes in end users. The contents were further simplified and contextualized based on the principles of meeting the basic education level of village doctors and availability of medicines in the villages. A paper-based demo version of the contents on follow-up visits, training materials, and medicine lists was then reviewed by stroke specialists. Using the clinical guideline as references, stroke specialists provided their feedback on contents during a workshop meeting and verified that the contents after the simplification process were in line with the clinical guideline recommendations after the simplification process.

Step 3: Iterative Design of the Mobile Health System

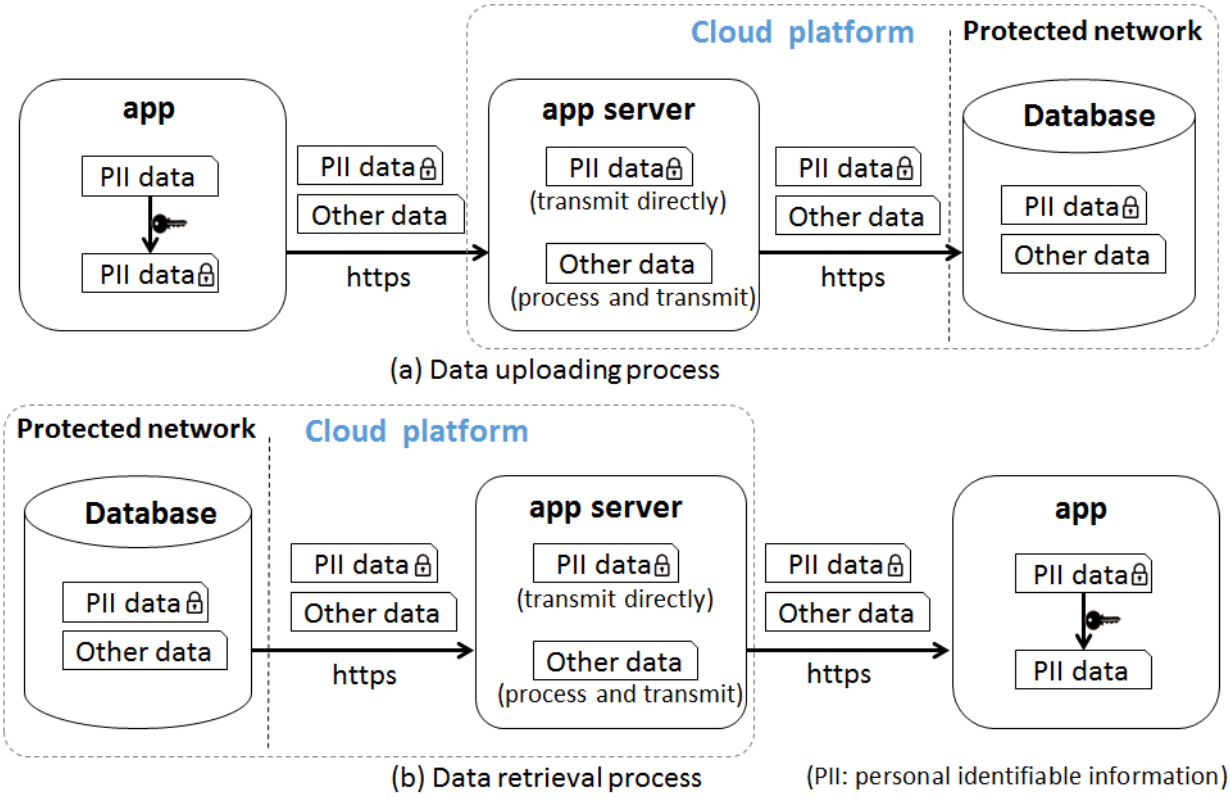
Design of the System Architecture

After clarifying the functions and modules, we designed the system architecture. The whole system comprised an app client and a cloud platform (Figure 2). The client was a 3-in-1 app for village doctors, township physicians, and county managers, which was running on an Android mobile platform, with different user interfaces and functional modules based on the type of roles assigned. The main reasons for choosing the Android phone were that a range of affordable phone models were available and that they were very popular among village doctors, which would facilitate future scale-up of the system in rural areas. The cloud platform contained 2 parts, the app server and database server. The app server had built-in functions of security authentication, services management, and data analytics as well as communication with the third-party voice and short messaging service (SMS) text messaging gateways. The database server was deployed in a protected network (private network) inaccessible to the public network, ensuring that the database service only opens the data ports to the app server.

Medical data and personal identifiable information (PII) are sensitive data concerning a user's privacy that need to be transmitted over the network and stored in a secure manner to avoid data loss, breach, or malicious attacks [18]. PII data security, as one of the key issues raised by end users, was thoroughly discussed within the team and was emphasized in this system under the premise of architecture safety (Figure 3). In our system, to ensure the security of the data on the mobile phone, the app client did not store data [22]; all the data were obtained through the network, and they were automatically erased when the app was closed. For the data uploading process, first, the PII data were encrypted using Advanced Encryption Standard in the app with random keys, and then the https, a secure data transmission protocol, was used to transmit the data over the network; finally, the data were stored in the database server on the cloud. This dual method of encryption offered more effective data protection. Encrypted PII data were directly stored in databases, which enhanced the level of data storage security. Similarly, for the data retrieval process in which the app client requested for data stored in the database, the cloud transmitted the encrypted PII and other data requested to the app client to be used by the end user. As the app server needed to obtain the plain text of a patient's phone number for sending an SMS text messaging, the phone number was not encrypted on the app client but encrypted on the app server.

We designed the SINEMA mHealth system with the methods of modularization [23] and good encapsulation to implement separate service modules and commonly used components [24] of tools to meet the iterative design and development needs [25].

Figure 3. Information safety processing diagram.



User Interface and User Experience Design

The user interface should be designed to be friendly and efficient, which is the key to improving users' experience in utilizing and engaging with the app. Our team has designed a human-centered app by following the principle of a friendly and efficient user interface with thorough consideration of users' needs and characteristics [26].

First, the user interface and user experience design should reflect users' mental models. As our target users are professionals, including doctors from village clinics and from township and county-level hospitals as well, the design of the interface took full account of their respective needs and expectations as well as limitations. In line with the results from the contextual research, we assessed the users' proficiency in using smartphones by choosing an extensively used app as a benchmark. Considering that county and town hospital doctors are already familiar with Web-based health care information system, we adopted similar structure design and visual styles.

Second, the design should improve workflow efficiency, avoid information-entry errors, and provide smooth app access for users. Therefore, we designed simple and easily recognizable icons, such as contrasting colors for positive and negative information and distinctive graphical shapes to indicate different click status, to quickly draw users' attention and help them understand the information effectively. In addition, we used uniform marks for navigation to make the transition and interaction of different interfaces clear and consistent. Designing with specific blocks to distinguish information contents and prefilling with defaults also improved the usability and reduced the chance of entry errors.

Step 4: Pilot Testing and Agile Development

Following the above studies, we then developed a fully functional app prototype, which was used for discussion in the multidisciplinary workshop as well as for demonstration to and interviews with the village doctors. On the basis of their feedback, we carried out the first round of iterative design and developed a testing version for the pilot study.

The pilot study was conducted in 4 rural villages of Nanhe County for 3 months. During the pilot study, each village doctor was provided with an Android phone with the app installed to implement the SINEMA intervention model. Each village doctor was asked to care for about 10 patients in his or her village. In-depth interviews with all the village doctors and township physicians were conducted after the pilot study to collect any feedback about the usability of the app and suggestions to optimize the app.

On the basis of the feedback from the end users, we conducted several rounds of revision of the app. During the process of development, we took advantage of the latest technologies to speed up the iteration, for example, the online tracking and positioning of bugs for rapid and efficient feedback and the hotfix technology for repairing and updating the app without releasing a new version of the app for village doctors.

Step 5: Main Trial and Users' Follow-Up Survey

The finalized app system was utilized to support the implementation of the SINEMA method in 25 villages, which had been randomized into the intervention arm of a cluster-randomized controlled trial covering 50 villages in 5 townships. The published protocol paper contains details

regarding the trial design [18]. Village doctors in the intervention arm were invited to complete a survey through qualtrics.[xm] (Qualtrics) online platform after the 1-year intervention. The survey included questions related to village doctors' demographic characteristics and their experience of implementing each component of the SINEMA method including this mHealth system. Village doctors were asked to report their agreement level with the statements regarding the usability and satisfaction on various functions of the SINEMA app according to the 5-level Likert scale, ranging from very disagree to very agree.

Analytical Approach

Verbatim transcriptions in Chinese were analyzed using a thematic analysis [27]. Researchers first read through all transcripts to be familiar with the data. Themes were then developed based on the interview guide and discussion among researchers to capture the important features of the data. Codes were generated for each transcript line by line and grouped into categories. Each category was then reviewed and examined again, and groups of main categories were refined before finalizing the major themes. Coding process and key themes were discussed within the research team. Coding was performed by WG and reviewed by EG, followed by a discussion to ensure the trustworthiness. Quotations used in this paper were translated from Chinese to English and then back-translated into Chinese to increase the transparency of the interpretation. NVivo 11 qualitative analysis software (QSR International) was used to facilitate the coding approach.

The survey data in this study were analyzed by using STATA statistical software (Version 15, StataCorp LLC). A descriptive analysis was performed, and frequencies and proportions were reported for categorical variables.

Ethical Considerations

The contextual research and pilot study were approved by the Duke Kunshan University Ethical Committee. The main SINEMA trial was approved by the institutional review boards of the Duke University Health System in the United States and Tiantan Hospital in Beijing, China. The trial was registered in ClinicalTrials.gov (#NCT03185858). All participants provided their written informed consent before the study began.

Results

Findings From the Contextual Research

In total, our team visited the study sites 3 times during the system design stage and conducted 49 in-depth interviews with various stakeholders, including 5 physicians at township and county hospitals, 12 village doctors, 22 stroke patients, and 10 family caregivers. On the basis of the analyses of the qualitative data from 17 in-depth interviews (12 village doctors and 5 township hospital physicians), we generated 4 broad themes related to the development of function modules. The data from 22 patients and 10 family caregivers were considered as a benchmark to identify the gaps between the existing and expected care services and were mainly used for informing the development of a messages-dispatching system, which will be reported in another paper.

Theme 1: Lack of Awareness and Knowledge on the Secondary Prevention of Stroke Among Village Doctors

On the basis of the interviews, most village doctors could identify stroke patients in the villages, but they were not able to provide effective preventive services for this special patient group. Most village doctors were not aware of the guideline on the secondary prevention of stroke and received none-to-minimum training related to stroke prevention. The insufficient awareness and knowledge on guideline-recommended pharmacological treatments and physical rehabilitation limited the services that village doctors could provide when stroke survivors failed to adhere to the essential medications prescribed at discharge or failed to do physical exercise and rehabilitations. The services that village doctors provide to stroke patients are mainly covered by the basic public health services, which focus on the management of hypertension and diabetes as risk factors.

Theme 2: No Existing Electronic Record System for Managing Patients' Visits in the Villages

During the interview, several village doctors mentioned that they were not able to keep records of the patients' visits because there is no electronic record system; most of their work is still paper based. The existing electronic systems, including a system for purchasing medicines and a system for uploading records of basic public health services, were all developed by the government and are recently being utilized by village doctors. However, these electronic systems were not equivalent to the hospital information system; thus, they were unable to support village doctors to manage patients' routine visits. A few village doctors mentioned that they took paper-based notes to record patients' visits:

> *We do not have electronic record system to record patients' visit in the clinic...I sometimes write the prescription on paper sheets, but actually I seldom review these paper sheets because the note is not kept systematically.* [Village doctor]

Owing to the lack of an electronic record system, the decisions made by village doctors were mainly based on unreliable recalls from patients and their family members:

> *These patients or their family members come to my clinic and tell me what medicines they want to purchase, and I will prescribe based on that.* [Village doctor]

Theme 3: Township Physicians' Supports and Supervisions Among Village Doctors

During the interview, several village doctors mentioned that their performance was supervised by township physicians who visited village clinics and checked paper-based records for the basic public health services as indicators for village doctors' performance. Township physicians also mentioned their roles in supporting and managing village doctors:

> *We are adopting the integration of management between township and villages. We have very close communications with village doctors. We organize monthly meetings among village doctors to provide updates mainly on basic public health services. We also invite village doctors to take part in trainings organized by county hospitals or the county health bureau.* [Township physician]

Theme 4: Great Interest in Applying Mobile Health Technology in Daily Work but the System Should Be Simple to Learn and Use

Village doctors were also interviewed on their use of smartphones and the availability of internet in the clinic. All village doctors we interviewed owned a smartphone and were accustomed to using multimedia apps. Most of the village doctors we interviewed mentioned that their clinics have good internet access and some of the clinics have Wi-Fi. However, only a few village doctors had actually installed health-related mobile apps to support their daily work, and the key concern was the simplicity and ease of use of the apps:

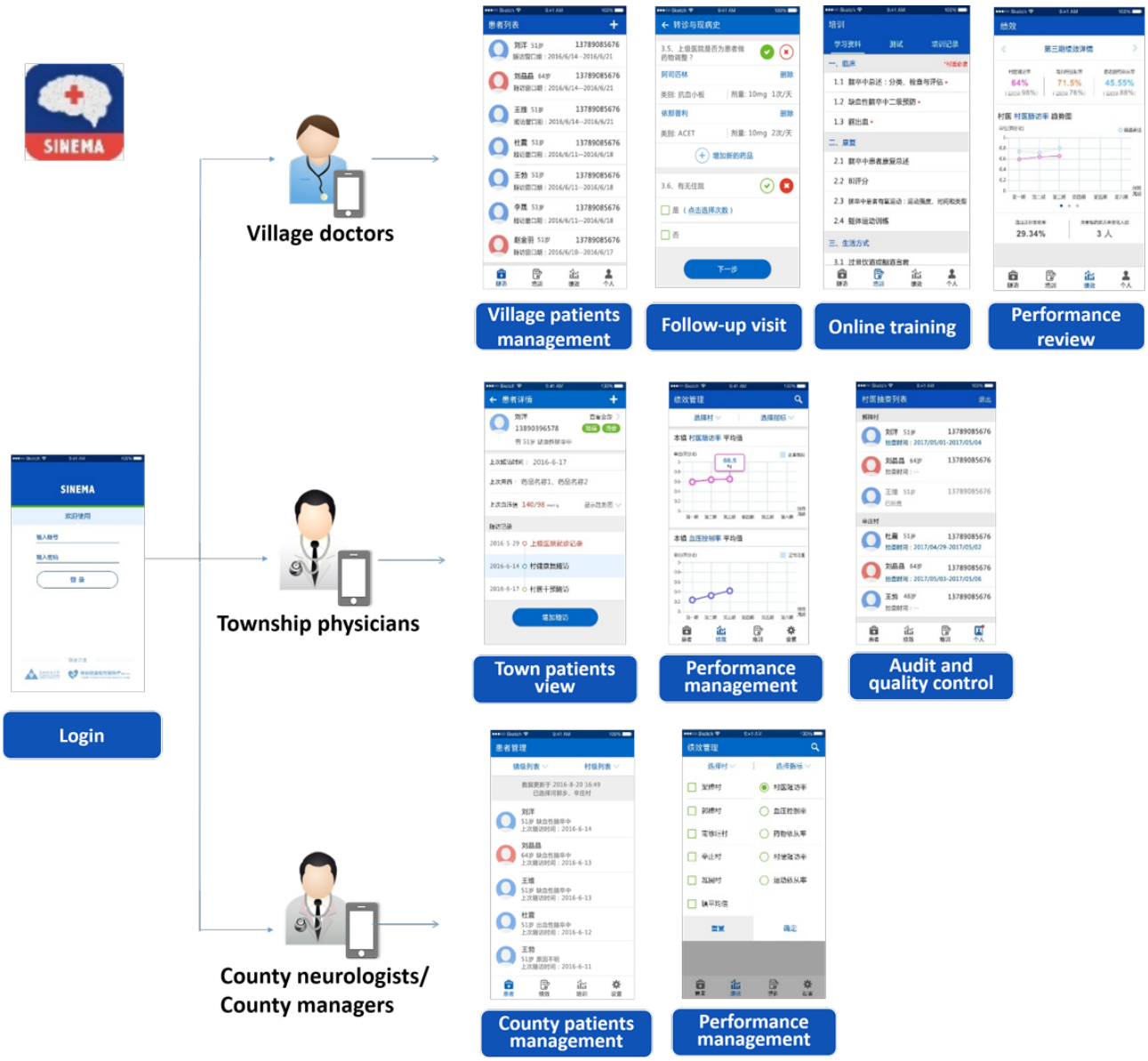
> *I am interested in using the app for managing stoke patients if it could make things more convenient, but if the APP is too complicated, then I won't use it.* [Village doctor]

Functional Modules of the System-Integrated Technology-Enabled Model of Care Mobile Health System

The findings from the contextual research and the targeted activities required by the SINEMA intervention model were translated into a needs document, which suggested the potential functional modules and the contents within each module. A multidisciplinary workshop was organized, and the functional modules were refined based on the end user's feedback. Details for each functional module are described below and shown in Figure 4.

- *Patient Management:* This module enabled village doctors to add basic information of stroke patients in the system and helped them reach the patients easily through phone calls. Village doctors and township physicians were also able to search for the records of patients within their responsible geographical areas.
- *Follow-up visits:* This module was designed for village doctors to record their patients' follow-up visits. The contents were translated and contextualized based on the clinical guidelines and were verified by stroke specialists, which enabled village doctors to communicate with patients based on a standard workflow consisting of evaluating symptoms, measuring blood pressure, asking about medication compliance, recording newly prescribed medicines, and uploading other supportive paper-based materials. In addition, the app would pop up alerts for special attention and referral if the recorded patients' status was abnormal.
- *Online training:* To enhance the knowledge and skills of village doctors, we designed a module for online training. The training materials were in line with the clinical guidelines but simplified by stroke specialists based on the knowledge level of village doctors. The training materials covering the topics of stroke treatment, rehabilitation, and lifestyle modification were displayed suitably in the format of videos, graphics, and texts. The training modules also contained quizzes to help village doctors evaluate their self-learning progress.
- *Reminders:* To facilitate the work planning of village doctors for their patients' monthly follow-up visits, we designed the function of reminders with 3 types of presentations: an independent follow-up reminder calendar, the next follow-up reminders on the patients list, and the daily pop-up reminders of a list of follow-ups required for a particular day.
- *Performance review and management:* To monitor the progress of each stroke patient and to motivate village doctors to achieve their performance indicators of the intervention effectively, we designed a performance management module. This module displayed in real time the summary performance data including the follow-up rate, the blood pressure control rate, and the medication adherence rate among all stroke patients under a village doctor's management. The township and county mangers could also review these indicators and make comparisons across all villages and townships of their respective responsibilities.
- *Random audit and quality control for township physicians:* To facilitate the supervision role of township physicians, we designed the random audit module for township physicians. Each month, the system will randomly select 3 patients for township physicians to conduct auditing phone calls.
- *Integrating with SMS text messaging and voice messaging system:* To fulfill the intervention need of delivering health education information via messages to stroke patients, the patients' list was linked with the message dispatching system.

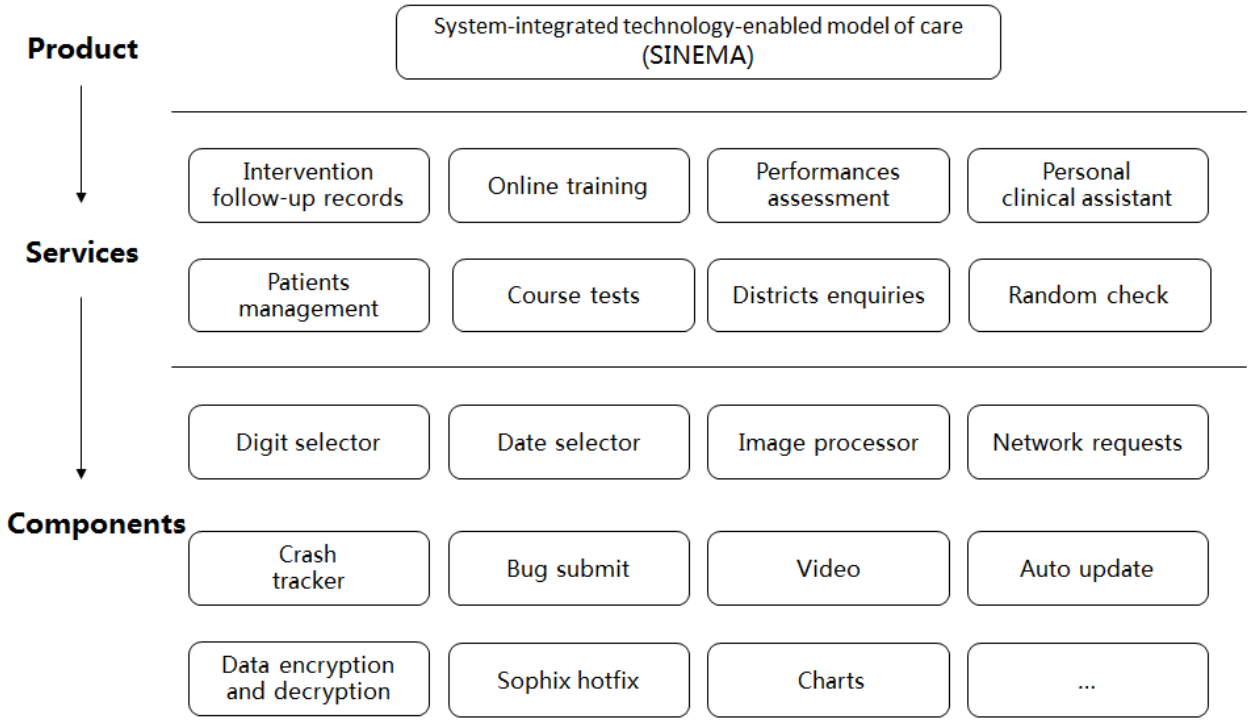
Figure 4. The screenshots showing the functional modules of system-integrated technology-enabled model of care mobile health app for the 3 types of end users.



Iterative Modular and User Interface Design

We translated the functional modules into a practical mHealth app by following the modular design principles of high cohesion, low coupling, and good scalability (see Figure 5) [28,29]. We addressed several technical difficulties throughout the system design and development process. First, to fulfill the needs of multirole end users, including village doctors, township physicians, and county managers, we implemented a complex service logic, which enabled the SINEMA mHealth app to display different functions and data on the same page according to the role of the users. Second, we designed a data structure of stack to store all the data for every node at all layers to ensure the flexibility of the intervention follow-up for village doctors. By doing so, we were able to avoid the long workflow and prevent function error on page jumps, cross-page data transfer, and page fallback. Finally, to achieve the media features, including taking pictures, image processing, and online video download and playing, we compressed images effectively with a compression rate of 94%, which could reduce system memory overhead, power consumption, and the consumption of mobile data traffic. In addition, iterative development could be accelerated through adopting the latest open-source technologies. Depending on the resources available in the deployment environment, the mHealth system server is able to support secure access from 100,000 users.

Figure 5. Modular design of the Android app architecture.



On the basis of the results from analyzing the most popular apps among village doctors, we adopted the style of social interactions and linear path for the user interface design. As displayed in Figure 4, we designed simple and intuitive icons and applied consistent gestural design (taps or swipes or pinches or scrolls) to increase the functionality of the app. We also displayed information in various formats, including plain texts, choice questions, graphs, and videos, to strengthen the engagement of the app. In addition, the design was further refined based on feedback from end users. For example, we simplified the information briefing on the patients' list page and added a ranking mode to the patients' list to help end users find the right record more efficiently.

Pilot Trial and Revision Based on Iterative Design

Before using the mHealth system on a large scale, we tested the system and the intervention model through a pilot trial. A total of 4 village doctors in Nanhe County, from 4 villages, were equipped with the SINEMA mHealth app to manage a total of 54 patients for 3 months. After the trial, we interviewed the end users to collect their feedback about the SINEMA model and the mHealth system design. We had since refined the mHealth system and generated 4 iterative versions of the system to better cater to the local situation. Examples of improvements included adding a detailed list of medication guidelines in the follow-up module to support village doctors' decision making during follow-up visits, adjusting the algorithm of message sending by considering the low literacy rate among stroke patients, refining the contents of health education by emphasizing on physical activity and medication adherence, revising the calculation methods of performance indicators, and adding the module of phone-call auditing for township physicians to fulfill the needs of quality control of the intervention. The final version of the SINEMA mHealth system was granted a software copyright register from the China National Copyright Administration (Registration Number 2017SR502445).

Survey Results on the Feasibility of Using System-Integrated Technology-Enabled Model of Care Mobile Health System

During July 2017 and July 2018, the SINEMA mHealth system supported 25 village doctors, 5 township physicians, and 2 county managers in managing 637 stroke patients. After the 1-year trial, 24 out of 25 village doctors (response rate=96%, including 4 females) completed the survey. On average, they were 46.5 years old (SD 7.9) and had 24.4 years (SD 8.8) of clinical service. Table 1 shows the results from the survey. All participants self-reported that the app was easy to learn and use, and 22 out of 24 (92%) reported that they did not have any technical or functional issue during the yearlong usage. Over two-thirds of respondents strongly agreed that the app was able to standardize their workflow of the follow-up visits (71%) and help them make the right decision (67%). Most of them regarded that the functions and tools enabled them to easily connect with their patients, review patients' history, and share information with township physicians, which were very helpful features. Overall, 22 village doctors (92%) strongly agreed or agreed that they would like to continue using the app after the trial.

Table 1. Village doctor's survey responses at 12 months of the main trial (N=24).

Village doctors' demographic characteristics and feedback	n (%)
Demographic characteristics	
Gender	
Male	20 (83)
Female	4 (17)
Age (years)	
30-39	4 (17)
40-49	11 (46)
50-59	7 (29)
60-69	2 (8)
Education level	
High school or equivalent	13 (54)
Community college	8 (33)
College degree	3 (13)
Years of being a village doctor	
1-10	3 (13)
11-20	4 (17)
21-30	12 (50)
30+	5 (21)
Agreement toward statements related to System-Integrated Technology-Enabled Model of Care app	
I spent very short time in learning how to use the System-Integrated techNology-Enabled Model of cAre app	
Strongly agree	18 (75)
Agree	6 (25)
I did not have any technical or functional issue during the 1-year usage	
Strongly agree	11 (46)
Agree	11 (46)
Neither agree nor disagree	2 (8)
This app helped me connect to my patients easily	
Strongly agree	15 (63)
Agree	8 (33)
Disagree	1 (4)
This app helped me standardize patients' follow-up visit	
Strongly agree	17 (71)
Agree	6 (25)
Neither agree nor disagree	1 (4)
I reviewed the patients' previous records in the app during the follow-up visit	
Strongly agree	18 (75)
Agree	5 (21)
Neither agree nor disagree	1 (4)
This app support decision making for medication prescription	
Strongly agree	16 (67)
Agree	8 (33)
Sharing information with township physicians through this app is important for me	

Village doctors' demographic characteristics and feedback	n (%)
Strongly agree	10 (42)
Agree	12 (50)
Neither agree or disagree	2 (8)
I am willing to continue using this app after the trial	
Strongly agree	10 (42)
Agree	12 (50)
Neither agree or disagree	2 (8)

Discussion

Principal Findings

This paper described in detail the design and development of the SINEMA mHealth system and reported the results from the users' survey. To research and develop this mHealth system, our multidisciplinary research team applied various research methodologies, adopted an iterative design approach, and involved end users throughout the whole process. The SINEMA mHealth system featuring 7 distinctive functional modules has fulfilled its intended goal in supporting the delivery of the SINEMA intervention method. Building upon the mHealth technology, the system has demonstrated the potential to empower village doctors to carry out patient management, self-training, and follow-up visits. The system is also able to facilitate township and county managers in auditing and supporting village doctors. The survey among the dominant group of end users (village doctors) revealed that most of them were satisfied with the functions of the mHealth system in formalizing the follow-up visits and improving clinical skills, and they were keen to continue using the system after the trial.

The overall structure and individual functional modules of the SINEMA mHealth system were designed to align with the distinct roles of end users in the conventional health care system. A review of mHealth intervention studies in China indicated that most previous studies focused on patient education and behavior change, with almost no work centering on interprovider communications and health services management [30]. Previous studies also revealed that the key enabling factors for an mHealth system's adoption and use [14] are organizational support environment, facilitating collaboration between coworkers, and integration with health care system. With a view to integrating the existing health care protocol with more active interactions across different tiers of health care providers, we designed a single system catering to 3 types of health care providers: village doctors, township physicians, and county managers. To fulfill their respective needs, various functional modules were designed based on the scope of their work. On the one hand, shared functional modules, such as the patients' management module and performance management module, promoted an active and efficient information exchange among end users. On the other hand, the functional modules on training and follow-up visits were specifically for village doctors to learn relevant medical knowledge and skills and to perform follow-up services. Therefore, the introduction of the SINEMA mHealth system with both shared information and specific functional modules among 3 types of end users supported the delivery of the SINEMA intervention model that promotes the integration of the health care system across the village, township, and county levels.

In addition to the structure of the mHealth system, the contents of each functional module have been designed by fully considering the needs of the end users. Although studies on using digital health technologies for preventing and controlling chronic diseases have proliferated in recent years, the evidence of their effectiveness is not abundant. Studies have found that the levels of user engagement greatly impact the outcomes of the interventions [31,32]. These findings support a user-centered design approach to developing digital health solutions [33]. In our study, we involved end users throughout the whole development process. We assessed the end users' needs and work patterns through in-depth interviews and simplified the contents of training and follow-up visit modules to match their knowledge levels. In addition, we took account of the end user's phone use habits in user interface design and iteratively refined the system based on their feedback and comments. The highly intensive involvement of end users in both content and interface design ensured the high usability of end users in the SINEMA study and led to high satisfaction among users, as reflected in the survey results.

It should be noted that this mHealth system resulted from the concerted efforts of an international multidisciplinary team including public health researchers (medical anthropologists, public health practitioners, and behavior scientists), clinical practitioners (stroke specialists, rehabilitation therapists, and clinical pharmacists), and information technology experts (product manager, user interface designers, app platform architects, and software engineers). Collaborations among experts of different disciplines are never easy [34,35]. Inherent differences in domain terminology, priorities, and work cultures may create barriers for effective collaborations. Sharing of common goals and a mutual understanding are essential but not adequate to overcome these barriers. Frequent communications, patience, and persistence are also needed to ensure the success of the collaboration.

Strengths and Limitations

This mHealth system is innovative in several ways . First, to the best of our knowledge, it is the first one ever built to deliver quality essential care on secondary prevention of stroke in rural China. The development of the SINEMA mHealth system provides a novel technical solution to address the increasing

burden of stroke in China. The SINEMA mHealth system attempts to strengthen the primary health care system in terms of health care service delivery, health workforce, and health information system as the building blocks of the health system [36]. By equipping grassroots health care providers in the rural communities with the SINEMA mHealth system, the intervention has the potential to increase the delivery of and access to high-quality services related to secondary prevention of stroke, to improve the communication and task sharing among providers from tiered institutions, and to establish a health records system for stroke patients' management and follow-up. Second, the SINEMA system is one of the very few mHealth systems that enable patient engagement and behavior changes at individual levels, as well as novel health care delivery models in the era of a connected world. Although the digital health industry expanded fast in China in the past years, the development of a digital solution for public health interventions remains premature, with little exploration of how a digital solution could be adopted by the existing health care system [30]. Finally, multiple technology design methods have been adopted, such as user-centered design, IT system research framework, supported by a multidisciplinary research team. This study adds new practical knowledge to the field in developing a digital health solution to address real-world public health challenges.

Our study and the mHealth system also have some limitations. We were able to involve end users' feedback and conduct a pilot testing but were not able to conduct a comprehensive evaluation on all aspects of the mHealth system. However, according to the survey results among all the village doctors, they highly valued the usability of this mHealth system with a strong willingness to continue using the app after the trial. The system can be further improved along several directions. For example, artificial intelligence-based voice technology can be used to operate a more complex algorithm that enables dispatching personalized voice messages based on the updated medical records by village doctors. In addition, better integration of the mHealth system with the existing public health system and local hospital electronic medical record system is desirable. Such integration can facilitate the information exchange across health care facilities, reduce the duplicated workloads of village doctors, and promote a patient-centered continuum of stroke care.

Conclusions

In summary, the SINEMA mHealth system, designed in a user-centered and iterative way by a multidisciplinary team, achieved high functionality, feasibility, and user satisfaction among village doctors in rural China. The evaluation of the clinical effectiveness of the system to improve patient outcomes is currently being undertaken. If proven effective, the adoption and scaling up of the system to more areas for a longer term has the potential to reap large public health benefits through improving quality of primary care and reducing disease risks from stroke. The system can also be adapted to managing other chronic conditions such as hypertension, diabetes, or heart disease. In future iterations, newer technology features and better integration with the existing digital health system will further enhance its impact.

Acknowledgments

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Authors' Contributions

NW and EG drafted the manuscript and contributed equally, WG conducted the coding of qualitative data, and all coauthors contributed to the manuscript revision and approved the final version for publication.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Semistructured interview guides.

[PDF File (Adobe PDF File), 98KB - mhealth_v7i7e13503_app1.pdf]

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Abbreviations

mHealth: mobile health
PII: personal identifiable information
SINEMA: System-Integrated techNology-Enabled Model of cAre
SMS: short messaging service

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Original Paper

"Seeing Pain Differently": A Qualitative Investigation Into the Differences and Similarities of Pain and Rheumatology Specialists' Interpretation of Multidimensional Mobile Health Pain Data From Children and Young People With Juvenile Idiopathic Arthritis

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Abstract

Background: In contrast to the use of traditional unidimensional paper-based scales, a mobile health (mHealth) assessment of pain in children and young people (CYP) with juvenile idiopathic arthritis (JIA) enables comprehensive and complex multidimensional pain data to be captured remotely by individuals. However, how professionals use multidimensional pain data to interpret and synthesize pain reports gathered using mHealth tools is not yet known.

Objective: The aim of this study was to explore the salience and prioritization of different mHealth pain features as interpreted by key stakeholders involved in research and management of pain in CYP with JIA.

Methods: Pain and rheumatology specialists were purposively recruited via professional organizations. Face-to-face focus groups were conducted for each specialist group. Participants were asked to rank order 9 static vignette scenarios created from real patient mHealth multidimensional pain data. These data had been collected by a researcher in a separate study using My Pain Tracker, a valid and acceptable mHealth iPad pain communication tool that collects information about intensity, severity, location, emotion, and pictorial pain qualities. In the focus groups, specialists discussed their decision-making processes behind each rank order in the focus groups. The total group rank ordering of vignette scenarios was calculated. Qualitative data from discussions were analyzed using latent thematic analysis.

Results: A total of 9 pain specialists took part in 1 focus group and 10 rheumatology specialists in another. In pain specialists, the consensus for the highest pain experience (44%) was poorer than their ranking of the lowest pain experiences (55%). Conversely, in rheumatology specialists, the consensus for the highest pain experience (70%) was stronger than their ranking of the lowest pain experience (50%). Pain *intensity* was a high priority for pain specialists, but rheumatology specialists gave high priority to *intensity* and *severity* taken together. Pain *spread* was highly prioritized, with the *number of pain locations* (particular areas or joints) being a high priority for both groups; *radiating pain* was a high priority for pain specialists only. Pain *emotion* was

challenging for both groups and was only perceived to be a high priority when specialists had additional confirmatory evidence (such as information about pain interference or clinical observations) to validate the pain emotion report. Pain qualities such as particular word descriptors, use of the color red, and fire symbols were seen to be high priority by both groups in interpretation of CYP pain reports.

Conclusions: Pain interpretation is complex. Findings from this study of specialists' decision-making processes indicate which aspects of pain are prioritized and weighted more heavily than others by those interpreting mHealth data. Findings are useful for developing electronic graphical summaries which assist specialists in interpreting patient-reported mHealth pain data more efficiently in clinical and research settings.

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KEYWORDS

mHeath; pain assessment; juvenile idiopathic arthritis; focus group; qualitative research

Introduction

Pain in Juvenile Idiopathic Arthritis

It is challenging to assess and manage pain in children and young people (CYP) with juvenile idiopathic arthritis (JIA). A significant proportion of CYP with JIA report severe pain [1,2], and for 17% of CYP, pain remains consistently high throughout long periods of the disease [3]. Pain in the context of JIA is unpredictable, and importantly, fluctuations in pain qualities can act independently of the levels of inflammatory disease processes in these patients [2,4,5]. This means that separate assessments of pain and disease domains are essential. Self-report of pain is advocated as the *gold standard* in assessment [6]; however, for CYP it can be particularly challenging to articulate and summarize their pain [7].

Pain Assessment and Communication Issues

Pain is an inherently subjective concept [8], hence pain experiences are difficult to communicate to others. Communication between patients with JIA and health care professionals (HCPs) is further complicated by infrequent clinic visits, where pain is reported retrospectively and often by proxies, rather than children themselves [9-11]. Most reporting tools require researchers or HCPs to interpret scores from linear or unidimensional self-reported pain scales [12]. Pain interpretation is also a subjective process, and it can be difficult for others to interpret pain experiences as expressed by CYP [13,14]. The salience of scale points may not be equivalent (eg, a difference between a 7 and 8 on a unidimensional numerical rating scale may hold more significance than that between a 1 and 2) to those considering patients pain scores. In more recent research, there has been a move toward using multidimensional tools that collect even more comprehensive data on several aspects of the pain experience, including location, intensity, severity, emotion, and other pain qualities such as pain interference [15-17]. These tools can provide many advantages for pain assessment, particularly in their digital forms whereby pain can be recorded frequently (ensuring richer pain data collection) and remotely outside of the clinic (avoiding recall bias) [17-19]. Scores from these more comprehensive, multidimensional pain depictions then require synthesis and interpretation.

Methods of interpreting pain assessments are largely dependent on subjective scoring systems, which have been found to be particularly problematic in HCPs managing CYP with JIA. Some studies suggest HCPs provide overestimations of their young patients' pain [11], and others have found that they are more likely to underestimate [20]. Little is known about the decision-making processes behind how others score and interpret CYP pain and how or why they might report overestimations or underestimations.

Multidimensional Pain Interpretation

Recent research on the implementation of multidimensional pediatric pain assessment tools has primarily focused on development [21,22] rather than on the utilization and interpretation of information from such measures. Given the increase in the availability and adoption of mHealth tools for the management of chronic pediatric conditions, it is important and necessary to understand how the data collected via these methods are being used to make choices about the management of long-term conditions with associated pain symptomatology [23]. The primary aim of this study was to identify which aspects of pain were considered to be the most salient in the prioritization and utilization of CYP pain data from an mHealth pain assessment tool, by 2 key stakeholder groups involved in the interpretation of pain in JIA: pain specialists and pediatric rheumatology specialists.

Methods

Study Design

A total of 2 separate face-to-face semistructured focus groups were undertaken, 1 with pain specialists and 1 with pediatric rheumatology specialists. Stimulus material in the form of real mHealth multidimensional pain data from CYP with JIA was presented to participants in the form of vignette scenarios. This approach was used to provoke and elicit underlying opinions about the degree of pain represented by these datasets and to stimulate a structured discussion within the focus groups.

Sample and Recruitment

In total, 2 groups of participants recruited through purposive sampling took part in the study: international academic pediatric pain experts (termed pain specialists throughout the paper) and HCPs managing CYP with JIA in pediatric rheumatology departments in the United Kingdom National Health Service (NHS; termed rheumatology specialists throughout the paper). These groups were recruited to reflect 2 key professional

stakeholder groups and interests involved in the research and clinical management of pain in CYP with JIA. Participants were selected based upon their specializations in pain assessment and/or management and were members of professional member organizations (The International Association for the Study of Pain and/or The British Society for Paediatric and Adolescent Rheumatology). Selected participants were emailed a participant information sheet with the aims of the study and briefed about what would be involved if they chose to participate. Within the information sheet, participants were also given a brief background to the rationale of the study, the research group's work, and who the researchers involved in the study were. Interested participants responded directly to the authors and were encouraged to send the email to colleagues with similar interests or specializations (snowball sampling [24]).

Setting

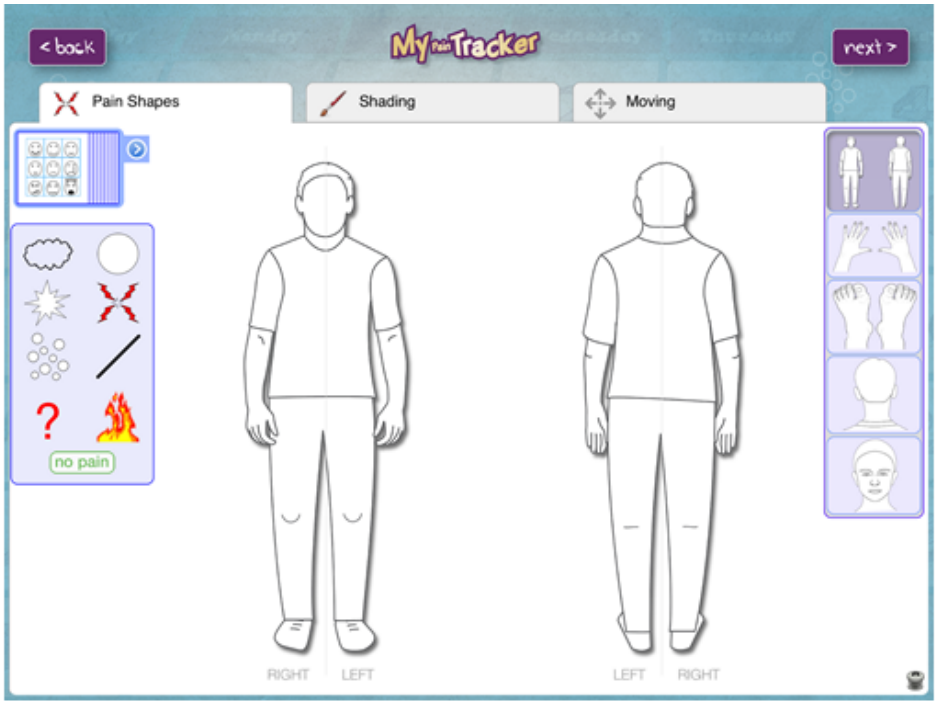
A total of 2 separate focus groups were conducted, with the pain specialist focus group held at an international pain conference (United States) and the rheumatology specialist focus group held at a national rheumatology conference (United Kingdom).

Materials

This study used real-world mHealth multidimensional pain data collected from CYP with JIA using My Pain Tracker (MPT), an mHealth pain assessment app for iPads (version 1.1.5). MPT has been found to be a usable, valid, and acceptable pain assessment and communication tool for CYP with JIA within the research group, when compared with the use of other scales (Visual Analog Scales and the Faces Pain Scale). MPT was first adapted from an interview tool for reporting pain in CYP in forensic settings [25-26]. Since its initial conception in 2000, the tool has been adapted into appropriate versions for different pain contexts such as acute postoperative pain [27] and recurrent pain (personal communication by J Twynholm, 2009) and in its latest version used in this study, it has been used for the assessment and communication of persistent pain in the specific context of JIA [28]. The tool enables CYP to discuss their musculoskeletal pain symptoms with a researcher or HCP through pain recording features (pain intensity, severity, location/spread, pictorial representations such as symbols and colors, word descriptors, and emotions; see Figure 1 for a screenshot of MPT main user page). Within the app, intensity is depicted through the throb of pain (the speed of movement of the chosen symbol), and severity is signified by the size of the pain. The pain quality symbols within the app were designed by CYP in a study that aimed to capture how they represent painful experiences through drawings [25]. In pilot tests, it has been found that these symbols do not have one unique meaning to CYP, instead, they are used to represent and signify several pain meanings dependent on individual connotation.

Vignette scenarios based upon real MPT data were provided as a sample set of stimuli for discussion. In total, 9 different vignette scenarios were chosen to represent a breadth of different multidimensional self-reports of pain experiences (Multimedia Appendix 1). The vignette scenarios were originally collected from CYP with JIA as part of an acceptability study. In the original study, MPT was completed by CYP (aged between 5 and 16 years) in a semistructured interview with a clinical psychologist trainee or researcher. Original data for the vignettes were collected at a tertiary pediatric rheumatology outpatient clinic in the North-West of England from participants with JIA enrolled in the Childhood Arthritis Prospective study [29].

Figure 1. Screenshot of the My Pain Tracker main user page.



Procedure

This paper has been reported in accordance with the Consolidated Criteria for Reporting Qualitative Research, a 32-items checklist [30] (Multimedia Appendix 2). Participant information sheets were provided to selected participants. Email confirmation to attend focus groups provided written consent. In addition to this, verbal consent to participate in the study was obtained at the beginning of the focus groups. Participants attending the focus groups were given a standardized presentation by the study team (AR, DG, and RRL) about the development of MPT, including the app, purpose, format, and completion process. At the time of data collection, AR was a research associate (trained to PhD level in Psychology and Medical research), and DG and RRL were PhD students (trained to MSc level in Health Psychology and trained in Psychology and Medical research). All researchers involved in data collection and analysis had conducted and been involved in previous qualitative research studies and were closely supervised in preparing and conducting focus groups by LC (senior lecturer and practitioner in Health Psychology). The researchers conducting this study did not have any particular experience of managing pain, either in a pain or rheumatology-focused medical context.

Participants were given a demonstration of how MPT works and were given the opportunity to briefly input mHealth data themselves. After the presentation, participants were asked to consider the vignette scenarios and rank them from *highest pain* to *lowest pain*. Participants were then asked to take part in group discussions to explain the reasoning behind their rankings. Focus group discussions provided qualitative data for analysis and were audio-recorded and transcribed verbatim for analysis. All audio-recorded interviews were uploaded to and analyzed in NVivo 10 (QSR International, Doncaster, Australia). Field notes collected by the researchers during the conduct of focus groups were used to provide additional context to the analytical process.

Data Analysis

Focus group data were analyzed using a step-by-step guide for conducting deductive latent thematic analysis by RRL and LC [31]. Latent thematic analysis is a technique that identifies meaningful patterns within data and involves interpretation of those patterns beyond description. Coders defined what would be considered a significant theme before data analysis (issues about pain prioritization and interpretation of pain features, in line with the aims of the study) and then became familiar with the data by repeatedly reading transcripts and listening to the audio recordings of focus groups. The author then generated initial thoughts and ideas (initial codes) before searching for larger themes that grouped codes together. Major themes and subthemes were reviewed and named. Thematic maps for each major theme were produced to organize data within and between participant accounts. Underlying ideas, assumptions, and beliefs about the prioritization of different pain facets were interpreted. Inter-rater reliability and validation of emerging themes was conducted by RRL and LC, who independently coded and discussed sections of both focus group data [32]. Frequencies for the highest and the lowest pain vignette rankings were calculated from paper-based feedback from participants.

Results

Participant Characteristics

A total of 19 participants took part in the focus groups, 9 pain specialists in 1 focus group (participants 1-9) and 10 rheumatology specialists (participants 10-19) in the other focus group (see Table 1 for participants' professional background and current work contexts). The pain specialist focus group lasted for approximately 48 min, and the rheumatology specialist focus group ran for approximately 75 min.

Vignette Ranking

Highest Pain Vignettes

Both groups selected vignette 6 (named *Ben*, see Multimedia Appendix 1) to represent the individual with the highest pain; 44% (4/9) of the pain specialist participants and 70% (7/10) of the rheumatology specialist group chose this vignette as the worst pain experience.

Lowest Pain Vignette

The most commonly chosen lowest pain vignette by pain specialists was vignette 2 (named *Samantha*), with 55% (5/9) voting for this. The vignette ranked the lowest by rheumatology specialists was vignette 3 (named *Anna*), with 50% (5/10) of professionals in this focus group voting for this.

Reordering Vignettes

Given the opportunity to rerank vignettes at the end of group discussions, none of the pain specialists chose to rerank any of their choices. However, in the rheumatology specialist group, 50% (5/10) of participants chose to reorder at least 1 of the vignettes they had chosen previously. Rheumatology specialists discussed some of the facets of pain that were prioritized differently in their reinterpretation of pain rankings following group discussions. These included different weightings upon age, emotion, labeling, number of sites, and severity.

Qualitative Themes of Pain Quality Prioritization

Overview

In total, 4 major themes were identified throughout the analysis. Themes were deductive in that they were based upon and informed by the specific components of data collected by MPT and included the prioritization of (1) pain intensity and severity, (2) pain location, (3) pain qualities, and (4) pain emotion (see Figures 2 and 3 for thematic maps of data). The thematic maps show the relationship between the key points discussed and divergences between pain and rheumatology specialist groups. Narrative accounts of each theme are presented alongside supporting quotations.

Table 1. Professional background of pain specialists and rheumatology specialists.

Professional backgrounds of the specialists and countries they worked in	Frequency (n)
Pain specialists' background	
Nursing	2
Health sciences	1
Psychology	4
Medicine	1
Anesthesiology	1
Country pain specialists worked in	
Canada	5
United States	2
United Kingdom	2
Rheumatology specialists' background	
Consultant rheumatologists	3
Pediatricians (with rheumatology interest)	4
Nursing	1
Physiotherapy	1
Occupational therapy	1
Country rheumatology specialists worked in	
United Kingdom	10

Theme 1: Prioritization of Pain Intensity and Severity

The high prioritization of pain intensity was uncontentious for pain specialists. Some talked about the importance of summing intensity information if pain was present in more than 1 area:

> *I was sort of mentally trying to take the averages of the intensities across the locations.* [Pain specialist 2]

Pain specialists questioned whether there were any real conceptual differences between intensity and severity, especially when they were talking to CYP about their pain:

> *I was a little confused about what the difference was meant to be between severity and intensity… from a conceptual point of view...how would you know the difference when you are speaking with a child.* [Pain specialist 3]

Some pain specialists discussed how the lack of distinction between the 2 concepts meant that they tended to think of them as meaning the same thing. For others, this meant that severity information appeared to be disregarded:

> *Severity and intensity is very difficult to differentiate between so I'd lose one of those and I think severity is the one I'd lose.* [Pain specialist 8]

For rheumatology specialists, intensity and severity together were a high priority in their interpretations of pain experiences. Although rheumatology specialists seemed to appreciate similar conceptual issues about considering intensity and severity separately, they mostly talked about both of these concepts interchangeably:

> *That's all the information I used...the severity and the intensity* [Rheumatology specialist 15]
>
> *For some people, they'd [severity and intensity] be synonymous, so you ask them the same question twice.* [Rheumatology specialist 13]

The high prioritization of pain intensity appeared to be unambiguous within the groups despite little explicit discussion around why it was an important feature of interpretation.

Theme 2: Prioritization of Pain Location

Pain location information was highly prioritized by both specialist groups. Both focus groups discussed the significance of the number of pain locations in their interpretations, although different discourses regarding this facet of pain were apparent between groups. Pain specialists talked about their prioritizations of the *number of different pain sites*, whereas rheumatology specialists referred to the *number of joints affected*, suggesting rheumatology specialists were linking pain reports with evidence of disease activity, such as inflamed, active, and arthritic joints:

> *This vignette only had one site so number of sites.* [Pain specialist 8]
>
> *So I kind of took into account how many patients' joints were involved.* [Rheumatology specialist 15]
>
> *Hot knees, very concise of where the pain is and the number of joints.* [Rheumatology specialist 16]

Figure 2. Thematic maps for themes 1 and 2.

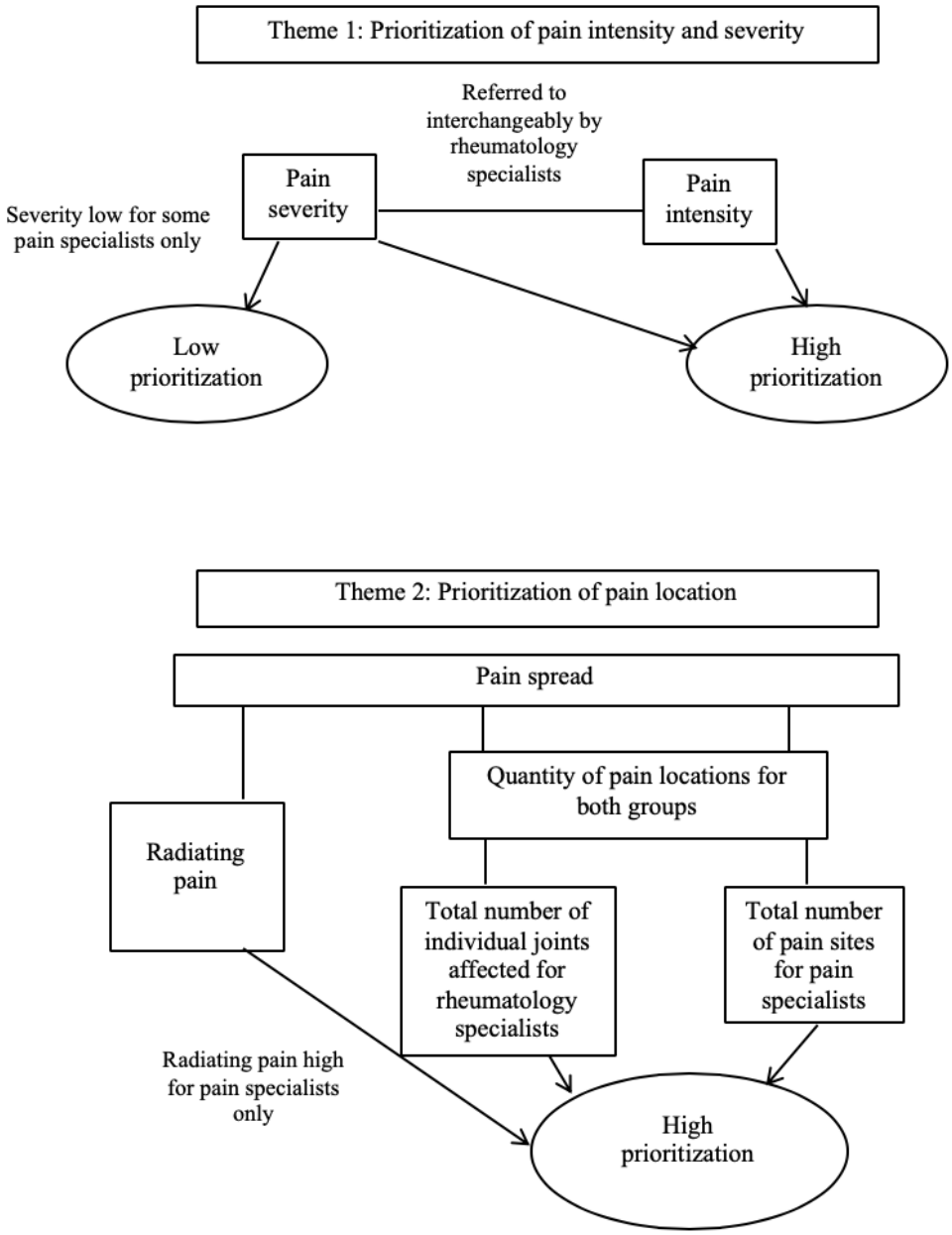
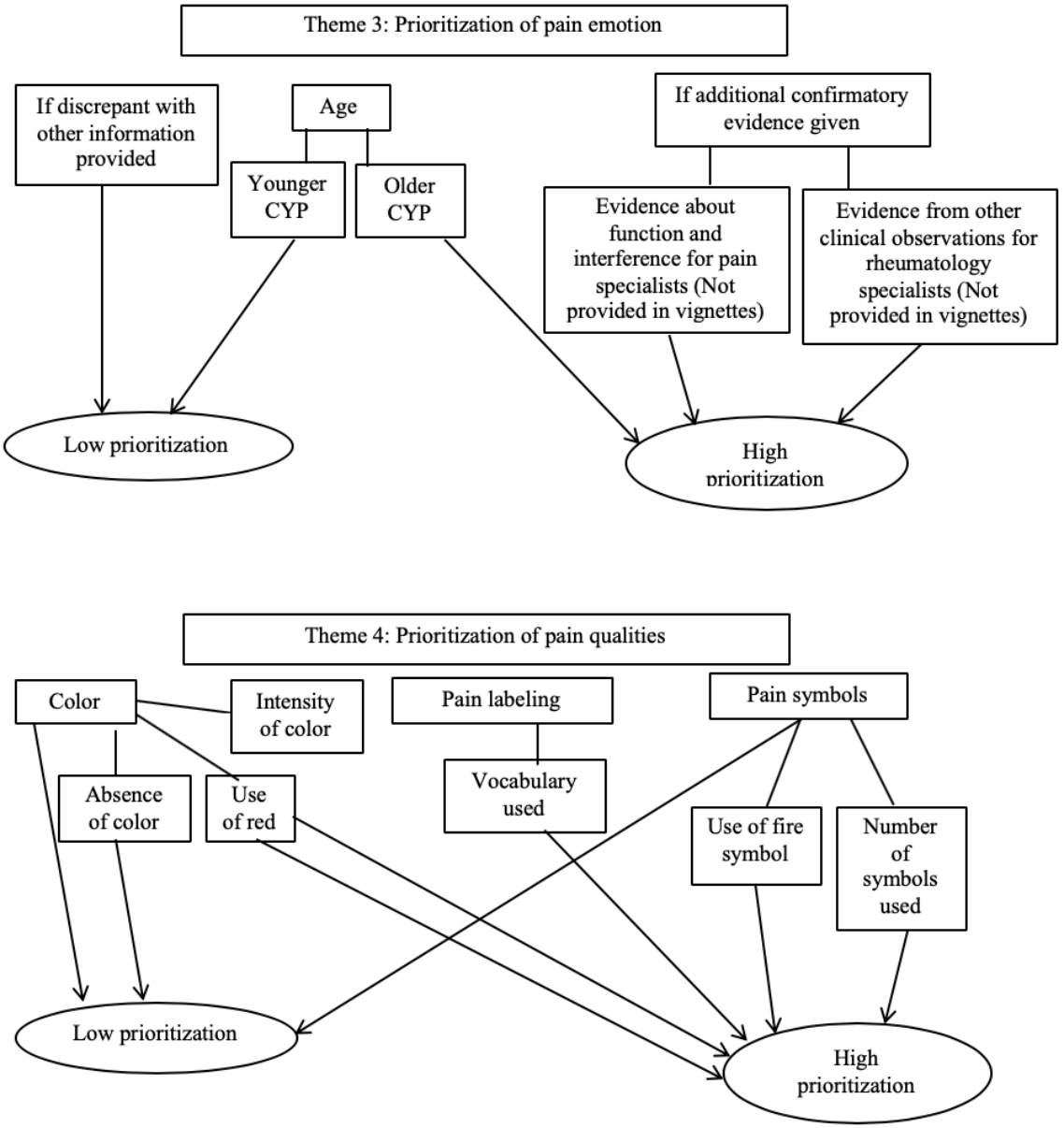


Figure 3. Thematic maps for themes 3 and 4.



Although specific pain in the joints was a high priority for rheumatology specialists, no particular pain location was considered to be significant to pain specialists. Another aspect of pain location information, which was a high prioritization for pain specialists only, was pain spread. Pain spread can relate to how many pain locations there are (as discussed), or how much pain in a specific area radiates to other sites. Pain spread that radiated across several sites appeared to be significant for some pain specialists, with 1 participant suggesting this could be an *over-interpretation*:

> *So I was over-interpreting that pain because it says elbow but marked her entire arm.* [Pain specialist 6]

Radiating pain across pain sites was not discussed by rheumatology specialists.

Theme 3: Prioritization of Pain Emotion

The biggest contrast in the prioritization of all multidimensional pain information collected was both between and within pain and rheumatology specialist discussions of emotion. For some pain and rheumatology specialists, emotion was a high priority when interpreting CYP pain:

> *I must admit I did look at the faces so that wasn't quite so severe perhaps.* [Pain specialist 4]

> *I would say I probably ranked using the emotional aspect probably slightly more...So it was more swaying myself towards the emotional impact of that pain.* [Rheumatology specialist 11]

There seemed to be a number of reasons why pain and rheumatology specialists were cautious about allowing scores on emotion to influence their overall perception of how severe the pain experience was. If emotion did not correspond and was discrepant with the rest of the information that had been given, pain experiences would be ranked lower by pain specialists particularly:

> *So I might have thought that tears would mean worse and yet it didn't seem to fit that well with the rest of the information so I ended up disregarding the faces on most of these rather than giving them priority.* [Pain specialist 9]

Both groups talked about the necessity of additional confirmatory evidence when interpreting emotion scores. Data about function and interference (with medications, mood, and sleep) were important for pain specialists as they sought to weight pain emotion within another concept that they could better understand:

> *I did somewhat look at the face but I was a little confused what to do with it...because I wasn't sure why I had only emotion and not function with it, I guess if I had all three (pain, function, and emotion), I might have integrated them.* [Pain specialist 6]

> *It's helpful to know if the child is doing well because of medications they're on...I always look at pain impact, moods, sleep...you know, interference.* [Pain specialist 2]

Rheumatology specialists believed that pain emotion should make sense within the context of other clinical observations. This context was necessary because distress could have signified CYP were unhappy with being at clinic, rather than because of the pain they were experiencing:

> *Because you get some people that are, oh my god, the worst pain I've ever had...and you know their heart rates completely normal.* [Rheumatology specialist 10]

> *Clearly none of them are happy. So I don't know whether they're not happy because they come to the clinic.* [Rheumatology specialist 17]

For both pain and rheumatology specialists, the age of CYP reporting pain was important in the interpretation of emotions. The emotions of older children were prioritized higher by both groups of specialists than that of younger children who would more commonly exhibit signs of distress as part of everyday life:

> *You know 16 year olds, if you're crying it must really be bad whereas when you are little, that's just a part of your daily life.* [Pain specialist 9]

> *A 16 year old may be better at coping with it, when they're 14 maybe they're a bit more emotional.* [Rheumatology specialist 16]

Rheumatology specialists particularly believed that older children might have more severe emotions associated with their pain because the pain experiences became worse:

> *It sometimes can be worse for people that are a bit older, they're in constant pain, so it can be difficult.* [Rheumatology specialist 10]

Theme 4: Prioritization of Pain Quality Representations

The use of color in pain reports of CYP was considered to be significant by some pain and rheumatology specialists and insignificant by others. For some, the absence of color in vignette scenarios made for a less powerful depiction of pain:

> *There wasn't any use of colour...the visual didn't seem as powerful to me.* [Pain specialist 2]

> *This [particularly ranking the middle vignette] was difficult because there was no colour.* [Rheumatology specialist 13]

For specialists who did prioritize the use of color in their interpretations of CYP's pain, use of the color red was high compared with the use of any other colors, as was the intensity of the shading:

> *Red to me is a colour that children will use when something is bad...there was more red, it felt more intense and more meaningful...Intensity of the colouring, I think there's something about...the intensity of the shading in.* [Pain specialist 8]

> *When they are putting red...for them it's too painful, red means too painful. And none of them put anywhere in green.* [Rheumatology specialist 17]

Pain and rheumatology specialists prioritized the use of pain labeling and word descriptors differently within groups. Whereas some viewed labeling as high priority, others placed it low in their interpretations. The vocabulary used was the most significantly prioritized aspect of this feature:

> *His word labels were sort of middle of the road so he used things like "a little bit."* [Pain specialist 6]

> *I did look at the label a little bit, um thinking about the word "throbbing" for example.* [Pain specialist 7]

> *Describing the pain, there is "cracking" painful, I think that was the main reason for ranking this vignette higher.* [Rheumatology specialist 14]

For some pain and rheumatology specialists, pain symbols were not prioritized highly in their interpretations of pain experiences. Some of the reasons contributing to this were that the meaning of the symbols was confusing, not useful, and too basic for understanding CYP's actual thought processes regarding pain reporting:

> *About the symbols, I don't really use those much either, they actually confuse me a bit.* [Pain specialist 4]

> *I think some of the symbols are not useful...If you look through, some have hardly been used.* [Rheumatology specialist 13]

> *It doesn't really give you any impression of what the child is thinking, they're just very basic symbols.* [Rheumatology specialist 18]

The only symbol that did seem to hold meaning was the use of the *fire* icon. The number of symbols used also appeared to factor into pain specialist's interpretation of pain experiences:

> *If the child's trying to say the type of pain really the only symbol here that makes sense is the "firey" one...I don't even know what the rest of them mean.* [Pain specialist 6]

> *I didn't find the symbols very useful except with fire, obviously you know what they feel by fire.* [Rheumatology specialist 13]
>
> *I didn't pay much attention to which symbol but this vignette put two pictures on it.* [Pain specialist 9]

There were general overarching differences and commonalities in the ways that the 2 groups prioritized pain quality information. The commonalities for both groups were that prioritization of the color red was high, as was the particular use of the fire symbols in CYP's pain depictions. The prioritization of use of the color red and fire symbols could again relate to specialists' focus on disease activity indicators in CYP with JIA.

Discussion

Principal Findings

This study is the first to explore the synthesis, salience, and prioritization of multidimensional mHealth pain data from CYP with JIA by key stakeholders involved in long-term pain management. Significant aspects of the researchers' and HCPs' subjective scoring systems for interpreting mHealth data were identified through qualitative themes. There were some shared understandings between groups (such as the salience placed upon pain intensity, caution in interpreting pain emotion, and overall low priority of pain quality information) but far more divergent ideas about other features (such as the disregard of pain severity by pain specialists [but not rheumatology specialists], differences in the use of pain location information [importance of sites vs joints], the salience placed upon radiating pain by pain specialists [but not rheumatology specialists], and the type of additional information necessary when interpreting pain emotion and general ambiguity about the prioritization of pain colors, symbols, and labels).

The importance of joint pain for rheumatology specialists indicates the prioritization of disease activity indicators in their pain appraisals. Other findings strengthened the idea that links between pain and disease markers were continuously sought by rheumatology specialists, for example, the attention given to the clinical context when interpreting pain emotion. This presents a challenge because a wealth of research supports the premise that pain levels often do not mirror levels of disease activity [2,4,5]. Presuming that pain and inflammation are equivalent is problematic in this particular group of patients. The pain body manikin adopted in the pain field encourages specialists to quantify pain in terms of body sections [33], whereas in rheumatology, active or limited joints are specified [34]. Quantification of active inflamed joints is a core outcome variable in the assessment of improvement in JIA [35], and our findings demonstrate that rheumatology specialists interpret and affix the salience of pain location information in the context of disease.

Pain emotion was prioritized very differently to other features of multidimensional pain data. This pain facet was only prioritized if other contextual information could be provided (which was not included in the vignette scenarios used in this study), whereas pain location, intensity, and severity were valued independent of any other information. Pain and rheumatology specialists generally disregarded pain emotion because there was no corresponding interference, function or clinical observation data provided for additional context in this study. This suggests that where possible, pain data alongside activity/clinical information should be provided to those managing CYP pain. Following this study, we adapted MPT by adding an assessment of pain interference which appears in MPT after users complete the main pain reporting page.

The reasons why specialists might challenge younger children's emotion reports could be because they believe that those who are younger are not able to report emotion reliably. Cognitive developmental research suggests that children may differ in the way they explain their emotions [36]; however, the use of emotion-descriptive language has been observed in children as early as 2 years [37]. Vocabulary for pain was important in this study, particularly in the interpretation of pain labels. CYP develop pain vocabularies as young as 18 month and use a select number of words to describe their pain at this age (such as *hurt*, *ow*, and *ouch*) [38]. In younger children, parents and caregivers act as the primary responders, interpreters, and communicators of the children's pain experiences to HCPs. These dynamic pain communication processes reshape children's perceptions of pain-specific experiences and emotions over time [14,39]. It could also be that specialists recognize the key roles played by the parents in the reporting of pain-related emotions and therefore recognize the need to interrogate these data to better understand the contextual influences upon pain reporting.

Comparisons With Previous Work

The importance placed upon pain intensity by pain specialists is not surprising given that intensity is a predominant assessment recommendation by pediatric pain expert groups [40]. Although assessment of pain is mostly neglected in composite outcome measures for JIA, measurement of pain intensity using single-item rating scales occurs in some clinical practices [41]. The conceptual overlap between pain intensity and severity is recognizable from both focus group discussions and from the literature. Operationalization of these key pain terms is almost nonexistent. To our knowledge, only 1 paper discusses key differences between these 2 concepts. Pain intensity has been argued to be defined as how much a patient hurts in quantifiable terms of pain magnitude [42]. However, pain severity is defined as a more global construct that incorporates both intensity and its interference. These data show that professionals attempt to make a distinction between intensity and severity, although the conceptual overlap leads to the disregard of pain severity in some instances and the amalgamation of both intensity and severity in others. The lack of operationalized definitions for professionals is concerning given that CYP are asked to make the same distinction when using pain rating scales [43]. Some specialists in our study were concerned that CYP would choose size of pain based upon the size of the body placement area, rather than to reflect the magnitude of the pain intensity or severity. This emphasizes the need to explore how CYP also denote pain magnitude in multidimensional assessment.

Many of the prioritizations of both pain and rheumatology specialists reflected the focus of professional training and recommendations (for example, rheumatology specialists'

attention to disease activity and clinical context and pain specialists' attention to interference). For pain specialists, the significance of providing data on function is highlighted in recommendations for the measurement of pediatric chronic pain in clinical trials [40]. Similarly, the significance of clinical contextual factors in rheumatology is apparent throughout core outcome domains for the improvement of JIA [35]. Perceptual set theory is useful in interpreting this finding. This theory posits that the processing of stimuli is actively influenced by a bias or predisposition to pay attention to particular aspects of data, which is usually influenced by individuals' expectations and culture (including their professional culture) [44,45]. This study indicates that professionals' interpretations of pain may be influenced by schemata about pain, which have been shaped by specialist training and recommendations. These schemata appear to be guiding the professionals' different synthetization processes when presented with the same set of pain stimuli.

Strengths and Limitations

The use of specific stimulus materials in this study encouraged participants to access their own metacognitive thinking (an individual's awareness of their own cognitive processes [46]) regarding the interpretation of real CYP pain data. 'Focus group discussions may have been superficial without stimulus prompts to encourage discussions, and participants may have been less likely to talk in-depth about the processes behind their interpretations. Group discussions lead to validation and extension of individual participants' accounts, which is important when the topic area is this complex [47].

A limitation of this study concerns the participants working in different health care systems, which may have influenced their interpretations of pain data. Many of the findings of this study can be related to professional measurement recommendations that are country specific. The pain specialist group was predominantly based in Canada and the United States, whereas the rheumatology specialist group worked in the United Kingdom.

The data collection methods used within this study also had some limitations. The setting for the focus groups in which data were collected may have added extra pressure to the participants whose attention and time were already stretched because of their conference attendance. This may have had an impact on the breadth and depth of issues explored. However, participants had received the vignettes before the meeting, which ensured that they had additional time to reflect on the issues. In addition, the contributors were all professionals and were therefore accustomed to expressing their views in time-limited contexts.

Future Research

These findings could be used to inform the ways in which pain information is best presented to key stakeholders in pain management in the future. Data presented could emphasize only informational features that are high priority, could reduce the burden of certain decision-making processes where information can automatically be combined, or could take away any redundant informational features. Information visualizations are useful for representing rich, abstract, and complex information by simulating people's natural perceptual processes in a more efficient manner [48]. To develop these, exploiting and capturing pain interpretation processes based upon group, rather than individual, decision-making processes is necessary for creating less subjective systems of interpretation. However, in our other study developing MPT, we found that CYP want to be able to communicate all of the components of pain as featured in the app. If we reduce the amount of burden on interpreters, we risk detracting from the context and nature of these types of assessments. Multidimensional tools are advantageous in that they encourage discussion and communication about pain, which is important to continue to accommodate in practice, even where professionals might only use specific parts of pain information to inform their management decisions.

Conclusions

To our knowledge, this study is the first to focus on the processes of interpreting mHealth multidimensional pain data rather than on the development of such tools, which is important given the increase in the use of mHealth technology in the management of pediatric chronic conditions [23]. The conceptual framework of pain assessment and interpretation is complex. These findings are important for the development of interpretive guidelines for new pain assessment tools that aim to capture complex data. Particularly, these findings are useful for future research that aims to develop appropriate pain data visualizations that are useful to key stakeholders managing pain in clinics and research.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Vignette scenarios provided.

[PDF File (Adobe PDF File), 1MB - mhealth_v7i7e12952_app1.pdf]

Multimedia Appendix 2

Consolidated Criteria for Reporting Qualitative Research checklist.

[PDF File (Adobe PDF File), 67KB - mhealth_v7i7e12952_app2.pdf]

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Abbreviations

CYP: children and young people
HCP: health care professional
JIA: juvenile idiopathic arthritis
mHealth: mobile health
MPT: My Pain Tracker
NHS: National Health Service
NIHR: National Institute for Health Research

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Original Paper

A Mobile-Based Patient-Centric Passive System for Guiding Patients Through the Hospital Workflow: Design and Development

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Abstract

Background: A hospital is an unfamiliar place to patients because of its style, atmosphere, and procedures. These hospital characteristics cause patients to become confused about responding to protocols, which slows down the procedural flows. Some additional information technology infrastructure facilities and human resources may be needed to solve these problems. However, this solution needs high investment and cannot guarantee an accuracy of information sent to patients. To handle this limitation, EasyHos has been developed to help patients recognize their status (for example, “waiting for an appointment at 11am“) during their stay in a hospital using all existing infrastructure and hospital data and without changing existing hospital's process.

Objective: The objective of this study was to provide a design of the EasyHos system and the case study in hospitals in Thailand. The design is usable and repeatable for small- and medium-sized hospitals where internet infrastructure is in place.

Methods: The EasyHos system has been designed based on existing infrastructure, hospital data and hospital processes. The main components include mobile devices, existing hospital data, wireless communication network. The EasyHos was deployed at 2 hospitals in Thailand, one small and the other with a medium size. The experimental process was focused on solving the problem of unfamiliarity in the hospital. The criteria and pretest conditions regarding the unexpected problem have been defined before the experiment.

Results: The results are presented in terms of criteria, pretest conditions, posttest conditions in the hospitals. The posttest conditions show the experimental results and impact of the system on users such as hospital nurses/staff and patients. For example, the questions from patients were reduced by 83.3% after using EasyHos system while nurses/hospital staff had 5 min more to do their routine work each day. In addition, another impact is that hospitals can create new information values from existing data, which now can be visible and valuable to patients.

Conclusions: Hospitals' unexpected problems have been reduced by the EasyHos system. The EasyHos system has been developed with self-service and patient-centered concepts to assist patients with necessary information. The system makes interaction easier for nurses/hospital staff members and patients working or waiting in the hospital. The nurses/hospital staff members would have more time to do their routine works. Hospitals can easily set up the EasyHos system, which will have a low or nearly zero implementation cost.

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KEYWORDS

user-centered design; health care informatics; mobile computing; data analytics; mhealth

Introduction

Several hospitals encounter certain problems, such as the size, place, lack of available examination rooms, management system, and budgets. The differences between a hospital and patient’s home can cause confusion to patients. A hospital is an unfamiliar place for patients because of its style, atmosphere, and procedures. These hospital characteristics cause patients to

become confused about responding to protocols, which slows down the procedural flows. Moreover, each hospital has different protocols for their procedures to maintain orderly patient flow in the hospital. For instance, different queue management systems are deployed in various hospitals. Typically, the queue is addressed by the nurse, and in some hospitals, it is displayed on monitors installed on the walls. The massive crowds waiting in the foyer of the examination room area indicate that these queue management systems do not work effectively. In particular, the level of sound coming from conversations in a crowded waiting room prevents the announced queue information from being heard. Furthermore, the queue display on the monitors is available only in specific areas. Therefore, patients are obliged to stay in the foyer until they are at the head of the line. Different solutions have been proposed, such as increasing the resources, evaluating demand management, performing operations research [1,2], redesigning the ideal procedure [3], and dividing the services into specialized units. Examples of these include chest pain observation units [4], rapid assessment zones [5], and clinical decision units [6]. Despite previous efforts, limited scientific knowledge has been obtained regarding approaches to improve patient flow [7].

To assist patients and reduce the hospital staff's frustration, a system that encourages self-service concepts for the situation is a solution. Self-service is defined as the practice of serving oneself. Another term that relates to self-service is *customer self-service* (CSS). CSS defines types of electronic tools and items that support users who must obtain access to information and perform routine tasks using technology without requiring human assistance. Technologies that support the CSS model include software apps and kiosks. Software apps allow customers to interact through a software program on a mobile device to perform specific tasks such as internet banking. Developing a more self-service and patient-centered type of system that provides patients with their status and information could alleviate the problem of unfamiliarity and assist with overcrowding in a hospital [8,9]. Thus, the development of EasyHos, with its self-service and patient-centered concepts, would alleviate these problems for patients.

The EasyHos system was developed as a mobile phone app. This system was purposely developed with self-service and patient-centered concepts for patients staying at the hospital. It is simple and effective, with a user-friendly graphic user interface. The necessary patient information and guidance are provided and displayed on the EasyHos system, such as the examination room number, queue monitoring, the duration of stay, and the amount of the medical bill payment. The EasyHos app assists the patient in queue monitoring and notifies them when they move to the head of the line through a mobile phone. The EasyHos system allows patients to move around the hospital using the hospital's map and directions. Patients can return on time to the location of their service based on the queue information provided, without the need to jump ahead in the line. The system assists patients immediately and at any time and frequency that the patient wants. The updates for the patient information are performed automatically in a passive approach by the EasyHos system. Thus, patients are satisfied by receiving the information that they request. Consequently, the hospital staff will be relieved from stress and will be able to perform their routine work more efficiently because the patients do not need to continually inquire about their status. The EasyHos system is necessary to address these issues.

This study aimed to present a tool, called the *EasyHos* system, as a strategic resource to reduce the unexpected problem at hospitals. This tool has been designed to improve the patient flow and prevent a delay in hospital services.

Literature Review

The literature on health care technology exists in various forms. The health care and medical systems' perspectives mostly address technologies such as location-based services (LBSs) [10], automated patient management systems [11], patient tracking tools [12], and complex event processing [13]. LBSs such as the global positioning system (GPS), Wi-Fi positioning systems, and Bluetooth Low Energy (BLE) and radiofrequency identification (RFID) technologies have been designed for indoor and outdoor navigation. The Connexient [14], Locatible [15], StandleyHealthcare [16], and SmartIndoor [17] technologies use the Wi-Fi fingerprint, BLE Beacon/iBeacon, or Handset Sensor Fusion to navigate, track inside a building, and provide indoor maps. All these tracking systems share the common purpose of determining a patient's location in a hospital. These wireless location tracking technologies are key components for implementing an indoor tracking system.

The patent literature US2006/0011941A1 Automated Patient Management System [11] describes a patient activity management system. This technology allows patients to track their own status. The system allows users to view patient information on hospital servers through a kiosk or their own device using wired and wireless connections. This patent has objectives similar to those of the EasyHos system. Moreover, the output of this system is also similar to that of the EasyHos system because it presents patients with status information. Nevertheless, this technology relies on humans to enter the information into the system. Then, the system operates automatically. The limitation of this system is its reliance on human input because humans can cause errors and delays in entering the information. Another limitation of this system is the inflexibility of the process to support the hospital workflow. The hospital often improves its service by adjusting its workflow. To use a new workflow in the system, all the devices must be reset and the data must be re-entered. In contrast, the EasyHos system does not require data to be entered by humans and contains a flexible process. For this reason, the EasyHos system is more accurate, with 0% error. In addition, the EasyHos system supports the hospital's workflow by using data analytics in processing the patients' information according to the hospital conditions. The EasyHos system would be correlated with the hospital information system (HIS); therefore, if the hospital's workflow changed, the system would automatically adjust without resetting each device.

A context-aware service is another technology that is used to track and provide an indoor map. The context-aware service requires more information from different sources. Bardram et al [18] deployed Bluetooth tags for tracking doctors, hospital staff, patients, and clinical management and status such as

operating room scheduling based on context and location information. The information regarding clinical management and status is generated once the doctors, hospital staff, and patients have interacted with the Bluetooth tag reader located at a specific location only. The Cisco Context-Aware Healthcare Solution [19] was developed to locate patients and nonhuman assets (eg, devices and instruments) using radio frequency identification (RFID) tags interacting with readers. Another research study conducted on "A Context-Aware framework for patient Navigation and Engagement" [20] used a rule-based approach in a context-aware study. The reviewed literature aimed to provide suggestion information to patients. This study analyzed the context information, including the location, patient's personal data, patient's symptoms, and disease diagnosis, using numerous preset rules and conditions before providing the finalized information suggestion to the patient. This literature has greatly depended on location tracking technology such as the GPS.

The reviewed studies considered event-driven systems, which emphasized the deployment of an active-driven approach to acquire information based on event data or context data. The event-driven approach has been widely used, as presented in studies such as the following: *the Event-DrivenContext Model InElderly Health Monitoring* [21], *MyHealthAssistant* [22], *Healthcare-Event Driven Semantic Knowledge Extraction With Hybrid Data Repository* [23], and *Intelligent M2M: Complex Event Processing For Machine-To-Machine Communication* [24]. These studies used a specific mechanism, which was an active-driven approach based on an event-driven approach. An active-driven approach alludes to a user (tag device) intentionally moving closer to a sensor or reader. The active-driven feature can be a burden to users because they must make their way to the sensors or readers to obtain information. The limitation of these studies was the lack of budget and reluctance to make changes to the hospitals. Furthermore, the users were not incentivized to use the app tools in the actual environment.

The model in health monitoring of the elderly [21] adopted the event-driven approach for monitoring an elderly person's movement using sensors to collect data. These movement data were analyzed for messaging notifications to the caregiver regarding whether the elderly patient needed an assistant or not. This research focused on the event of a single individual, which involved a small amount of data. In addition, the sensors and other hardware were used to help obtain data faster and were not as challenging as merely performing data analytics. Thus, to obtain accurate data, the sensors and experts would be required to set up and monitor the sensors closely.

MyHealthAssistant is an event-driven middleware for multiple medical apps on a mobile phone app-mediated body sensor network; a study by Seeger et al [22] proposed a middleware architecture for connecting the data and the various sensors on the mobile phone. The research did not report any prediction result using data analytics. The research contained shortcomings in merging the data from various resources to create the event data model because it was in an experimental phase. In comparison, using the EasyHos system, we successfully implemented the event data model and adopted it in an actual hospital environment.

Healthcare-Event Driven Semantic Knowledge Extraction With A Hybrid Data Repository [23] has proposed the use of multiple sources of data for an analytics model by emphasizing a data storage design. The research had the same aim as the EasyHos system. However, the research used the public data service app programming interfaces and analyzed the patients' data. On the contrary, the EasyHos system uses real-time data and real-time context analysis. This real-time context analysis technique is more challenging than mapping the data of patients' symptoms and behaviors because the data frequently change. Moreover, the EasyHos system has an architectural design that supports data movements for constant patient notifications. This system also includes an interface and data storage method, which are necessary for the data movements. This study did not discuss the design of the interface and data storage method layer. However, this paper was released in 2014, and the EasyHos system was already a patented system, with the technology disclosed in the same year.

Intelligent M2M, which uses complex event processing for machine-to-machine (M2M) communication [24], is an approach that uses concepts similar to those of the EasyHos system to analyze data in a software-based architecture. With the M2M connection or the Internet of Things technologies used in this research, the connection between machines would have a fixed format, that is, the M2M configuration is inflexible in comparison with human-to-machine communication such as that used in the EasyHos system. The EasyHos system allows users to move around or change the events all the time, such as queue changes. Furthermore, the research only discussed the system architecture and not the data analytics. The paper also did not report the system's shortcoming of not being used in a real-world environment. On the contrary, the EasyHos system has a clearly defined scope of designing the system to eliminate the constraint of hardware dependence, especially its capability of using any model of mobile phone. The EasyHos system design focused on not engaging any other hardware tools. The study did not mention the hardware that would be involved, such as sensors, but the researchers claimed that their system had a software-based architecture, which needs hardware to operate. The EasyHos system is designed to not interfere with workflows that are performed by humans.

In a hospital, massive amounts of information such as that related to the patient's treatment, the patient's place in line, and the duration of the service are consistently produced. Originally, all of the hospital's information is internally used exclusively among the hospital staff. This information is never visible to the patients, as it is meaningless raw data from the patient's perspective. An electronic health care system for personal electronic health records [25] would empower patients and enhance their communication with doctors through the system. These health care systems generally need the involvement of patients, and the systems themselves contain sensitive information about patients' symptoms and treatments [26]. However, these data are related to a patient's symptoms, the doctor's diagnosis, and the medical treatments. Furthermore, the data in the system are not being analyzed, such as in the

EasyHos system. The analyzed and transformed information would gain value by becoming exclusively available to a specific patient. The information that describes an event or the actions performed by entities is carefully considered. This information includes, for instance, patients' names that are added to the waiting list, which doctors the patients will see, the patients' status, and the time of patients' check-in and check-out at each department. This information can be used to track or measure an event for patients visiting the hospital [27,28]. To be precise, EasyHos uses a rule-based approach in a context-aware analysis to track patients. This method has created a location tracking technology independent of other technologies, such as GPS.

Overall, most studies in the existing literature are hardware dependent and implemented location-based systems or event-driven systems. These systems require funding for the hardware and incentives for the users to actively acquire information based on the event data or context data. To save costs and effort, it is necessary to conduct research on event-driven systems with a passive approach. Using this approach, the users are not required to input data, and no additional location tracking technologies are required. The idea of deploying this passive event–driven approach in a hospital with the context based on the patients' requirements is explained and discussed in the EasyHos Development section.

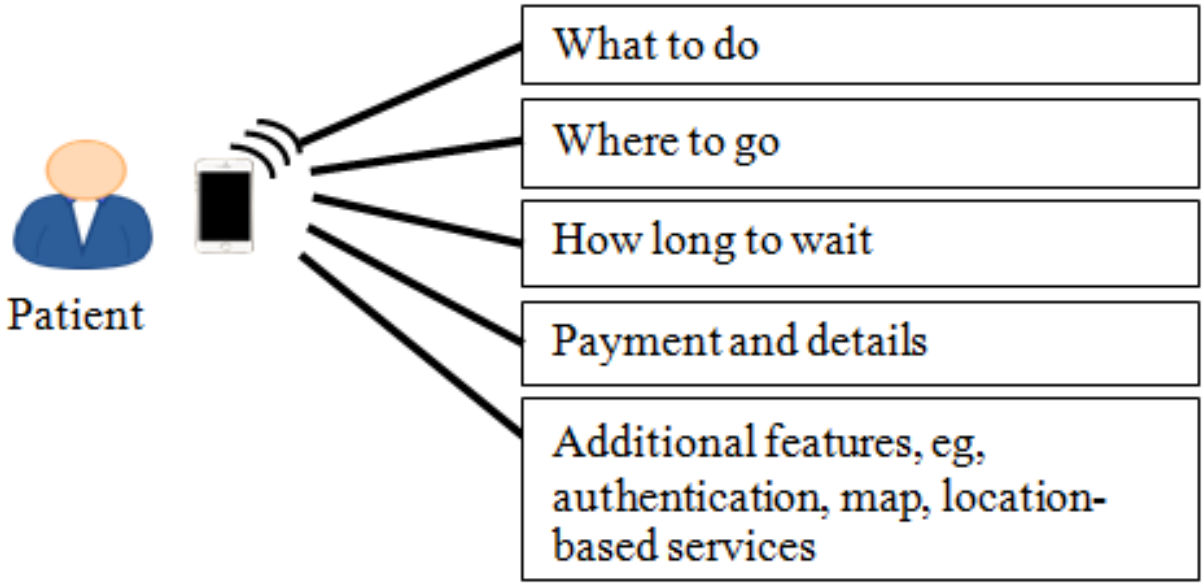
Methods

The proposed system was objectively designed to assist patients and the hospital. The EasyHos app simply works by scanning the barcode on the patient's hospital card. The hospital number (HN) verifies their identity. The EasyHos system connects to the hospital's server and database view to retrieve a fraction of the patient's context. Consequently, the system uses the context analytics of the patient to categorize and display an up-to-date set of information on the patient's mobile phone. Furthermore, the mobile phone can display the locations of the patient passively from the context analytics. The data analytics is performed in association with preset rules and conditions throughout the system operation to provide information suggestions to the patient. Once connected to the hospital's server, the nonsensitive patient information is extracted and displayed on the mobile phone. Thus, a patient's confidential information is not accessed.

A total of 3 main components are implemented as the EasyHos app for patients: (1) mobile devices (mobile phone and tablet), (2) existing hospital data, and (3) a wireless communication network (Wi-Fi or 3G). For the hospital's perspective, the EasyHos system can be implemented without an additional hardware investment. Moreover, the hospital does not have to change their existing business processes or change their routine to learn how to use the EasyHos system. Specifically, the EasyHos system adopts a passive approach that operates in the background.

In addition to the passive approach, the system also uses data analytics techniques. The entire system provides context-aware service information based on event-driven data, such as where the patient must go, which doctor the patient will see, how long it will take to reach the head of the line, and how much the patient's medical bill will be. The answers to these questions are displayed on the patient's mobile device as part of the EasyHos system. Figure 1 shows a description of these activities. The answers to these questions are displayed on mobile devices with the information acquired from the HIS, including the patient's personal data and service information. Personal data such as the patient's full name, address, and HN number are involved. The service information presents the patient's context that has been collected during their stay in the hospital. This service information includes the patient's check-in time, the number of patients waiting for the same doctor, the patient's service status, the medicine that the doctor prescribes, and the amount of the patient's bill. These 2 types of data analyses use a rule-based approach with preset rules and conditions. As a result, a new, understandable, and suitable set of information items is generated for patients.

Figure 1. Example of information provided by EasyHos system to patient.



To obtain a clearer idea, the case of a patient named John is used to explain the data analysis mentioned above. For instance, John comes to a hospital and wishes to see Dr Bob. However, John did not have an appointment with Dr Bob at the hospital today. John arrives at the hospital at the information desk and asks what to do and where to go. The hospital receptionist asks John to scan a QR code of the EasyHos app system for installation on his mobile phone. At this stage, the EasyHos system checks John's information in the HIS by scanning John's HN card or identification (ID) card. Then, a message is generated and displayed on John's phone, such as "John, please go to the medical record counter" to instruct John on what to do and where to go.

Once John has finished registration and made his appointment with Dr Bob, the EasyHos system checks for any changes that occurred to John's record and show a message: "John, please wait for Dr. Bob at Room 2B." The EasyHos system searches for the number of patients waiting for Dr Bob by searching all the records about *Dr Bob* and counting by filtering out who has a waiting status. For instance, there are 20 people waiting for Dr Bob. This acquired number of patients waiting in line is displayed on the mobile phone as follows: "John, there are 20 patients ahead of you at the moment. Please wait for Dr. Bob at Room 2B." The number of people in line would decrease after a patient leaves the examination room. This decrease is because the doctor would update the HIS with the diagnosis, treatment, and prescription medicine information.

Normally, the HIS has features to calculate the total cost of the service and medical bill automatically. This calculation is for the convenience of the staff. As John is examined by Dr Bob, his information on the service and medical cost would be updated by Dr Bob. This information would be sent to the receptionist as well as to John's mobile phone. On John's mobile phone, a message such as "John, please go to the receptionist. Your total payment is 100 USD. Thank you." is displayed. This message is the last message displayed to John for his hospital visit that day. The payment amount is displayed to avoid the surprise of overcharged fees. In addition, John can check with Dr Bob immediately if the bill is incorrect. This feature is to prevent wasting time for both the doctor and patient in checking the bill, correcting the bill's details, and waiting at the receptionist again. Furthermore, John can prepare for the payment by withdrawing money from the automated teller machine because he knows the amount of the payment beforehand.

The EasyHos system was designed to be personalized and context based for each patient. The new view table of existing data in the database management system was created. These view tables contain *only need-to-know* information for patients such as their full name, location, and place in line. Therefore, no patients can see other patient's information. The EasyHos system does not access the HIS and database directly; it only accesses the necessary table's extraction of the HIS. This access approach means that confidential information such as treatment methods and diagnoses are not violated. Then, a data query from the view table was developed to display the status of the patient on a mobile device, as shown in Figure 2. Therefore, the displayed message changes automatically when the context related to an individual changes or analyses are performed, as presented in Table 1 that shows the sample context between the HIS's table view and the patient's views.

In Table 1, the view of the HIS is presented on the left side. Data such as the patient's name, doctor, register time, and status are extracted. These data are analyzed and become the information that is displayed on the patient view that is presented on the right side of Table 1. The context analysis was performed by looking at all the records and comparing them. For instance, to analyze how many patients are left before John can see Dr. Bob, 8 records are present in the view table, and the system searches for the patient named *John* and retrieves his record. Then, the system searches for patients who see Dr Bob and who have registered a time earlier or equal to John's register time (10:16 am) to narrow the number of records searched. The search result leaves 4 patients on the list; they are *David*, *Jane*,

Albert, and John. The next step is to see the statuses of all 4 patients who are still *waiting* and *in service*. In this case, there are 3 patients left. As David was examined by Dr Bob, he is no longer in the waiting queue. Jane, on the contrary, is in the examination room with an *in service* status; therefore, Jane would be the first person in line. Then, the next in line would be Albert, who has the status *waiting* and a register time before *10:16 am*. This information means that Albert is the second person in line. Thus, John would have to wait for 2 patients to see Dr Bob. This is the method used for data analysis.

Figure 2. Process for extracting information from raw data.

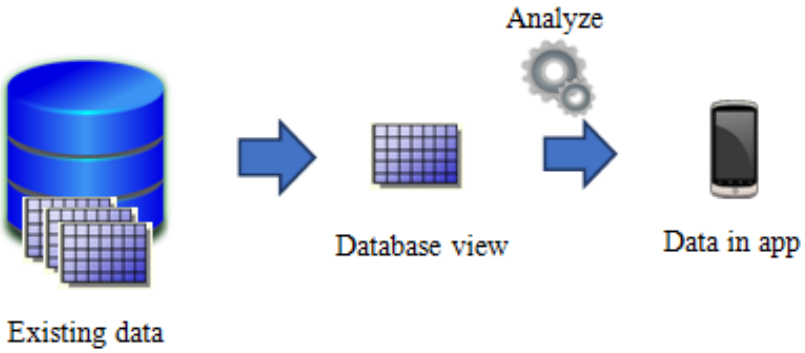


Table 1. Data in a hospital view compared with the desired information in a patient view.

Hospital view (existing)				Patient view
Patient	Doctor	Register time	Status	What the patient should know
David	Dr Bob	10:00 am	Finished	David: go to cashier—how much?
Kim	Dr Roy	10:05 am	Finished	Kim: go to cashier—how much?
Jane	Dr Bob	10:07 am	In service	Jane: during treatment
Albert	Dr Bob	10:09 am	Waiting	Albert: see Doctor Bob—where? Wait 1 patient
Dan	Dr Roy	10:11 am	In service	Dan: during treatment
John	Dr Bob	10:16 am	Waiting	John: see Doctor Bob—where? Wait 2 patients
Peter	Dr Bob	10:30 am	Waiting	Peter: see Doctor Bob—where? Wait 3 patients
Ben	Dr Roy	10:31 am	Waiting	Ben: see Doctor Roy—where? Wait 1 patient

The EasyHos software app development was performed using an Android operating system. The system was chosen because it is available for any mobile phone that has an Android operating system. Specifically, Android is a widely used operating system. The operating system is free and open source for the developer to create an app. The app designs the functionality that supports the scenario, which was explained at the beginning of the section. For a more comprehensive explanation, the workflow of the EasyHos System is drawn and displayed in Figure 3. The EasyHos mobile app starts working when a patient opens the app on their mobile phone. When the app fully starts, it asks the patient to scan a barcode on the hospital card for the HN. Alternatively, the EasyHos app can take the ID number on the ID card to retrieve the patient's data instead. It should be noted that the HIS must record the ID number for patient ID verification when they are first registered. Then, the mobile apps are connected to the HIS and send a request with the HN or ID number.

Once the HIS has received the request, a new record regarding the new patient is created in the HIS's database. Then, a new database view of the new patient is created according to the record in the database. At the request of an existing patient visiting the hospital, the patient's information is retrieved from the database using the HN or ID number as the search condition. The results of the database search, with the patient's information regarding their name, status, number in line, time of registration, and doctor's name, are then selected and extracted for saving in the database view. This information is sent back to the mobile phone for displaying to the patient. Subsequently, the system constantly checks the patient's status for any changes. The system is set to check for an update periodically, according to the configuration. However, if the patient's status is shown as finished or equivalent to the completion of the hospital's process, the EasyHos app terminates. Then, the system is ready for a new transaction for a new patient.

The EasyHos system provides flexibility for both patients and hospitals by adjusting the system to be suitable for both. From the hospital perspective, they can have different business processes or management systems. Even hospital wards can have different management systems. For instance, private and public hospitals have different business processes. This difference is because of the number of doctors and specialists available to patients. In a private hospital, there are more general doctors and specialists compared with a public hospital. Thus, the business processes and management systems are different, as the private hospital allows patients to directly see the

specialist. On other hand, public hospitals lack specialists or even general doctors. For this reason, all the patients have to see the general doctor first although they want to see a specialist.

The mechanism behind the EasyHos system that improves services contains preset rules and conditions, a centralized system (processing unit) for data analytics, a graphical user interface on a mobile device, and the connectivity of a HIS. Figure 4 presents an overview of the EasyHos system, which shows the relationship of the components. Each component has different functionality and produces a different outcome. For instance, the centralized system analyzes the data from the HIS and the preset rules and conditions. The centralized system extracts only the necessary data on what the users must know from the HIS. Then, the new view table of the dataset is created and arranged in a structure such as with the XML or JavaScript object notation (JSON). Subsequently, the HIS is disconnected after the complete data extraction. The new dataset is used instead of being connected to the HIS all the time. This new dataset is used to prevent the confidentiality violation of the patient's information and for the security of the information on a *need to know* basis.

In the implementation process, the preset rules and conditions unit plays a vital role to drive the passive push of a patient's information. The passive push of information is controlled by the centralized system. The push technology or server push is initiated by the centralized server, where the request for information to transmit to display devices occurs. Figure 5 shows an example of pseudocode that represents the preset rules and conditions. The preset rules and conditions are tied to the hospital business process. The consistency of the business process must be determined at the early stages to design preset rules and conditions. A hospital's business process that is inconsistent or that continually changes may lead to difficulty in creating rules and conditions later.

Figure 3. EasyHos system workflow on mobile application side. HIS: hospital information system; ID: identification.

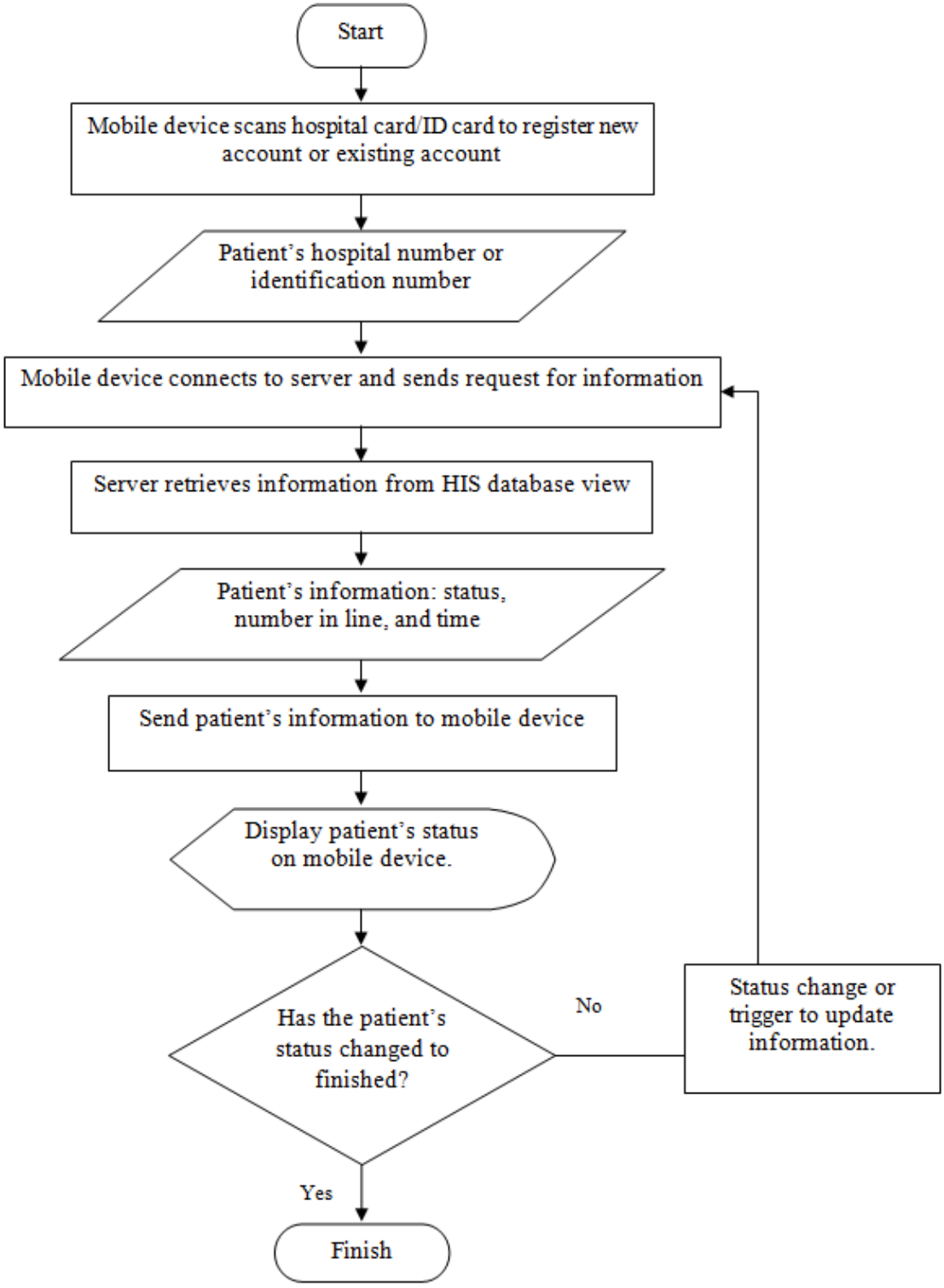


Figure 4. Overview of EasyHos system. HIS: hospital information system.

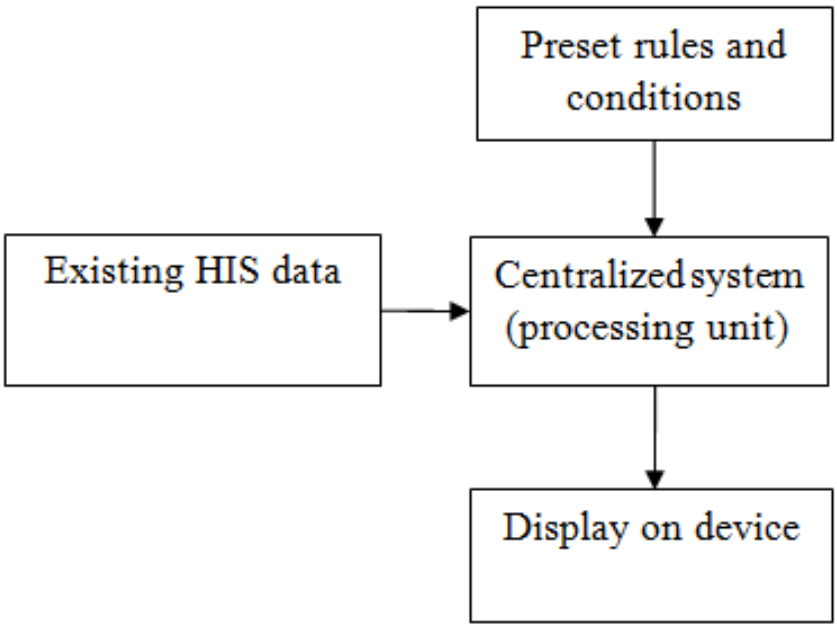


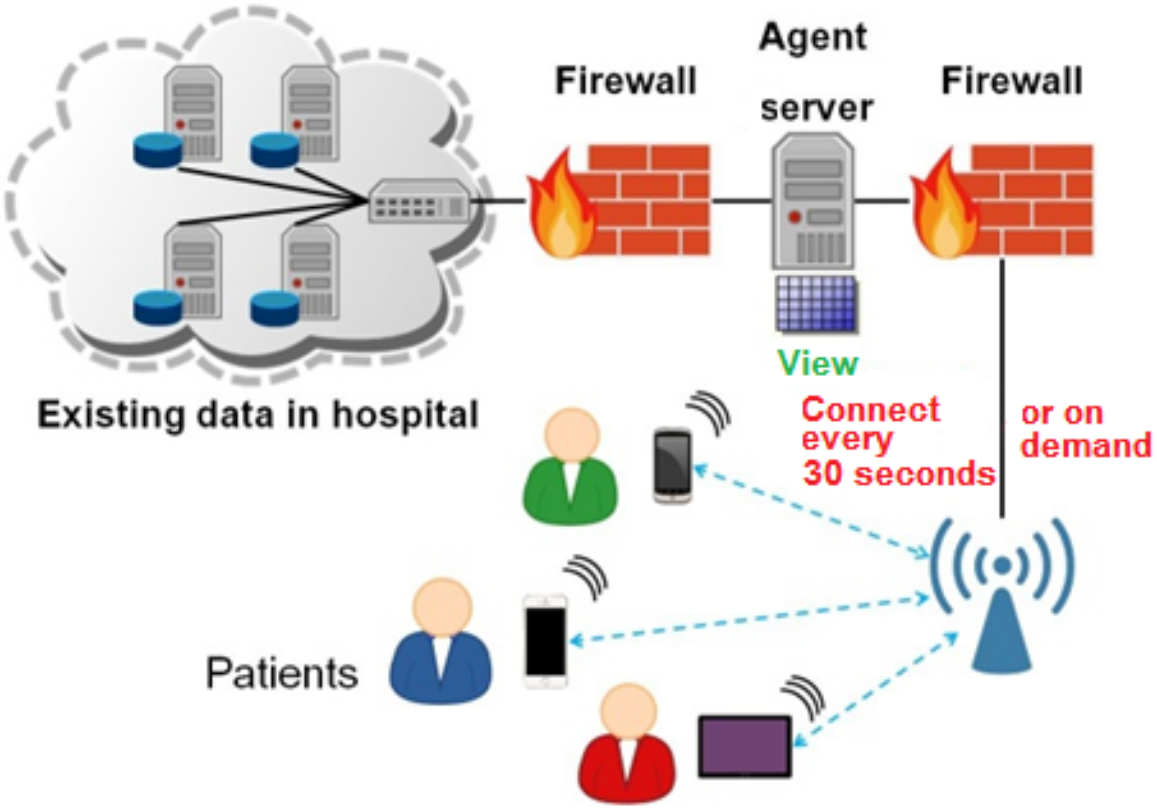
Figure 5. Example of pseudocode.

```
// determine whether John (patientID = 101) has registered or checked in
today.

IF not exist in (SELECT patientID and patient NAME FROM patient WHERE
patientID = '101' AND DATE = today) THEN

Display (patientNAME. 'please go to the registration desk')
END IF

// calculate the place in line by counting the patients who checked in before
John, had no payment record, and waited for Doctor Bob today.

IF (SELECT COUNT(patientID) FROM patient WHERE patientCHECKIN<John.CheckinTime
AND patientPAYMENT is NULL AND doctorNAME = 'Bob' AND DATE = today) THEN

      Display ('There are'.COUNT(patientID).' queues)
END IF
```

Issues about privacy and security may be raised by patients. However, the proposed mechanism is designed by mirroring the existing database system and extracting only information about a patient's activities, not sensitive data such as the date of treatment. People who do *shoulder surfing* cannot obtain patients' identities and treatment information. In addition, the EasyHos system is designed to prevent hacking by having 2 firewall layers in its architecture. The process of patients using mobile devices to connect to the HIS information is shown in Figure 6. The setup of the firewall is placed in between the mobile device and the EasyHos system server. Another firewall layer is set up between the HIS and the EasyHos system server. Patients can retrieve their status on mobile devices by connecting to HIS information every 30 seconds or as a preset.

The EasyHos system uses rule-based data analysis to check the rule for each patient in the same context. The EasyHos system is designed on the basis of event data analysis. The system consists of the development of the preset rules and conditions, a centralized system (processing unit), a graphical user interface on a mobile device, and connectivity to the HIS. Thus, these elements are discussed in the Experiments and Results section. This section includes a discussion of a hospital's pretest conditions and the posttest condition of the hospital after adopting the EasyHos system.

Figure 6. Process showing how patients use mobile devices to connect to hospital information system information.



Results

The EasyHos was objectively implemented, and an experiment was conducted for government hospitals. The EasyHos was deployed at 2 hospitals in Thailand, one small and the other with a medium size. EasyHos could also be deployed at a large hospital. However, this deployment was not conducted because of the unpredictable and complicated processes that affect the event data analysis using our EasyHos system. In addition, at large hospitals, patients often jump the line to see a doctor without registering their data in the computer system. Thus, a tool such as EasyHos would facilitate and solve this problem for both the patient and hospital.

The experiment with the EasyHos system focused on solving the problem of unfamiliarity in the hospital. During the operation trial, notes were accumulated statically. Moreover, the efficiency and technical aspects of the EasyHos app particularly focused on the delay in data retrieval, the accuracy of the data, and connectivity to the HIS server. The operation trial was performed for a 30-day period in a real hospital situation. The operation trial involved 10 nurses who carried mobile devices with an EasyHos system. However, kiosks were also available for some patients who did not have a mobile phone or had limited knowledge about mobile phones during the experiment. These actions were taken to assist the patients with their information, particularly for those who did not want to download and install the app or could not use the app for some other reason. Other components that were vital to setting up the EasyHos system were the HIS database and an internet connection. As mentioned earlier, the EasyHos system requires a connection to the HIS database using an internet connection through the hospital network.

Before the trial operation, the definitions of the criteria and pretest conditions regarding the unexpected problem were in place. The criteria were divided into 3 categories: (1) the statistics on queuing queries and related subjects, (2) information regarding what the patients wanted to know and related subjects, and (3) business process features. Table 2 lists the criteria and pretest conditions. In the first category, there were 3 questions related to the statistics for the queuing queries, as follows: (1) How often do patients ask nurses for their status per day? (2) How long does it take for the nurses to find answers and respond to patients? and (3) How often do the patients ask nurses about their place in line each day? These questions are listed in the first 3 rows of Table 2. In the second category, the questions were based on information that the patients wanted and related subjects, such as does the patient know what to do next or what information does the patient want while waiting and how many patients are not in the waiting area when the nurse announces their name. These questions are listed in the fourth to sixth rows in Table 2. In the third category, the question focused on the business process by looking at the error detection in providing patient services. The question is presented on the seventh row of the table.

Table 2. Criteria, pretest conditions, and posttest conditions in hospitals.

Criteria	Pretest conditions	Posttest conditions
How often do patients ask nurses for their status per day?	30 times	5 times
How long does it take for the nurses to find the answers and respond to patients?	10 min	5 min
How often do patients ask nurses about their place in line each day?	Average of 5 times per patient	1 time per patient
Does the patient know what to do next?	Patients do not know and keep asking constantly	Provide answers to patients immediately
What information do patients want while waiting to see a doctor?	How many patients are left?	None (EasyHos app provides patients with necessary information such as patient's status)
	How long will it take until their turn?	—[a]
How many patients were not in the waiting area when the nurse called out their name?	5 people per day	On average, 1 person misses their turn per day. EasyHos notifies patients to walk back to the waiting area.
Error detection in patient services.	No validation process until confronted with the damage	EasyHos provides information to patients at all times. Patients are immediately notified of any changes that occur. This error can be seen by patients or the nurse at random.

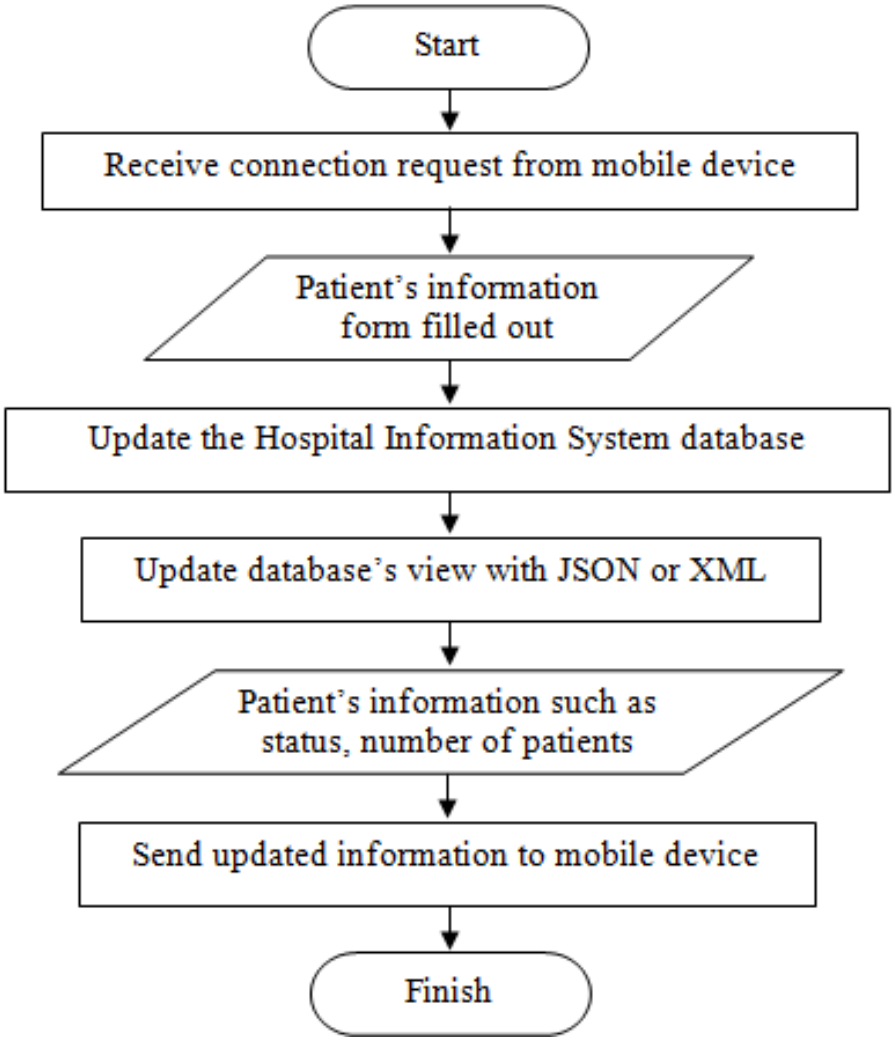
[a]Not applicable.

The pretest conditions were the conditions that existed before the trial operation of the EasyHos system. The pretest conditions were used in collecting the data related to the defined criteria mentioned above. The pretest conditions are listed in Table 2. At a later stage of the experiment, the pretest and posttest were compared for the final result. The pretesting conditions were described for a situation with particular criteria. For instance, when a patient asked a nurse a question, it took approximately 10 min to obtain an answer. Each day, nurses had to answer questions an average of 5 times for a single patient. Furthermore, patients did not know what to do next or where to go. The most frequently asked questions that patients asked the nurses were *How many patients left until their turn?* and *How long until they could see the doctor*? Often, there were cases where a patient was not waiting in the waiting area when their name was announced. This was because of the long queues, which resulted in patients getting hungry or needing to go to the restroom. Finally, the hospital does not have an error detection procedure for patient services in the hospital business process. The nurses or hospital does not know about an error until after it occurs. There is no validation process available to detect errors in patient services because there is no record of each step when checking the status.

The posttest conditions present the hospital conditions after adopting the EasyHos system. The posttest conditions show the experimental results and impact of the system on users such as hospital nurses and staff and patients. In addition, another impact is that hospitals can create new information values from existing data, which now can be visible and valuable to patients. The posttest condition measures are related to the defined criteria, as presented in Table 2. For instance, patients would ask the nurses 5 times per day regarding their status. The EasyHos system helps nurses find the answer for patients by providing a patient's information on a mobile phone, which uses 5 min of their time. With regard to the number of times patients have asked a nurse about their status, the number was reduced to one and then none per patient in each day. Usually, the patients do not know what to do next after each status and constantly ask the nurse. The EasyHos system provides the answer to the patient's need immediately and constantly or as often as the patient needs. Providing this information also eliminates the questions that patients ask while waiting. The number of patients who are not waiting in the waiting areas was reduced to an average of 1 person missing their turn per day. This reduction was because EasyHos notified the patients to walk back to the waiting area. In terms of the error detection in patient services, the error could be seen by the patients themselves. The patients could monitor their status information at all times, and the system notified patients of any changes immediately.

During the experiment, the server was another main component needed for the EasyHos system to operate. The diagram portrays the procedures initiated with the hospital nurses and staff when filling out the patient's information to retrieve their medical records. This process leads to updating the information on the hospital's server, resulting in the standardized data in the database view (or JSON, XML) format being updated. The hospital server keeps updating the view continuously. The mobile device sends a connection request to the hospital server to transfer the patient's information from the hospital database view. The hospital server remains connected to each other constantly to retrieve the updated data from the database view. The patient's information such as their status and number of patients who are waiting for the same doctor is extracted and transferred to the mobile device. These are the procedures for requesting and transferring the patient's information. The procedure that has been explained is described in the form of a workflow diagram and presented in Figure 7 as an example of the data flow on the server side.

Figure 7. Example data flow of server side. JSON: JavaScript object notation.



In addition to the front end (mobile device) and back end (hospital server) that make EasyHos operable, the analyzed result would generate information on the mobile device by means of a user-friendly graphical user interface. Figures 8 and 9 show an example screenshot of the EasyHos system on a mobile phone device (display device). The screen consists of graphics, text, and an icon. The text on the mobile device normally appears in the Thai language. However, the picture display in Figure 8 depicts an example screenshot display on a mobile device that has been modified using the English language. The information includes the receptionist location, total fee, reimbursable fee, and total time spent in the hospital. Figure 9 depicts a real system displaying billing details, extended from the medical bill.

During the experimental period, the EasyHos system had some hindrances. These hindrances occurred as a result of a shortage of mobile devices because some patients did not have a mobile phone. In addition, some patients had limited knowledge about how to use a mobile phone and did not want to install the EasyHos app on their mobile phone. Furthermore, the developer confronted compatibility issues during the Android and iOS operating system integration on the mobile devices. Therefore, a new kiosk version is suggested to supplement the mobile device version. The kiosk version can use an EasyHos tablet version that is exactly the same as the mobile device version. The only change is the use of a front camera instead of a back camera to allow patients to easily scan a barcode. This change resolves the mentioned hindrance. The hindrance and evaluations are discussed further in the Evaluations section.

Figure 8. Example of EasyHos screenshot.

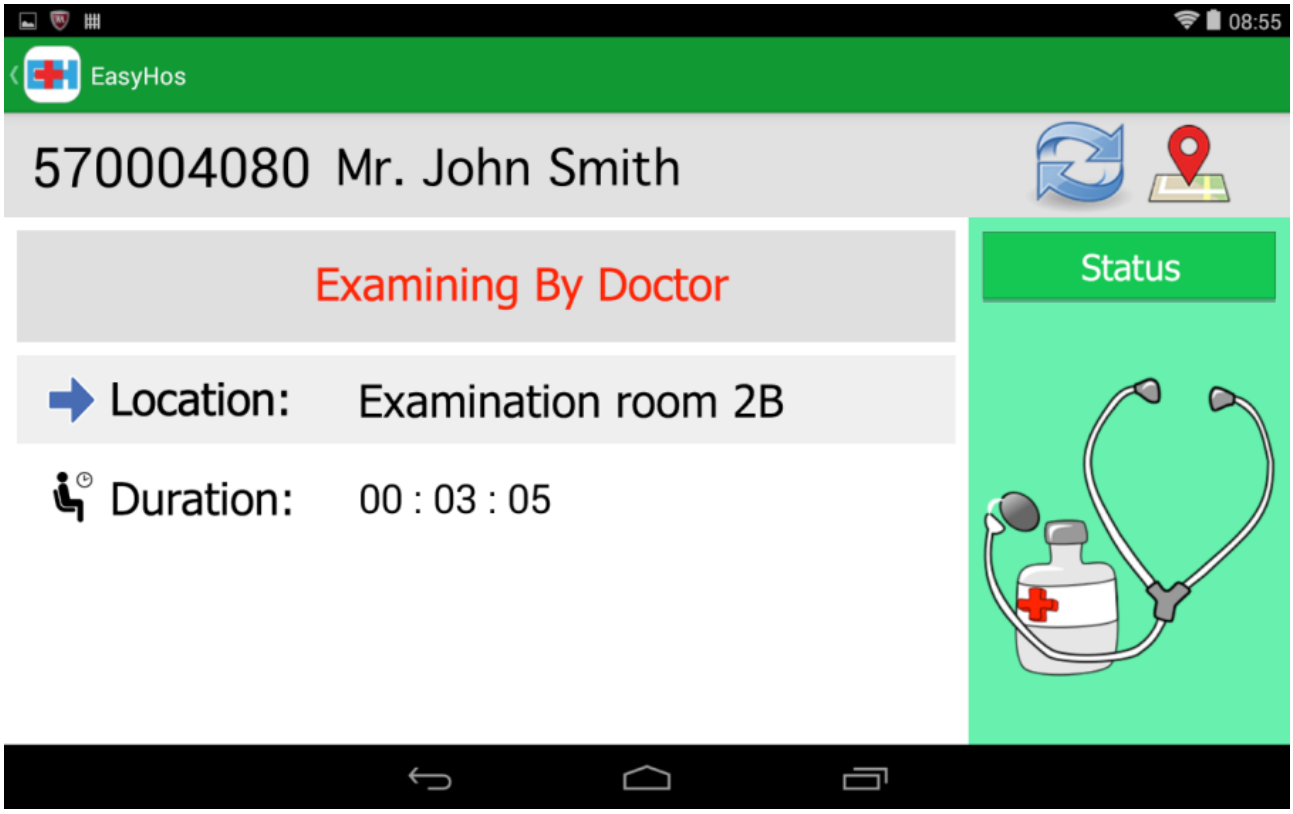
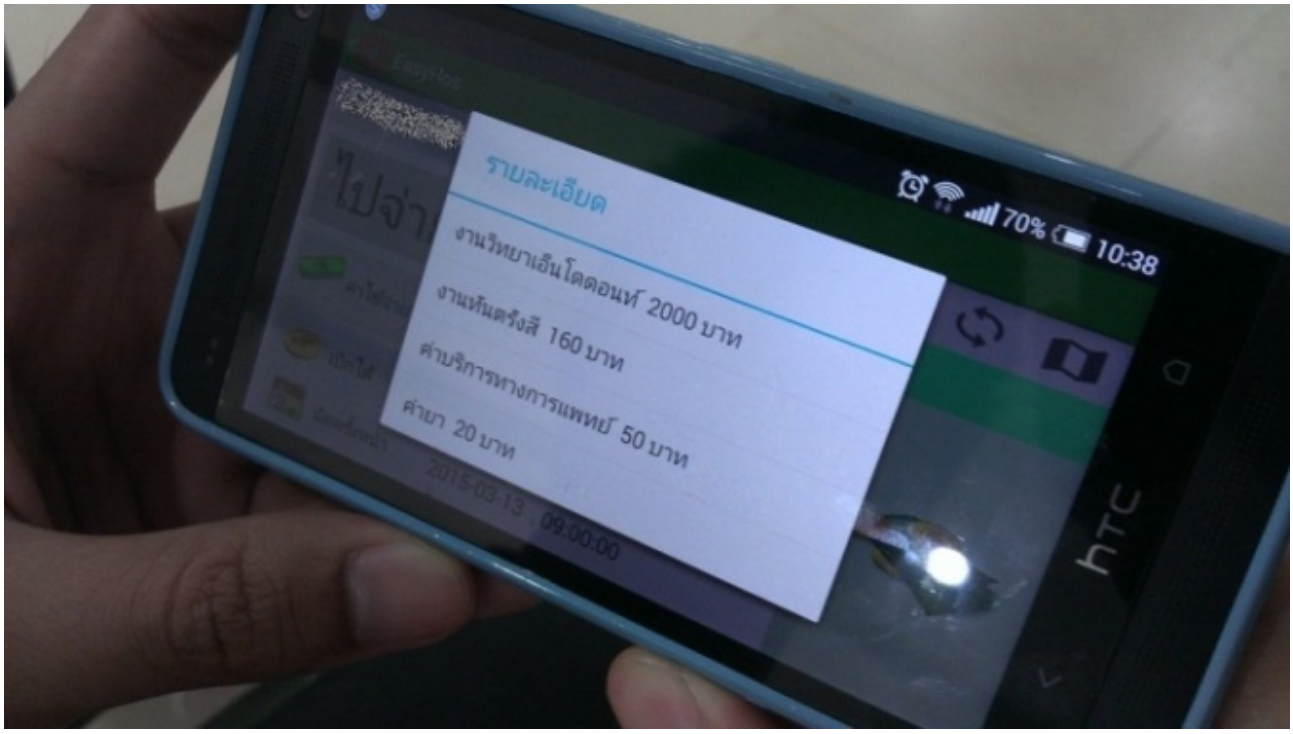


Figure 9. Real system showing billing details in Thai language.



Discussion

The experimental state of the EasyHos system is evaluated and discussed in this section. The results of the operational tests in 2 hospitals are shown with the correct information for patients because all the data involved in the analytics were based on existing data used on a daily basis. However, the system can send incorrect information to patients if the original data from the hospital system are wrong. In addition, it is clear that the hospitals did not require location tracking devices, as the proposed system uses only event-driven data extracted from the existing HIS. All these data were analyzed with preset rules and conditions, which finally created the information presented to patients based on the context or event. This system supports the

passive approach in its communication to patients by pushing the information to users instead of users moving toward the readers or sensors. Table 3 presents a comparison of the existing approaches and the EasyHos system by emphasizing the criteria mentioned above.

The experiment involved a 1-month trial with real-field operation in a hospital. During the operation trial, 10 on-duty nurses performed the experiment. The equipment used for the operation trial included mobile phones and tablets for the nurses. This equipment was used to provide information to patients who did not want to install the app or did not have a mobile phone. During the experimental period, the criteria and pretest were defined before the operation test, as discussed in the Experiments and Results section.

The evaluation of the experimental results referred to the defined criteria. The number of pretest and posttest conditions present discussed here is the average number of criteria that occurred daily. The results of the evaluation of using the EasyHos system in responding to criteria are as follows: (1) the questions from patients were reduced by 83.3% after using EasyHos system, (2) nurses and hospital staff had 5 min more to do their routine work each day, (3) the patients rarely asked the nurses/hospital staff about their place in line and status, (4) the patients knew what to do and where to go from the information provided by the EasyHos system, (5) patients could go other places or do other things and relax while waiting on their doctor, (6) patients knew when to come back to the waiting area because EasyHos notified them and provided a map to assist in walking back to the waiting area, and (7) EasyHos had a double-check system for the hidden flaws in the process. The display information on a patient's mobile devices would reveal any error that occurred in the process. Thus, the process had to be modified to resolve that error. Table 4 presents the criteria, pretest conditions, posttest conditions, and evaluation results.

As previously mentioned, the system has the limitation that the rules and conditions must be consistent, and all the data used for analyses are from the existing HIS. However, in many cases, especially in large hospitals, the rules and conditions can always change depending on the situation. Furthermore, if the data in the existing HIS are incorrect, the message generated from the system are also incorrect. Thus, the scenario mentioned is outside the scope in this study.

Security and privacy issues are also important concerns that should not be overlooked. People have expressed the concern that the proposed system may affect the HIS data. This concern involves the data extracted for data analysis from the HIS, which affects the system performance and availability of the HIS server. In addition, the HIS server is vulnerable to attacks if the EasyHos system allows more access to the HIS server. To reduce the vulnerability of the HIS, another server agent was deployed that only extracted and stored need-to-know data from the HIS server. Therefore, the HIS server is accessible only by this new server, and not directly accessed by end users.

In terms of privacy issues, sensitive data such as a national ID number or patient identity can be encrypted. The system may use 1-way encryption such as a hash function or other appropriate methods applied in a mobile environment [10]. In addition, encryption should be done end-to-end during transmission to ensure that sensitive data are not intercepted and understood by unauthorized persons.

After the experimental period, a full operation was conducted. The data collected over 6 months showed that the number of patients was 16,385 (average 2731 per month) at a small hospital and 25,238 (average 4206 per month) at a medium hospital. The uptime was 100%. The results on the data accuracy were not different from the trial because the accuracy depended on the existing hospital data.

However, during the trial and full operation, other hindrances were found. The cameras of mobile devices were unable or slow to read the barcode on the patient's card. This issue was caused because the contrast setting of each camera is different when scanning the barcode. In addition, the barcode on the card is a traditional 1D barcode, which is an outdated technology. To resolve the problem, the traditional 1D barcode can be converted to a 2D code, such as a QFR. In addition, EasyHos has the flexibility to enter either the ID number on an ID card or a patient's HN instead.

Table 3. Comparison with and results from other existing approaches.

Features and solutions	Location-based Services	Connexient	Locatible	StandlyHealthcare	SmartIndoor	Cisco Context-Aware Healthcare solution	The proposed scheme
Location or context based	Location based	Location based	Location based	Location based	Location based	Mainly location based and partially context based	Completely context based
Tracking hardware	GPS[a]	GPS	GPS	GPS	Bluetooth device	Tag and reader	Not required
Active or passive communication	Active	Active	Active	Active	Active	Active	Passive
Data analytic method	From location	From location	From location	From location	From location	From location	From rules and conditions
User interface/user experience design	Input from users required	Input from users required	Input from users required	Input from users required	Input from users required	Input from users required	No input from users required

[a]GPS: global positioning system.

Table 4. Evaluations regarding defined criteria.

Criteria	Pretest conditions	Posttest conditions	Evaluation results
How often do the patients ask nurses for their status per day?	30 times	5 times	The questions from patients have been reduced by 83.3%.
How long does it take for the nurses to find the answers and respond to patients?	10 min	5 min	Nurses and hospital staff have 5 min more to do their routine work each day.
How often do the patients ask nurses about their place in line each day?	Average of 5 times per patient. This is not including the patients checking on the medical folder placed in front of the examination room themselves.	1 time per patient	When using the EasyHos system, patients rarely ask the nurses and hospital staff about their place in line and status.
Do the patients know what to do next?	Patients do not know and keep asking constantly.	Provides answer to patients immediately	The patients know what to do and where to go from the information provided by the EasyHos system.
What information do the patients want while waiting to see a doctor?	How many patients left?; How long does it take until their turn?	None (EasyHos provides patients with necessary information such as patient's status)	Patients can go or do other things and relax while waiting on their queue.
How many patients were not in the waiting area when the nurse called their name?	5 people per day	On average, 1 person misses their turn per day. EasyHos notifies patients to walk back to the waiting area.	Patients know when to come back to waiting area. EasyHos notifies patients and provides a map for patients to walk back to the waiting area.
Error detection in patient services.	No validation process until confronting the issue.	EasyHos provides information to patients at all times. Patients will immediately be notified of any changes that occur. This error can be seen by patients or any nurse.	EasyHos has a double check system for hidden flaws in the process. The display information on a patient's mobile device would reveal the error that occurs in the process. Thus, the process must be modified to resolve that error.

In addition to the barcode issue, there was an incompatibility issue that occurred in one of the hospital systems. This error caused the information to be unsynchronized and absent from the HIS server. The hospital's information and communications technology system had a workstation-based architecture, which meant other types of devices could not connect to the HIS. During the trial, appointments and notes were taken using a notebook to make it easier to move around; this was the reason that the data were not saved, and the information could not be displayed on a portable device. This constraint prevented unauthorized access to the HIS and tampering with the information. It was necessary for the nurse or staff to re-enter the recorded information on the hospital's workstation again. This re-entering was to maintain the consistency of patient's information in the HIS.

In terms of user feedback, most users, both hospital staff members and patients, were satisfied because of the ease of use and reduction of confusion. However, many users raised an issue about the shortage of mobile devices because some patients did not have a mobile phone. Some patients did not have a phone device that supported the barcode reader app. Some patients had limited knowledge on how to use a mobile phone, and some did not want to install the EasyHos app on their mobile phone. In addition, the developer confronted an issue with the mobile device operating system integration between Android, iOS, and Windows. As mentioned earlier, the EasyHos system was developed on the Android operating system. Therefore, patients were unable to install the app on an iOS operating system because of the different architecture and different programming language used. Therefore, a new kiosk version was suggested to supplement the mobile device version. The kiosk version can use an EasyHos tablet version that is exactly the same as the mobile device version. The only change is the use of a front camera instead of a back camera to allow patients to scan a barcode easily. This change resolves the mentioned hindrance. The evaluations are discussed in more detail in the Evaluations section.

Recommendations for Future Work

This study has presented a new approach to reduce the unexpected problem in hospitals. The EasyHos system was developed with self-service and patient-centered concepts. The EasyHos assists patients by providing information about their place in line, notifying the patient when their name is almost at the top of the list, and providing the examination room number through a mobile phone. Patients can move around or do other things and come back on time to be seen by the doctor. The system also provides a hospital map and directions for patients in case a patient has lost their way. The system assists the patients immediately, at any time, and as often as the patient wants. The patients were satisfied to obtain the information they wanted passively and automatically. Consequently, the system has eased the workload of the nurses and hospital staff and makes it easier for patients waiting in the hospital. The nurses and hospital staff will have more time to do their routine work.

The EasyHos system has proved to be truly passive-oriented and secure and has a low additional cost. The EasyHos architecture was designed to support the scale of hospitals and assist hospitals in implementing the scheme without starting from zero. The system was designed to track the activities of patients without additional hardware devices such as readers or sensors. Therefore, no new hardware equipment is required, unless the hospital's computer network infrastructure is insufficient. This method not only provides additional savings on hardware costs but also avoids business process modification. In addition, there are no new processes to be added to the hospital operation process. Furthermore, this advantage allows users to move freely without the need to use tagging with readers or sensors at a particular spot to obtain updated information. The system analyzes all of the activity data from the context or event extracted from the HIS to obtain information. The system does not directly access the HIS database but creates a database view that extracts necessary data. Thus, the information sent to patients would be private and accurate, because it is extracted from the HIS. Previously, hospitals were unable to disclose a patient's information because of the confidentiality regulation. This policy prevents patients from seeing their own medical record. However, with the EasyHos system, hospitals have allowed the patient's information to be disclosed at a certain level, which is valuable to the patient. However, this case depends on each hospital's judgment about revealing information to the patients. By this action, hospitals have value added to the existing data.

During the experimental period, we found that the hospitals had inconsistent processes, with not many ad hoc processes or unexpected processes. For instance, some hospitals had policies and processes to allow special patients or priority patients, such as a military hospital giving priority to military personnel. In addition, other cases of priority and privilege in queue skipping occurred, such as with a monk, or patients who were over 70 years old and had first priority in the queue. The EasyHos system scope only supports ordinary processes, which do not include priority and privilege queues and VIP patients. In addition, the priority queue limits the EasyHos system operation in a hospital; therefore, the accuracy of the information sent to patients might be low. This is because the information sent to patients is fully reliant on the data from the HIS, which can be incorrect data. In other words, if the original source of information contains incorrect data, the extracted information that is sent to patients is also incorrect. Other hindrances that occurred during the experiment were the shortage of mobile devices, the shortage of knowledge on how to use mobile devices, and patients declining to install the EasyHos app. In addition, the developer confronted an incompatibility problem in the Android and iOS operating system integration on the mobile devices.

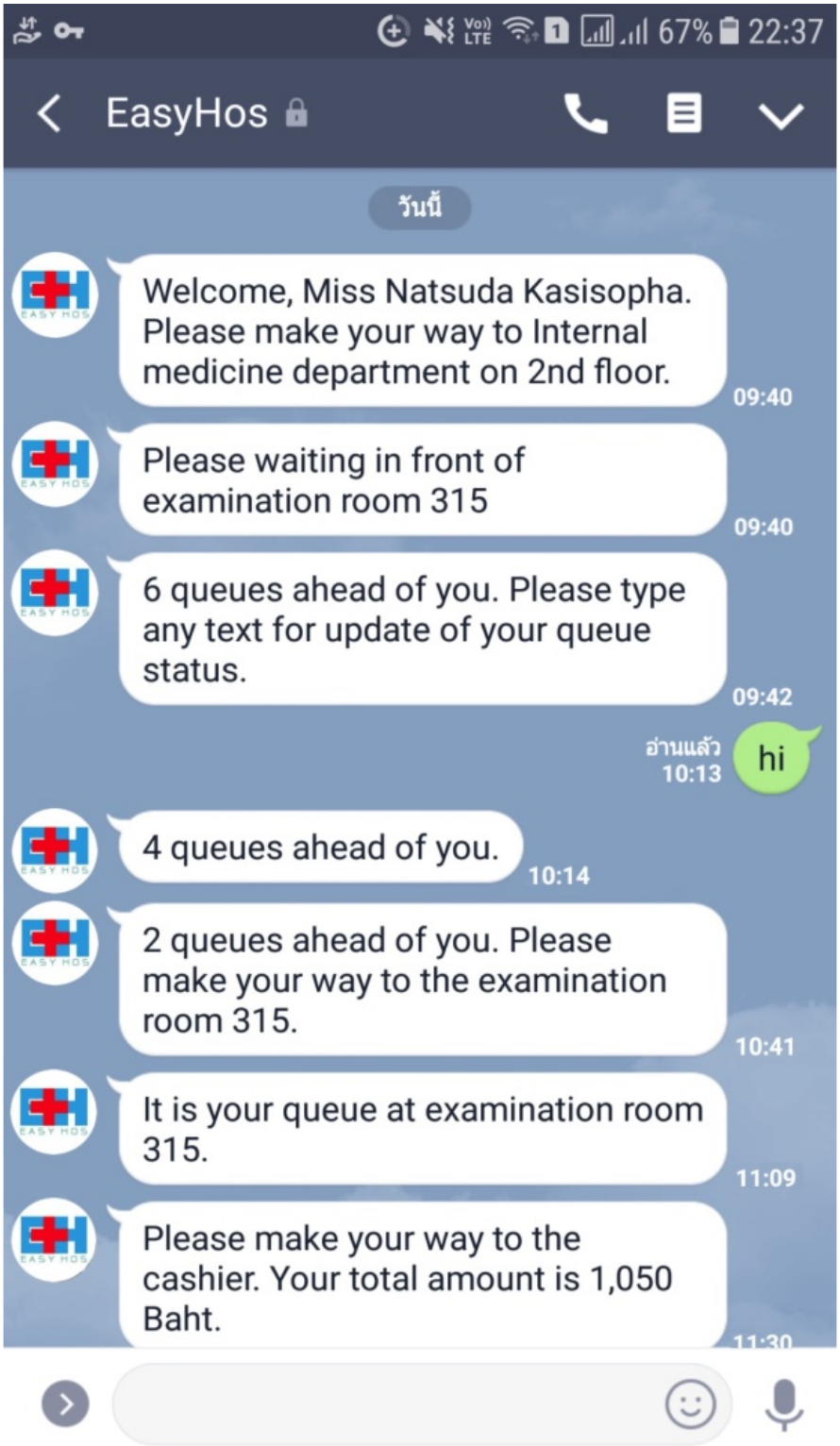
To resolve the aforementioned hindrances, a new kiosk version of the EasyHos system was suggested to supplement the mobile device version. The kiosk version uses the EasyHos tablet version, which is exactly the same as the mobile device version. The only change with the Kiosk version is the use of a front camera instead of a back camera to allow patients to scan a barcode easily. Moreover, the screen resolution may need to be adjusted to be suitable for the display screen.

An additional solution to the hindrances would be the development of EasyHos as Chatbot, similar to existing messaging apps such as LINE [29] and WhatsApp [30]. The patients can add friends with EasyHos. Then, EasyHos continues sending updated information to the patients themselves. For instance, notification messages continuously pop up at the patient's LINE account when there are updated. The notification message would be "Please wait in front of the examination room. There are two patients ahead of you in line" or "Please go to the receptionist. The total amount is 1,000 baht." Figure 10 portrays the text message of Chatbot for the cross-platform of EasyHos that notifies patients on LINE messenger. The advantage of installing EasyHos on cross-platform messaging is that patients do not need to download and install the EasyHos app on their mobile device and can save more memory on mobile devices. Moreover, this method resolves the hindrance of the incompatibility between the Android and iOS operating systems on mobile devices.

In the future, we will create a database standard view that every hospital can use. The database standard view will allow a variety of different hospital database formats to work coherently with the EasyHos system. This feature will allow the EasyHos system to integrate with the hospital database no matter how complicated the hospital business processes are. The integration of the EasyHos system could be done easier and faster, and it will support various hospital database formats. The EasyHos development supports interoperability, allowing it to operate on top of various HISs. Thus, the architecture of EasyHos will be improved in response to the interoperability by extending it from a mobile app to a platform.

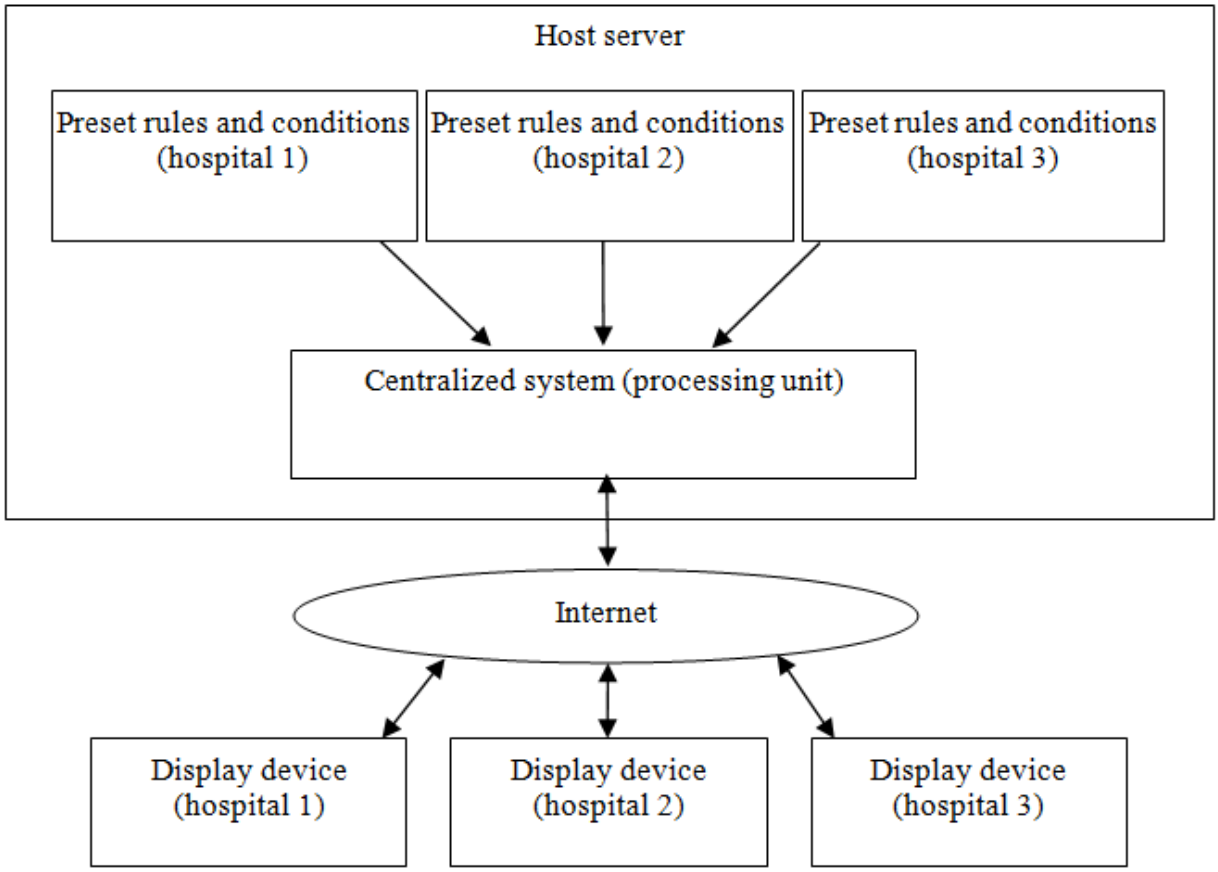
The EasyHos system in the sense of a platform will be able to operate as a centralized system (processing unit), where the system can work with different hospitals with different preset rules and conditions. In other words, EasyHos will be able to run on top of various operating systems and database formats. Therefore, new standards-based interfaces and open interfaces need to be defined to allow the app to interoperate on multiple hospitals' platforms. This change will make EasyHos more effective by developing the EasyHos system to run as a platform as a service (PaaS) with a cloud architecture.

Figure 10. Example screenshot of Chatbot-like text from EasyHos system.



The EasyHos system as a PaaS will allow the app to be executed and managed without the complexity of building and maintaining the infrastructure that is typically associated with developing and launching an app. Therefore, the reason for selecting the PaaS is to eliminate hindrances such as redesigning the software algorithm, server, and network infrastructure, which is time consuming. A hospital or service provider hosts software and hardware infrastructures, but, in the meantime, also provides a platform service that allows other hospitals to modify rules and conditions. In a real situation, other hospitals only use mobile devices (display devices) to connect to the host server to send a request or receive the suggestion information. In this case, hospitals may communicate with the host server using the internet through Wi-Fi, 3G and 4G, or a secured channel such as virtual private network. The architecture of the PaaS is shown in Figure 11.

Figure 11. Platform as a service design of EasyHos.



Finally, the recommendations and future work for the EasyHos system will greatly impact hospitals by creating new information value from existing data. Furthermore, the recommendations will provide flexibility to hospitals, nurses and hospital staff, and patients and increase the efficiency for those entities.

Conclusions

A hospital's unexpected problem has been reduced by the EasyHos system. The EasyHos system has been developed with self-service and patient-centered concepts to assist patients with necessary information. The system makes interaction easier for nurses and hospital staff members and patients working or waiting in the hospital. The nurses and hospital staff members would have more time to do their routine works. The hospital can easily set up the EasyHos system, which has a low or nearly zero implementation cost. Because EasyHos fully relies on the data in the HIS, the limitation is that the data accuracy depends on the existing data stored in the system. Another version of EasyHos such as a kiosk or chatbot version would allow patients to use the system without installing an app on their own mobile device. Furthermore, a platform version of EasyHos would allow the system to operate as a centralized system (processing unit), where the system could work with different hospitals with different preset rules and conditions. This provides the alternatives and flexibility for patients and hospitals to use the EasyHos system.

Conflicts of Interest

None declared.

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Abbreviations

BLE: Bluetooth Low Energy
CSS: customer self-service
GPS: global positioning system
HIS: hospital information system
HN: hospital number
ID: identification
JSON: JavaScript object notation
LBSs: location-based services
M2M: machine-to-machine
PaaS: platform as a service
RFID: radiofrequency identification

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Original Paper

Electronic Patient-Reported Outcome Measures in Radiation Oncology: Initial Experience After Workflow Implementation

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Abstract

Background: Mobile health (mHealth) technologies are increasingly used in various medical fields. However, the potential of mHealth to improve patient care in radiotherapy by acquiring electronic patient reported outcome measures (ePROMs) during treatment has been poorly studied so far.

Objective: The aim of this study was to develop and implement a novel Web app (*PROMetheus*) for patients undergoing radiotherapy. Herein, we have reported our experience with a focus on feasibility, patient acceptance, and a correlation of ePROMs with the clinical course of the patients.

Methods: In the period between January and June 2018, 21 patients used PROMetheus to score side effects, symptoms, and quality of life–related parameters during and after their treatment. Items of the Patient Reported Outcome version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE) were chosen based on the primary site of disease, 27 items for head and neck tumors, 21 items for thoracic tumors, and 24 items for pelvic tumors.

Results: In total, 17 out of the 21 patients (81%) regularly submitted ePROMs and more than 2500 data points were acquired. An average of 5.2, 3.5, and 3.3 min was required to complete the head and neck, thorax, and pelvis questionnaires, respectively. ePROMS were able to detect the occurrence of both expected and unexpected side effects during the treatment. In addition, a gradual increase in the severity of side effects over the course the treatment and their remission afterward could be observed with ePROMs. In total, 9 out of the 17 patients (53%), mostly those with head and neck and thoracic cancers, reported PRO-CTCAE grade III or IV fatigue with severe impairments of activities of daily life.

Conclusions: This study shows the successful implementation of an ePROM system and a high patient acceptance. ePROMs have a great potential to improve patient care in radiotherapy by providing a comprehensive documentation of symptoms and side effects, especially of ones that are otherwise underreported.

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KEYWORDS

mHealth; eHealth; radiation oncology; patient reported outcome measures

Introduction

Mobile Health and Patient Reported Outcomes

Mobile health (mHealth) is a rapidly growing field and has, according to the World Health Organization, *the potential to transform the face of health service delivery across the globe* [1]. In oncology, there has been great interest to use mHealth technologies for the acquisition of *patient reported outcome measures* (PROMs), which are then termed electronic PROMs (*ePROMs*) [2-5]. A variety of studies have shown significant benefits of PROMs in terms of improved communication, patient well-being, detection of unrecognized problems, and also, most strikingly, long-term survival [6-9]. ePROMs bring the additional advantage of the immediate availability of PROMs, avoidance of data entry errors, or the possibility of triggering notifications. It has been shown that the data acquired do not differ between a traditional *paper- and pencil-based* assessment and an acquisition via ePROMs [10]. Recently, this was again validated by Matthies et al, who reported highly significant correlations between a paper-based version of the *Functional Assessment of Cancer Therapy—Breast* questionnaire and an electronic version designed for breast cancer patients [11]. For patients undergoing radiotherapy, data regarding the use of ePROMs are sparse despite surveys showing a considerable interest to use mobile technologies in clinical practice, both on the caregiver and patient side [12,13].

Electronic Patient Reported Outcome Measures in Radiotherapy

In radiotherapy, where the majority of treatments are performed in an outpatient setting, ePROMs might be a useful tool to monitor acute toxicities during therapy and shortly afterward, as well as late toxicities. Furthermore, signs of disease recurrence or progression might be detected at an earlier stage. We developed a Web-based application, *PROMetheus*, that allows patients to submit ePROMs over the internet to the treating team. We hypothesized that ePROMs will be well accepted by our patients and provide a complete and comprehensive documentation of side effects and quality of life (QoL)–related parameters during radiotherapy. In this study, we report our initial experience with a focus on feasibility, patient acceptance, and a correlation of ePROMs with the clinical course of the patients.

Methods

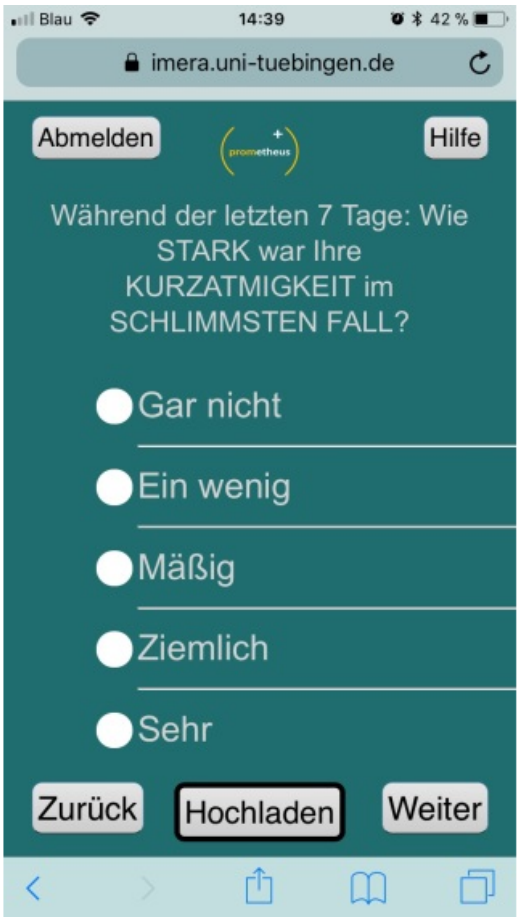
Participants and Recruitment Process

In the period between January 2018 and June 2018, 21 patients used PROMetheus to score symptoms and QoL-related parameters. Patients who had provided an email address in their demographic data were approached by a physician before treatment or latest during the first week of treatment and asked if they were interested to use PROMetheus. All the patients who were offered to use PROMetheus provided consent. If requested, the first scoring was completed under supervision. After this, the patients were instructed to complete a Web-based questionnaire whenever desired but at least once weekly. A reminder to complete the questionnaire was sent once a week via email. In general, patients were approached by the treating physician whenever Patient Reported Outcomes-Common Terminology Criteria for Adverse Event (PRO-CTCAE) grade IV toxicity was reported on the Web or when a 2-point increase from grade I to grade III was observed. ePROMs were reviewed daily by the principal investigator of the study (CG). We had defined that no medical intervention or treatment would be initiated solely based on ePROMs without a confirmatory interaction of the treating physician with the patient. Irrespective of the ePROM submission, patients had weekly consultations with the treating physician to assess toxicity according to our institutional standard. If a patient was admitted for inpatient treatment, the patient was asked to continue the ePROM submission and email reminders were continued. Free Wi-Fi access was offered to all inpatients in the study. This study was approved by the institutional review board of the medical faculty in Tuebingen, Germany (approval number: 421/2018B02).

Technology Platform Development

PROMetheus was developed as a progressive Web application using HTML5, CSS3, and JavaScript and is accessible through browsers on all internet-compatible devices such as smartphones, tablets, or computers. Patients log in with an alphanumeric pseudonym and a password and are then immediately forwarded to the first item. Figure 1 depicts a screenshot of PROMetheus. PROMetheus is built on the *Integrated Mobile Health Research Platform* (IMeRa), which facilitates the submission of data from the patient to the hospital network over the internet. IMeRa provides a Secure Sockets Layer–encrypted Web service for Web applications. Via this Web service, the patients' answers are transmitted in the *Mobile Data Repository for Research* of the IMeRa platform (based on an Oracle Relational Database Management System [RDBMS]). The IMeRa platform also provides the physician with a Web-based data browser where patient data can be selected, displayed, and exported for further statistical evaluations.

Figure 1. Screenshot of PROMetheus during usage (functions of the buttons: top left=sign out, top right=help, bottom left=back, bottom center=upload all items answered so far, and bottom right=next). The question displayed assesses the severity of shortness of breath with a 5-tier scale from not at all to very.



Structure of the Questionnaires

The questionnaires fed into PROMetheus were based on the certified German translation of the PRO-CTCAE developed by the National Cancer Institute [14]. In short, the questions assess severity, frequency, and impact on activities of daily life (ADL) on a 5-tier scale from *none* to *very severe* or from *never* to *almost always* based on the average of the last 7 days. Questions referring to the severity or the impact on ADLs of an item were automatically skipped if the given symptom was not present. We defined 3 different sets of questions for the included treatment categories: head and neck (up to 27 questions), thoracic (up to 21 questions), and abdominal (up to 24 questions) tumors, respectively (Multimedia Appendices 1-3). For head and neck cancer patients, we individually developed 3 items that assessed pain and swallowing. Patients had the opportunity to discontinue and submit the completed items at any point; however, it was not possible to skip questions.

Data Analysis

Regarding *patient acceptance*, we defined ePROMs as accepted by a patient if the ePROMs were submitted at 5 time points at least, which approximately corresponds to weekly submissions. For descriptive data, median values and interquartile (25th to 75th quantile) ranges (IQR) are reported. For statistical analysis SPSS version 25 (IBM) and Microsoft Excel were used.

Results

Patient and Treatment Characteristics

Patient characteristics are shown in Table 1. All the patients (n=21) completed radiotherapy with a median treatment dose of 60 Gy (IQR 50.4 Gy to 64 Gy). Patients received either radiotherapy alone (5 patients) or radiochemotherapy (16 patients). In total, 12 patients received the concomitant systemic treatment in a preplanned inpatient setting. In most cases, this inpatient treatment took place during the first and fifth week of treatment, whereas treatment was conducted in an outpatient setting on the remaining days. No admissions for inpatient treatment occurred because of toxicity.

Table 1. Patient and treatment characteristics.

Characteristics	Value
Total number of patients, N (%)	21 (100)
Sex, n (%)	
Male	14 (67)
Female	7 (33)
Age (years), median (IQR[a])	59.4 (51.5-66.5)
Treatment, n (%)	
Radiotherapy	5 (24)
Radiochemotherapy	16 (76)
Radiotherapy dose (Gray), median (IQR)	60 (50.4-64)
Primary site of cancer, n (%)	
Pelvic	10 (48)
Thoracic	5 (24)
Head and neck	4 (19)
Upper gastrointestinal	2 (10)
Stage[b], n (%)	
I	1 (5)
II	5 (24)
III	13 (62)
IV	1 (5)

[a]IQR: interquartile range.

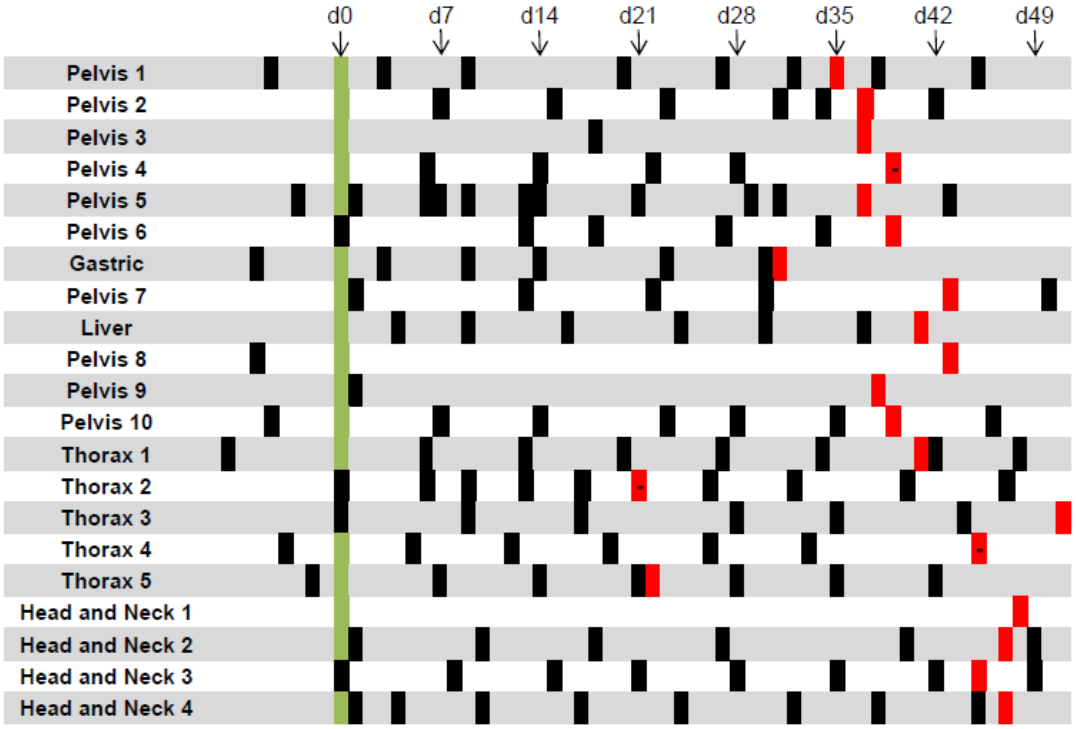
[b]One patient with a tumor of an unknown primary site was excluded.

Feasibility and Patient Acceptance

ePROM acquisition with PROMetheus was feasible. None of the patients reported any technical issues that prevented the submission of ePROMs or problems in understanding the usage of PROMetheus. In terms of patient acceptance, 17 out of 21 patients (81%) regularly submitted ePROM data during treatment, with a median of 6 (IQR 4 to 8) submissions (Figure 2).

The patients required a median of 5.45 min (IQR 4.65 to 5.91 min), 2.39 min (IQR 2.38 to 4.78 min), and 2.95 min (IQR 2.72 to 3.36 min) for the completion of the head and neck, thorax, and abdominal questionnaires, respectively. By including the submissions after the end of treatment, we were able to collect more than 2500 data points in these 21 patients. In all the submitted questionnaires, all items had been completed.

Figure 2. Time points with electronic patient-reported outcome measure (ePROM) submissions of the 21 patients in our cohort. d0 (green) indicates the day of the first treatment, time points filled in red indicate the last day of treatment. Red bars with a dash indicate ePROM submission on the last day of treatment. d: day.



Clinical Examples of Electronic Patient-Reported Outcome Measures Assessed During and After Treatment

Figure 3 shows an example of a 75-year-old patient who was treated for a locally advanced tumor at the base of the tongue (cT2 cN2b cM0) using definitive radiotherapy with 70 Gy and concomitant chemotherapy with weekly Cisplatin (40 mg/m²). A percutaneous endoscopic gastrostomy (PEG) tube was placed 2 days before the initiation of the treatment. Treatment toxicity and impairment of ADL continuously increased with treatment time. Taste changes and lack of appetite were the PROMs to reach grade III or higher. Three weeks after the end of treatment, all high-grade toxicities had resolved.

ePROMs from 2 other patients with rectal cancer and gastric lymphoma are shown in Multimedia Appendices 4 and 5. The first patient (male, aged 50 years) was treated using preoperative radiochemotherapy (50.4 Gy) with concomitant 5-fluorouracil during the first and fifth week for locally advanced rectal cancer. The only PRO-CTCAE grade IV toxicity during the treatment was the *severity of vomiting* reported on the third day of radiochemotherapy. Further investigation revealed a norovirus as the cause of this toxicity. The other patient was a 55-year-old female diagnosed with mucosa-associated lymphoma tissue (MALT) lymphoma of the stomach. Treatment using radiotherapy with a total dose of 39.6 Gy was planned, and prophylactic intravenous antiemetics were offered. On the basis of the patient's request, only oral antiemetics were prescribed and ePROMs were assessed during the treatment. No nausea or vomiting of PRO-CTCAE grade III or IV was scored during the treatment. Instead, fatigue and *sleeping problems* were the highest scored items. The patient completed the treatment without any intravenous treatment.

Figure 3. Example of the course of electronic patient reported outcome measures in a 75-year-old patient who underwent definitive radiochemotherapy for locally advanced head and neck cancer. Day 45 constitutes the last assessment during therapy; d76 was approximately 3 weeks after the end of treatment. d: day; ADL: activities of daily life.

Item	d1	d4	d10	d17	d24	d32	d38	d45	d76
Xerostomia-severity	0	0	1	2	3	3	3	4	2
Constipation-severity	0	1	2	3	0	1	3	4	1
Cough-severity	0	0	0	1	3	2	3	2	1
Cough-ADL impairment				1	2	3	4	2	0
Pain-frequency	2	1	2	1	0	1	0	0	0
Pain-severity	2	1	1	1		1			
Pain -impairment ADL	0	1	1	1		1			
Sleeping problems-severity	1	1	2	2	1	2	3	2	0
Sleeping problems-ADL impairment	1	1	2	1	0	2	2	1	
Fatigue-severity	0	2	2	3	2	3	4	4	1
Fatigue-ADL impairment		2	2	3	2	3	4	4	1
Dysphagia-severity	2	0	1	2	3	4	3	4	0
Trismus-severity	0	0	0	0	2	3	2	2	0
Trismus-ADL impairment					2	3	2	2	
Oral or neck wounds-severity	0	0	2	1	2	1	0	1	0
Oral or neck wound-ADL impairment			1	1	2	1		1	
Coarseness-severity	1	1	0	1	2	3	4	4	2
Taste change, severity	0	1	3	3	4	4	4	4	1
Lack of appetite-severity	0	1	3	4	4	4	4	4	1
Lack of appetite-ADL impairement		1	2	3	2	4	3	3	0
Nausea-frequency	0	2	2	1	1	2	1	1	0
Nausea-severity		1	1	1	1	1	1	0	
Vomiting-frequency	0	0	0	0	0	0	0	1	0
Vomiting-severity								1	

Fatigue as the Most Frequently Reported Single Item

With regard to fatigue, 9 out of the 17 patients (53%) who regularly submitted ePROMs reported PRO-CTCAE grade III or IV fatigue at the end of the treatment; in all cases, impairment of ADLs was scored as PRO-CTCAE grade III or IV as well. All the patients except one with head and neck or thoracic cancer had PRO-CTCAE grade III or IV fatigue, whereas only 1 patient with a pelvic primary had scored high-grade fatigue.

Discussion

Principal Findings, Strengths, and Limitations

This study is one of the first to report ePROMs for the assessment of treatment toxicity and QoL aspects in patients undergoing radiotherapy. We observed high acceptance with over 80% of the patients regularly submitting complete ePROM datasets. We believe that this was facilitated by the very simple setup of PROMetheus and the weekly reminders for the completion of the questionnaires, which confirms the results of a patient survey conducted by El Shafie et al who reported a great interest in patients to use mobile technologies during radiotherapy and thereafter [12]. The potential benefits of ePROMs are manifold. First, concerns regarding a potential underreporting of toxicities in clinical trials have repeatedly been expressed [15]. Usually, toxicity during treatment is evaluated by a physician at regular intervals and entered into the patient's chart, either already graded according to a standard scoring system or as descriptive text. In case of the latter, this information needs to be *translated* into a grading system (potentially by a third person) if a graded score is required, for instance, for entry into a research database. All these individual steps are prone to errors or loss of crucial information [16,17]. With ePROMs, this information is immediately available as digital and parametric data. Furthermore, patients can go through the items at home or in the waiting area, without the stress associated with a doctor's visit. It has been suggested in many studies that self-reporting increases patient contentedness and potentially enables physicians to recognize adverse events at an earlier time point [18,19]. Clearly, a limitation of this study is the sample size, which does not permit detailed subgroup analyses. The rationale for the sample size was to evaluate the feasibility and patient acceptance at an early time point before moving forward to large-scale randomized trials. Even though the patient cohort in this study is small, it represents patients with various tumor entities and age groups.

Further Benefits of Electronic Patient-Reported Outcome Measures

Self-reporting may also improve communication between physicians and patients, as investigated by Velikova et al who showed in a randomized trial that regular assessment of QoL improved patient-physician communication even resulting in better emotional functioning and overall QoL [7]. We made the experience that offering a Web-based PROM solution lowered the patients' threshold to contact the treating physician, for instance, via email when symptoms occurred that were not assessed by the predefined questionnaires. For example, 1 patient with nonsmall cell lung cancer and receiving definitive radiochemotherapy developed severe lower back pain only a few weeks after the end of treatment. As no PRO-CTCAE item in our questionnaires assessed pain outside the treated area, the

patient submitted this symptom via email, which prompted a face to face assessment of pain characteristics, physical examination, and, subsequently, a computed tomography within a few days, confirming the suspected metastatic disease and the swift initiation of systemic treatment. It appears likely that the early detection of disease progression, as in our exemplary case, played a crucial role in a recently published study of ePROMs in the care of cancer patients undergoing palliative chemotherapy. In this randomized trial of 766 patients, in which the sole intervention was the inclusion of a Web-based ePROM platform in the experimental arm, a 5-month benefit in overall survival was seen [8].

We consider ePROMs as a very useful complement to face-to-face patient-physician interaction and not a replacement. First, according to a recent survey, a considerable number of patients would refuse ePROM usage because of the wish for personal contact with the treating physician [13]. Second, and most importantly, self-reported high-grade toxicities and symptoms scored with ePROMs need clinical validation before any diagnostic or therapeutic intervention is initiated. This is well reflected by the mentioned case of a rectal cancer patient whose severe diarrhea and vomiting during the first week of treatment turned out to have a viral origin rather than being a treatment-related side effect (Multimedia Appendix 4). As we approached patients who had provided an email address during the registration process, our cohort has to be considered a positive selection in terms of computer experience. This is an important aspect, as Basch et al showed a correlation between Web usage before enrollment and log-in times during data acquisition [16]. On the contrary, the benefits of ePROM usage in terms of survival and frequency of emergency room visits have been shown to be independent of computer experience [19]. It is likely that the technological progress and the increasing incorporation of the internet into our daily life will soon limit the patient cohort that is either not able to or not willing to use ePROMs.

Content Validity of the Selected Items

Content validity is an important aspect in the context of PROMs. In an interview-based study among radiotherapy patients—published before we designed our questionnaires—Sandler et al found that all except 5 frequently reported toxicities were covered by PRO-CTCAE items. In total, 3 of these items were seen in patients with head and neck cancers (mucus production, oral pain, and pain when swallowing) [20]. Indeed, when we compiled the items for the 3 treatment sites, we saw the need to add additional items that assessed PEG usage and pain medication intake.

The Challenge of Big Data

A major challenge faced when implementing ePROMs in clinical practice is the huge amount of data, which needs to be reviewed. Notification systems that inform the treating team of either uncommon symptoms or critical severity of toxicity before meeting the patient need to be implemented. Defining these thresholds for all items already constitutes a challenge of its own and warrants further research [21-23].

Electronic Patient-Reported Outcome Measures and Cancer-Related Fatigue

It is well known that cancer-related fatigue (CRF) is an underreported symptom in patients undergoing treatment [24]. Conventional symptom assessment by clinicians has been shown to diagnose *subjective* symptoms, such as fatigue, less frequently than self-reporting using PROM items [25]. Indeed, almost all patients who received treatment of the head and neck or thoracic tumors self-reported a severe level of fatigue. Even more important is that all these patients considered their fatigue to be impairing their activities to a high degree. Several groups were able to show that exercise may have an impact on the severity of CRF [26]. A meta-analysis by Tomlinson et al reported a positive effect of exercise on fatigue as well as depression and sleep disturbance. At our department, we are currently evaluating the potential of commercially available activity trackers to tackle CRF and to implement ePROMs as a tool to monitor CRF [27,28].

Optimization of Normal Tissue Complication Probability Models Through Electronic Patient-Reported Outcome Measures

The large amount of data that accumulate when PROMs are implanted into the clinical workflow can have a much broader use than the sole monitoring of PROMs. Weighing the likelihood of acute and long-term toxicities against tumor control probabilities is the daily routine in radiotherapy. Normal Tissue Complication Probability models have been established to estimate the likelihood of a specific toxicity [29]. The majority of these models are based on clinician-assessed endpoints with the associated limitations discussed earlier. One can envision that PROM data could be used to further refine these models and improve their ability to predict long-term toxicities, similar to an approach presented by Miften et al [30]. Here, the selection of the adequate items is crucial, and a recent review has shown that only a minority of PROM-based models is accurate or can be generalized on external validation [31].

In conclusion, our results show that the implementation of an ePROM system for the assessment of treatment side effects and QoL during radiotherapy is feasible and well accepted by the patients. We, therefore, consider ePROMs as a very useful tool to complement face-to-face patient-physician interaction. However, randomized trials will have to prove whether a measurable benefit through ePROMs in terms of QoL, side effects, or even survival can be achieved [32]. Furthermore, the development of strategies to handle the large amounts of data is among the major challenges that need to be addressed in the future.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Questionnaire for patients with head and neck cancer.

[PDF File (Adobe PDF File), 785KB - mhealth_v7i7e12345_app1.pdf]

Multimedia Appendix 2

Questionnaire for patients with thoracic tumors.

[PDF File (Adobe PDF File), 784KB - mhealth_v7i7e12345_app2.pdf]

Multimedia Appendix 3

Questionnaire for patients with abdominal or pelvic cancer.

[PDF File (Adobe PDF File), 786KB - mhealth_v7i7e12345_app3.pdf]

Multimedia Appendix 4

Electronic patient-reported outcome measures of a 50-year-old male patient who received preoperative radiochemotherapy for locally advanced rectal cancer are depicted. The only grade IV score was the severity of vomiting at a very early stage of treatment. After a medical history, this turned out to be caused by a noroviral infection.

[PDF File (Adobe PDF File), 38KB - mhealth_v7i7e12345_app4.pdf]

Multimedia Appendix 5

Electronic patient-reported outcome measures of a 55-year-old female patient who underwent radiotherapy of the stomach for mucosa-associated lymphoma tissue lymphoma. Although nausea or vomiting were not an issue until the end of the treatment, fatigue and sleeping problems were the predominant symptoms during the treatment.

[PDF File (Adobe PDF File), 36KB - mhealth_v7i7e12345_app5.pdf]

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Abbreviations

ADL: activities of daily life
CRF: cancer-related fatigue
ePROM: electronic patient-reported outcome measure
IMeRa: Integrated Mobile Health Research Platform
IQR: interquartile range
mHealth: mobile health
PEG: percutaneous endoscopic gastrostomy
PRO-CTCAE: Patient Reported Outcomes-Common Terminology Criteria for Adverse Events
QoL: quality of life

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Original Paper

A Smartphone App for Improving Clinical Photography in Emergency Departments: Comparative Study

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Abstract

Background: Digital photography is crucial for electronic medical records (EMRs), particularly for documenting dermatological diseases and traumatic wounds. In modern emergency departments (EDs), digital cameras are commonly used for photography, but the process is time-consuming. The problems of addressing patient privacy issues and that of interruptions and heavy workloads can cause archival errors when uploading photos. However, smartphones are widely available and cheap, so with a suitable app many errors could be mitigated.

Objective: The aim of this study is to design and test a smartphone app to improve the efficiency of clinical photography and improve patient privacy in the ED. The app is connected to the hospital information system to verify patient identification and enable archiving, and the app can automatically delete images after upload to the patient's EMR.

Methods: This study enrolled 48 experienced ED nurses trained in clinical photography. Each nurse was first assigned a digital camera for photography and then a smartphone with the app preinstalled after it was launched. The time taken to upload images to a patient's EMR was then recorded and the efficiency of the digital camera and app groups were compared.

Results: The average time taken to upload images to a patient's EMR for the camera and app groups were 96.3 s (SD 19.3; $P<.001$) and 26.3 s (SD 4.7; $P<.001$), respectively.

Conclusions: The app effectively reduced processing time and improved clinical photography efficiency in the ED. Some issues of patient privacy in the camera group were revealed and resolved in the app group.

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KEYWORDS

smartphone app; health informatics; clinical photography; patient privacy

Introduction

A picture is said to be worth a thousand words, which may now also be true in medical diagnoses. Patient photography has changed the way health care providers (HCPs) document, discuss, and deliver modern medical care. Medical photography is frequently used for the following: (1) documentation and consultation; (2) education; (3) patient and family instruction; and (4) journal publications [1]. In emergency departments (EDs), traumatic injuries and dermatological diseases are frequently recorded photographically first [2]. The Taiwanese National Health Insurance (NHI) administration regulates photographic records created by hospital staff to assess corresponding payments and treatment. Photography is also used to record and document healthcare issues for legal and judicial applications [1,2]. Because of the rapid development of information technology (IT) systems in healthcare, photographic film is not used in modern hospitals. Electronic

medical records (EMRs) provide a suitable tool for communication within care teams and tracking of patients. Because clinical photography only has to record the actual condition of patients, even nonprofessional photographers can create records using photography in EDs [3].

Although digital images are becoming increasingly popular, several concerns regarding patient privacy need to be addressed [4,5]. From the perspective of patients, hospital-owned photographic devices are preferred over personal devices [5]. Digital cameras are currently the most common method of recording and uploading images to EMRs in hospitals. EMR systems typically have strict IT security to approve, restrict, and record the access of users, so the connection of cameras and transmission of images have consequently become somewhat time-consuming processes. Occasionally, archival errors can occur, and patient safety and privacy can be endangered. In addition, clinicians need to delete photos on the capture devices manually to prevent a privacy breach, which also takes time [6].

Modern smartphones with high quality cameras and software are now highly advanced and are more similar to laptops or handheld computers. A market for smartphone applications devoted to healthcare is emerging [7,8], and many apps serve numerous users in various fields, including clinical practice, medical education and patient instruction [9]. Medical devices and apps are already invaluable tools for HCPs, and as the range of features and uses expands, they are expected to exhibit greater market penetration in all aspects of clinical practice [10].

Smartphones are already competing strongly against single-purpose cameras in the photography market. However, unlike most digital cameras, the transmission capabilities of smartphones make them highly vulnerable to privacy breaches [11,12]. Leveraging the benefits of smartphones while avoiding their vulnerability to privacy breaches would be a considerable development in healthcare. In this study, we reviewed the research and designed an app that can reduce the time required to record and upload images as well as reduce archival errors. Patient confidentiality and privacy improvements are also discussed.

Methods

Application Design

By using the programming language Cordova, we designed and created a purpose-built app for the Chia-Yi Christian hospital (CYCH), referred to as the *CYCHFastshot*. The app is currently specific to the Android operating system and is only used for ED photography. The app has multiple functions (Figure 1), including: (1) scanning a barcode on the patient's wrist band; (2) connecting wirelessly to the hospital information system (HIS) through an intranet network to verify patient identity (Figure 2); (3) capturing patient photos by using the phone's built-in camera; (4) enabling convenient photograph selection (Figure 3); (5) sending the selected photos, wrapped in a data packet, to a folder on the patient's EMR through the HIS; (6) notifying users about failed transmission through notices on the screen (the photos are stored temporarily in the app, and users can choose to either resend or restart the app to resume the upload); and (7) deleting of all the patient's photos after securely uploading the image data packet to the EMR, due to a signal from the HIS [7].

Here, smartphones with the app were all hospital-owned and delivered encrypted photographic data packets over a Wi-Fi intranet network without using a subscriber identity module (SIM) card [13]. This absence of internet service prevented patient information from being leaked or hacked, thus maximizing patient privacy. All hospital-owned devices were tagged with the hospital's logo and barcode to facilitate the ability to discern them from private devices and thus improve instrument management.

Figure 1. The workflow of the functional steps of the Fastshot app. HIS: hospital information system; ID: identification.

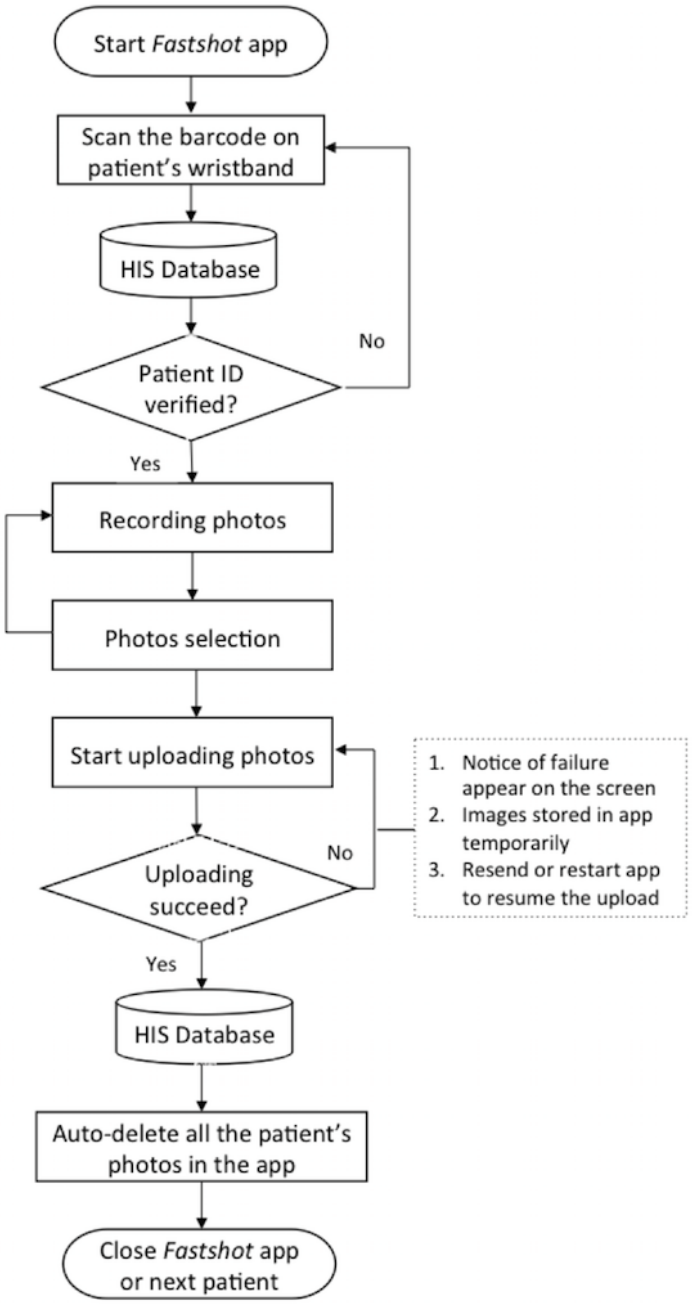
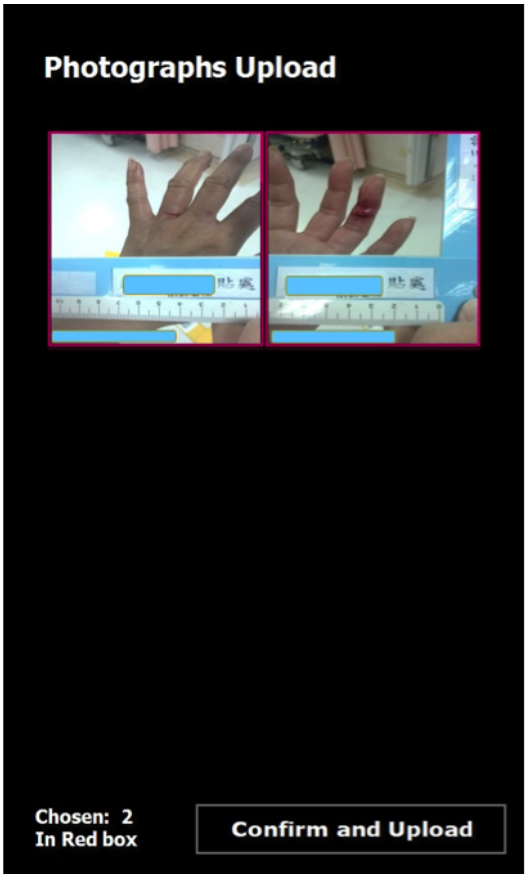


Figure 2. Scan a wrist band and connect to hospital information system to verify patient identity. HIS: hospital information system. ID: identification.

Figure 3. Photo selection and upload.



Study Design

A comparative study was conducted at a busy, academic, urban ED that has approximately 100,000 visits annually. The upload efficiency of ED patient photography using digital cameras and the app was compared. In the ED, nurses serve as photographers when an appointed physician makes a request. On these occasions, another nurse on the team manages positioning and treatment of the patients with multiple or complicated wounds, ensuring that one nurse can focus entirely on only recording photos.

Here, the recruited nurses had all received standard training in ED clinical photography so that they could quickly record and identify clear photos. They also knew how to place a measurement device for scale, <1 inch from the point of the target lesion, and how to record photos with properly identifiable body parts. All the recruited nurses had more than 3 months of experience using both the camera and the app for photography.

Data Collection

Each nurse was assigned two types of photography both before and after the app launch. An observer recorded and calculated the time spent from starting the devices to completing an upload to the EMR. The observers were a registered nurse and a research assistant who were familiar with ED nursing, the requirements of clinical photography, and the execution of the research plan. The photography processes of each group were segmented and calculated for comparison according to the time spent on each step. The entire upload operating procedure for each device is presented in Table 1.

Every computer in the nursing station was equipped with a card reader and a connector cable for the camera. The Wi-Fi intranet system was set up for data transmission from laptops, secondary monitors, and ultrasound machines in the ED. The specific devices used in this experiment were a Panasonic DMC-FH4 (digital camera) and an HTC U11 (smartphone).

Table 1. Photography processes for the digital camera and smartphone app groups.

Process	Digital camera group	Smartphone app group
(0) Start patient verification	N/A[a]	S0: Start app to scan the barcode on wristband
(1) Record photos	D1: Start digital camera to record photos	S1: Record photos
(2) Upload photos	D2: Move to computer and connect the DC or storage card, select photos to upload to EMR[b]	S2: Select and upload photos to EMR
(3) Delete photos	D3: Manually delete photos from storage card	N/A

[a]N/A: not applicable.

[b]EMR: electronic medical record.

Data Analysis

Recording and uploading multiple photos of a single patient required the nurses to spend extra time on them. Thus, the cases were divided into subgroups for comparison according to the number of photos uploaded. Few cases required an upload of more than three photos, and these cases were excluded from the study as outliers. Similarly, interruptions unrelated to photography were excluded. However, delays caused by equipment failure, connection or data transmission were retained. The observers were expected to keep records and check that photos were successfully transmitted to the correct patient EMR archives. For analysis of the timing data, a two-tailed paired *t* test was performed to compare the mean values between the digital camera and smartphone app groups. The chi-square test was used to compare the distribution differences of different numbers of photos uploaded between the two groups.

Results

Initially, 50 qualified nurses were recruited, but one resigned and another took parental leave before app implementation. Finally, 48 nurses completed camera and app photography both before and after the smartphone app implementation. Each nurse successfully recorded photographs of different patients by using digital cameras and the smartphone app. The total process time of the camera and app group was 96.3 s (SD 19.3; $P<.001$) and 24.6 s (SD 4.7; $P<.001$), respectively. The time spent on individual process segments was calculated for analysis. The process codes are listed in Table 1.

S0 (5.8 s; SD 0.9) represents the time spent in barcode scanning and identification. D1 (14.5 s; SD 5.8; $P<.001$) and S1 (11.9 s; SD 3.5; $P<.001$) represent the time spent taking photos. D2 (71.5 s; SD 17.8; $P<.001$) and S2 (6.9 s; SD 1.2; $P<.001$) represent the time to connect and select photos and uploading photos. D3 (10.3 s; SD 2.1) represents the process of manually deleting photos from the digital camera storage card. All findings are presented in Table 2.

The photography time considerably differed between the two groups. The number of photos recorded for each group is listed in Table 3. Some cases required only a single photograph; however, the majority of cases fell into the two-photo subgroup as nurses often had to record a second photo if the target body part was not sufficiently distinguishable in the first photo. There was no significant statistical difference between the digital camera and smartphone app groups in terms of the distribution of the different number of photos uploaded ($X^2_2=.384$; $P=.83$).

The data were divided into subgroups according to the number of photos recorded in both groups to enable specific process comparison. The total process time for both groups, according to the number of photos uploaded, is illustrated in Table 4.

Table 2. Time spent on individual segmented processes (in seconds).

Process	Minimum	Maximum	Mean (SD)	*t* test (df)	*P* value
(0) Start patient verification					
Digital camera	N/A[a]	N/A	N/A	N/A	N/A
Smartphone (S0)	4	8	5.8 (0.9)		
(1) Record photos				4.3 (47)	<.001
Digital camera (D1)	7	20	14.5 (5.8)		
Smartphone (S1)	5	19	11.9 (3.5)		
(2) Upload photos				25.2 (47)	<.001
Digital camera (D2)	34	120	71.5 (17.8)		
Smartphone (S2)	6	11	6.9 (1.2)		
(3) Delete photos					
Digital camera (D3)	7	12	10.3 (1.4)		
Smartphone	N/A	N/A	N/A		
Total				26.5 (47)	<.001
Digital camera	54	152	96.3 (19.3)		
Smartphone	15	34	24.6 (4.7)		

[a]N/A: not applicable.

Table 3. Subgroup categories separated by number of photos uploaded.

Number of photos uploaded	Digital camera, n	Smartphone app, n
1	14	12
2	26	29
3	8	7

Table 4. Average time spent in each group according to the number of photos uploaded. All values represented are in seconds.

Variable	1 photo		2 photos		3 photos	
	Digital camera	Smartphone app	Digital camera	Smartphone app	Digital camera	Smartphone app
Recording time	10	7.3	15.3	12.4	17.9	16.9
Uploading time	56.8	6.6	74.9	7	80.4	7.3
Total	77.3	19.8	100.4	25.1	108.7	30

The photography processes were isolated for comparison of the digital camera and app groups, as shown in Table 4. Although the difference in photography time for the camera and app group was small, it was significant (P<.001), indicating that the selection and upload led to the largest difference between the two groups (Table 4).

In 12.5% of cases (6/48), the patient photos were left undeleted on the storage card by the previous users in the camera group. Because the observer randomly initiated the experiment the camera group did not have a chance to check the digital camera in advance, which is similar to the actual conditions they'd be operating under. These six cases (88.7 s; SD 15.6) actually took a longer time than the others did (72.1 s; SD 14.3; P<.001) to select and upload the photos.

Discussion

Principal Findings

The smartphone app group (24.6 s; SD 4.7) spent almost three times less time on the entire photography process than the digital camera group (96.3 s; SD 19.3). The average time of the barcode scanning and verification process was 5.8 s (SD 0.9). The speed of wireless data transmission and verification from the HIS was fast and steady when the app device was sufficiently close to scan the barcode and nurses were proficient with its use. The barcode system has been used widely and has been effectively implemented for patient identification, medication, and blood tubing [14,15].

The time spent on isolated photography processes differed significantly between the D1 (14.5 s; SD 5.8; P<.001) and S1

groups (11.9 s; SD 3.5; *P*<.001). This difference was due to two factors: (1) the app had a faster autofocus function than the camera; and (2) the device startup time for the camera was included in the data.

The major difference between the two groups was in the time taken for photo selection and uploading, with D2 taking 71.5 s (SD 17.8; *P*<.001) versus S2 taking 6.9 s (SD 1.2; *P*<.001). The digital camera group took considerably more time than the smartphone app group because they had to work on the computer. Connecting the device, selecting the patient's photos on the screen, and then uploading them to the target EMR file constituted a time-consuming process. On average, the app group spent one-tenth of the time of the camera group in this process segment.

Several types of hospital equipment transmit data over the wireless network and into the HIS, where the EMR archives are located [16]. In this study, the photos of both groups were all uploaded to the EMR archives without errors or leaks. Although the standard procedure was to manually delete the photos recorded by the digital cameras after upload, images were found on the device in 12.5% of the cases. The presence of images on the cameras may be due to negligence or time constraints for the previous users, which indicates that staff training programs in the future should include, and insist on, photo deletion. This should at least be the case in hospitals where the smartphone app method is not adopted. The photos left undeleted may not have even been uploaded to the EMR. In cases where photos remained on the camera, the user took longer in the reading and selection process (88.7 s; SD 15.6) than the average (72.1 s; SD 14.3 s; *P*<.001). The additional steps in the digital camera process and the multitasking nature of the nurses' occupation are the likely cause of this oversight [17].

Another factor to consider is that digital camera storage cards and card readers are often damaged due to the frequent connecting and disconnecting procedures. Because smartphones transmit data wirelessly, device fatigue is not usually a factor requiring consideration. In a few cases, broken screens due to accidental dropping of the smartphone during use were observed, however, the cost-benefit ratio of the equipment and widespread availability of the devices means this damage would likely be offset easily. Ultimately, a specific study on the cost-benefit ratio of smartphone use is required.

The main benefit of using a smartphone rather than a digital camera is efficiency, particularly in a busy ED. Since all the nurses in this study now prefer the smartphone app, digital camera photography serves as an alternative, backup solution after the launch of the app in the ED.

All patient photos are strictly confidential; however, photos of patients who were victims of sexual assault are stored on a separate storage card kept in a sealed box, accessible only to the police. These special conditions were excluded from the study.

In general, the smartphone app group demonstrated superior results compared with the digital camera group because all the photos captured were processed more quickly and deleted automatically. The manual deletion process in the camera group added an extra 10.3 s to the processing time.

Limitations

In this study, neither misfiled nor missing photos were observed in both groups. This absence of errors may be attributed to the observer effect or the small sample size. However, data from the hospital's nurse reporting system indicated that 9-13 cases of ED missing photos or archive errors occurred annually before the app was launched. Archive errors endanger patient safety and their correction requires a large amount of time. These problems increase stress levels, frustration, and discontentment because of the high risk of medical errors [18]. As mentioned, nurses endure high levels of discontinuity in the execution of their work and frequently have to manage interruptions; these factors increase the potential for errors. Strategies that reduce the number of interruptions or devices that mitigate dangerous interruptions are required [19]. The strongest advocates for foolproof devices and systems are the nurses themselves, and they were a key driving force in development of this app [20]. The nurses' heavy workload, with many interruptions and distractions throughout the day, also often leads to job dissatisfaction and burnout [21]. After taking photos in the ED, the camera group took several seconds to move to a nearby computer and upload the photos. However, in this short period, many nurses were interrupted or distracted by requests from patients, families, or colleagues. These incidents may explain the reason that some photos were left on the storage cards of the cameras and neither uploaded nor deleted.

The Wi-Fi connection at the hospital was strong and no transmission errors or delays were noted in the study. A strong and stable Wi-Fi network and support from the IT department was essential for the project's success.

Conclusion

Smartphones are becoming increasingly ubiquitous. A relatively simple photography app can add safety, security, and timeliness to a hospital's ED. Verifying patient identity, prevention of archival errors, and ease of use are all essential aspects of a smartphone app. The improvement of patient privacy and the prevention of leaks and hacks also improve the outcome of this study. This app could potentially increase the efficiency of clinical photography, reduce the workload of nurses, and mitigate stresses caused by frequent interruptions.

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Conflicts of Interest

None declared.

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Abbreviations

CYCH: Chia-Yi Christian Hospital
ED: emergency department

EMR: electronic medical record
HCP: health care provider
HIS: hospital information system
IT: information technology
NHI: National Health Insurance
SIM: subscriber identity module

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Original Paper

Customizing the Types of Technologies Used by Patients With Type 1 Diabetes Mellitus for Diabetes Treatment: Case Series on Patient Experience

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Abstract

Background: Despite the fact there are many wearable and mobile medical devices that enable patients to better self-manage their diabetes, not many patients are aware of all the options they have. In addition, there are those who are not fully satisfied with the devices they use, and those who often do not use them effectively.

Objective: The study aimed to propose possible changes to the combination of devices used by 6 specific patients for diabetes self-management. We assessed the suitability of selected technical devices for diabetes control.

Methods: Data of 6 patients (3 men and 3 women) with type 1 diabetes mellitus, who had been using the Diani telemedicine system for at least 3 months, were analyzed. The suitability of selected technical devices for diabetes control was ascertained using the data obtained via the Diani telemedicine system, as well as the patients' subjective feelings and statements, their everyday life habits, and self-management of diabetes. Informed consent was signed and obtained from each of the patients included.

Results: Each of the presented case studies describes how a given patient handled the system and its specific components based on his or her lifestyle, level of education, habits related to diabetes management, personality type, and other factors. At the conclusion of each case study, the best composition of devices for patients with similar personal descriptions was suggested.

Conclusions: We believe this study can provide relevant guidance on how to help particular patients choose the technology that is best suited for their needs, based on the specific patient information we are able to obtain from them. Furthermore, clinicians or educators should be aware of available technologies a given patient can choose from. In addition, there is a substantial need for proper patient education in order for them to effectively use devices for diabetes self-management.

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KEYWORDS

type 1 diabetes mellitus; technology; self-management; wearable electronic devices; education; telemedicine

Introduction

Background

Diabetes mellitus is a metabolic disease associated with the development of chronic complications. Slowing down or stopping the progression of these complications is associated with sufficient diabetes control, that is, maintaining blood glucose values within the recommended targets.

Despite the fact that various types of mobile and Web apps, wearable medical or fitness devices, and telemedicine solutions

are being developed to help achieve the goals of diabetes control [1-5], not many patients are aware of all the options they have or are not fully satisfied with the devices they use and, besides that, they often do not use them effectively [6-10].

This is because of the lack of (1) time clinicians can spend with patients during consultation and (2) the information about all the technological possibilities [11-13]. Therefore, patients are often provided with a device without an option to make a choice for themselves or detailed consultation about both its proper use and the option that would fit them the most.

However, it is very important to learn from how different types of patients use a given technology to understand what does truly help them in their self-management, what increases their adherence, what are their preferences, or otherwise, what are the drawbacks and limitations that keep them from using the technology itself. A deeper understanding of a patient's needs and abilities with respect to the self-management can help us to both tailor a given device for a particular group of patients and assemble the set and types of devices that comply with a patient's needs the most.

Objectives

This study aims to analyze the way of using different combinations of technologies for diabetes self-management in 6 specific patients with type 1 diabetes mellitus (T1DM) and, based on such an analysis, to propose possible changes in such combinations that would improve patients' overall satisfaction and adherence to its use.

Methods

Aim

The study aimed to analyze the suitability of selected technical devices for diabetes control based on data obtained via the Diani telemedicine system, patients' subjective feelings and statements, their everyday life habits, and self-management of diabetes.

Inclusion Criteria

The inclusion criteria were adults with T1DM for a duration of at least 1 year who had used the Diani telemedicine system for at least 3 months; completed a minimum of 2 consultations with the doctor and the technology educator, that is, before and 3 months after the system use; and shared information about their daily regimen, self-management, and experiences with diabetes-related technologies so far during the consultations.

Study Sample

The study included 6 patients (3 men and 3 women with average age of 43 [SD 23] years) with T1DM for a duration of at least 1 year, using specific combination of devices and having an experience with the Diani telemedicine system for 3 months (n=3), 6 months (n=1), or 4 years (n=2) in different times for the last 4 years. All the participants were of Czech nationality.

Collected Data

The data obtained from the Diani telemedicine system included blood glucose values transferred from a connected glucometer and a continuous glucose monitor (CGM), step counts collected via an activity tracker in 1-min intervals, and carbohydrate intake (in grams) and insulin injections manually registered in a connected mobile app.

Telemedicine System

The Diani telemedicine system is being developed under the university project of the First Faculty of Medicine (Charles University in Prague) and the Faculty of Biomedical Engineering (Czech Technical University in Prague). The system consists of wearable technologies, namely an activity tracker, a blood glucose meter, a diabetes diary mobile app, a smartwatch, and a Web app into which all the data from the wearables are synchronized automatically. The blood glucose meter transfers measured glucose values into the diary mobile app via Bluetooth. The data from the activity tracker are synchronized via smartphone as well. Using the smartwatch, the user can not only track his/her last data registrations about blood glucose, carbohydrate intake, insulin dose, and physical activity (PA) but can also use the watch to make these registrations, which are then transferred to the mobile app via Bluetooth [14]. Occasionally, some of the patients may wear the CGM that enables them to transfer data to the Diani Web app (see Multimedia Appendix 1) either automatically (using the xDrip device, The Nightscout Project) or manually (uploading the raw data file through the Diani Web app) [15-18].

Patient Instructions

Before using the system, each of the patients was properly instructed by a technology educator on how to operate each of the system components, and they were free to decide which data and how frequently they want to enter the data into the diary. The patients could choose not to use any of the devices if they felt uncomfortable using them.

Before starting to use the system and during the monitoring phase, the patients took part in interviews with a doctor and the technology educator about their daily regimen, technology capabilities, life preferences, and similar topics. The technology educator was also tracking patterns of handling the devices while educating the patients on how to use them. During the phase in which the patients were using the system in their daily life, the educator was also monitoring their behavior of entering and collecting the data via the Diani Web app. These types of interventions represented the most important approaches to get relevant feedback about the usability of the system.

The study involving human participants was conducted in accordance with the Helsinki Declaration and has been approved by the ethics committee of the Motol University Hospital in Prague. Informed consent was signed and obtained from each of the patients included.

Outcomes

The outcomes included glycated hemoglobin (HbA_{1c}) obtained from the patient's records of his/her caregiver, the average number of data registrations, and the frequency of hypoglycemia.

Results

Data Analysis

A total of 6 patients who met the criteria for the intervention were analyzed, based upon the collected data and individual face-to-face consultation.

General description of each patient can be seen in Table 1. The results from data evaluation are shown in Tables 2 and 3.

Case Series

Each of the following 6 case series describes how a given patient was handling the system and its particular components based on his/her lifestyle, level of education, manners in diabetes management, personality type, and other factors. At the end of each case study, we then propose the best composition of devices for patients with similar personal needs.

Case Study 1

Patient Information

A 45-year-old woman was diagnosed with T1DM in 2013, and since then, she has been on multiple daily injection (MDI) insulin therapy. Besides her diabetes, she is not suffering from any other diseases or diabetes complications.

Daily Regimen and Self-Management

This patient performs PA such as cycling, workouts in a gym, and others for 2 to 4 hours daily. Being a teacher with a stable daily schedule, she can include regular PA into her daily activities.

To keep her blood glucose within the target range and maintain a slim figure, she maintains a lower carbohydrate diet (approximately 100 g/day) and healthy food intake, besides the PA performance. She is able to maintain her blood glucose mostly within the target range, with a very rare occurrence of clinically important hypoglycemia [19] (see Table 3). The only problem she has is that of higher blood glucose levels at night probably caused by the later effect of fatty cheese and nuts she is used to eating later in the evening.

Table 1. Demographic and baseline characteristics.

Patient #	Gender	Age (years)	Type 1 diabetes mellitus duration (years)	Current therapy regimen	CGM[a] use experience for the last 1 year (patients' subjective evaluation)	Duration of Diani system use
1	Female	45	5	MDI[b]	Few times a year	3 months
2	Female	29	13	CSII[c]	Full time	6 months
3	Female	24	19	CSII	Full time	4 years
4	Male	27	26	CSII	Few times a year	4 years
5	Male	45	4	MDI	None	3 months
6	Male	87	36	MDI	None	3 months

[a]CGM: continuous glucose monitor.

[b]MDI: multiple daily injection.

[c]CSII: continuous subcutaneous insulin infusion.

Table 2. Data obtained from 3-month period of using the Diani system.

Patient #	Number of days with continuous glucose monitor	Average number of self-measured blood glucose per day[a]	Average number of carbohydrate registrations per day[b]	Average number of insulin registrations per day[b]	Average number of physical activity registrations per day[b]	Average number of step counts per day[a]
1	18	4.4	5.5	4.1	1.47	14,367
2	72	5.9	3.6	3.8	0.34	9309
3	30	6.6	1.4	1.6	0.18	10,888
4	6	4.3	2.0	5.1	0.60	10,350
5	0	2.5	0	2.9	0.03	4299
6	0	3.2	0.6	0.4	0.05	__[c]

[a]Measured values automatically transferred to a connected mobile app.

[b]Data manually registered to the diabetes diary mobile app.

[c]Missing data.

Table 3. Glycated hemoglobin (HbA_{1c}) values and frequency of hypoglycemia.

Patient #	HbA_{1c} before using the system (mmol/mol)	HbA_{1c} after 3 months' experience (mmol/mol)	HbA_{1c} after 6 months' experience (mmol/mol)	HbA_{1c} after 4 years' experience (mmol/mol)	Average number of self-measured hypoglycemia <3.9 mmol/L per week during the first 3-month period	Average number of self-measured hypoglycemia <3.0 mmol/L per week during the first 3-month period
1	51	48	—[a]	—	2.6	0.08
2	65	54	47	—	4.8	0.38
3	66	63	69	47	5.7	1.03
4	78	62	69	54	4.4	1.91
5	63	54	—	—	0.6	0.07
6	67	71	—	—	1.3	0.78

[a]Not applicable.

Patient's Attitude to Technology

Since the last year, she has been using 3 sensors for CGM monitoring, but besides that she has relied on self-measured blood glucose (SMBG) alone. Considering her higher educational level and age, she is familiar with using a smartphone and wearable technologies and has no problem to intuitively and quickly learn how to operate a new mobile app or a device for self-management. She has no problems wearing an activity tracker on a full-time basis (during the day and at night). She is also conscientious with respect to registering data into the diabetes diary app (see Table 2) and regularly reviews her data via both mobile and Web apps. She is used to discussing her diabetes difficulties with her clinician, using collected data. Many of these features can be seen on a 1-day graph (Figure 1) representing her regular day.

However, what troubles her are devices that are uncomfortable to wear when performing PA (for this reason, she was not willing to use the smartwatch) or treatment-related devices that are visible to other people. She tends to conceal her disease from the people around her very carefully and makes any treatment actions as discreetly as possible. Therefore, she fully refuses to use an insulin pump and prefers to inject the insulin with a pen in private areas (despite the usefulness of flexible dosing during PA that the insulin pump could enable her). She is willing to wear the CGM sensor only in places that are not visible behind the clothes from the outside.

The biggest benefit she gained from the telemedicine system after she started to use it was that she realized her blood glucose was affected by certain foods and drinks which she had not been covering with insulin dose. Another new information was a postmeal spike after a larger portion of carbohydrate intake, which was connected to a too short time span between the insulin dose and carbohydrate intake. In the long run, she can benefit from controlling her stable total daily dose of carbohydrates and total daily step count, in addition to the blood glucose measurements. By tracking her daily step counts and intensity of PA for a specific sport, she was able to compare her activity level with other friends. The knowledge that there had been nobody who would make a better performance made her feel even more motivated to continue in such regimen. Wearing a CGM helped her mainly to control her blood glucose during PA and discover the postmeal spikes. The receiver clipped on her pants did not represent any obstacle for her.

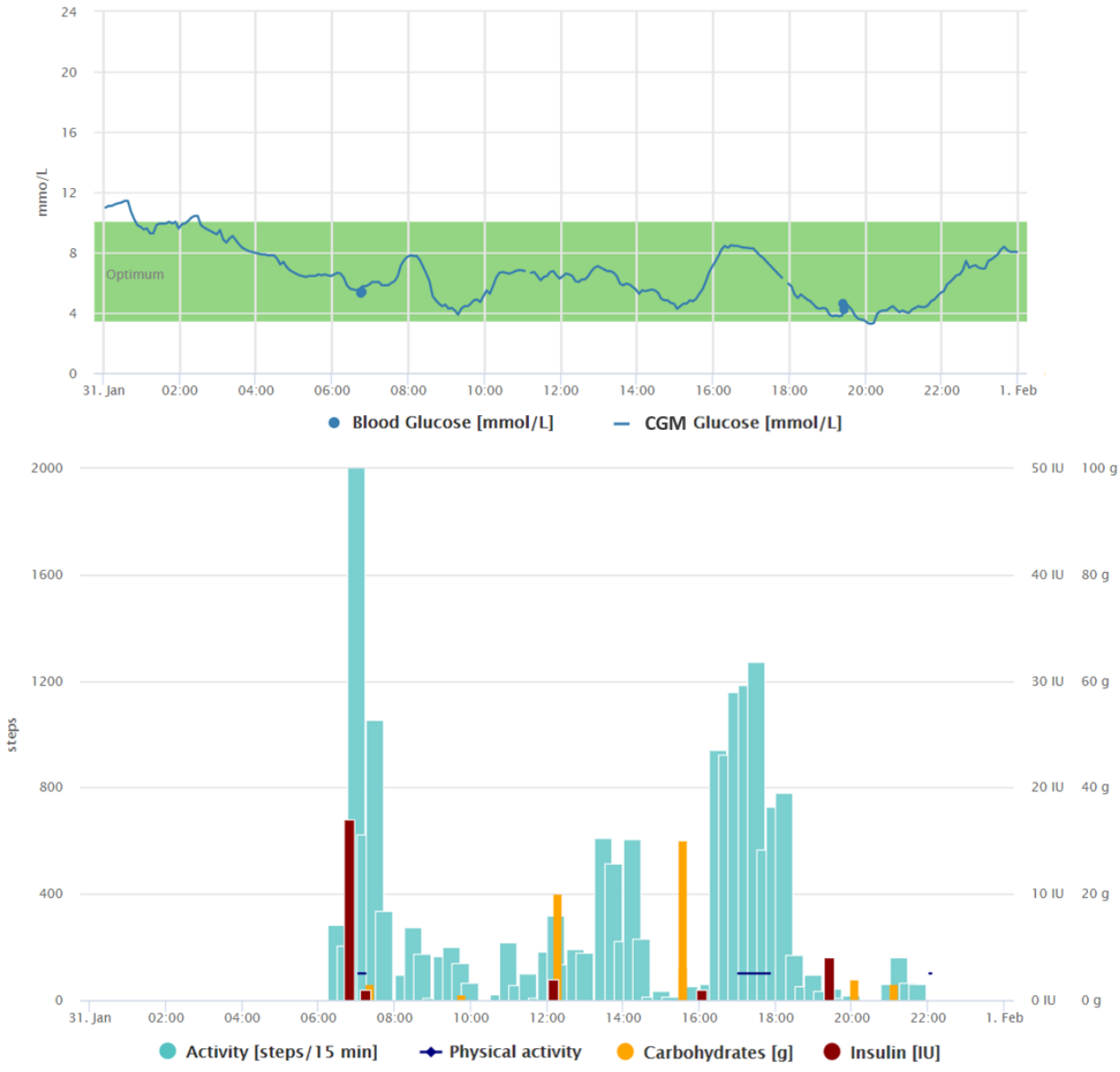
Suggestions for the Optimal Combination of Devices

The ideal tailored system for this type of patient could be a combination of devices that would transfer all the data into a mobile app or display the values on a screen of devices, which would not represent a stigma for them or be visible to the people around them. A thin wristband sensor for tracking activity and a sensor for glucose control would certainly be a good choice. No frequent notifications or alarms from the data analysis would probably be necessary, as this patient is able to review the data regularly. The alarms coming from the CGM system would need to be in vibration mode only to comply with the discretion requirements. Another option could be switching for a flash glucose monitoring, which would be a secret form of data capturing in case the patient would not mind not receiving alarms at night and could wear it on alternative places of the body. The implantable sensor could also work if being implanted in places, which the patient could cover with summer clothes.

Regarding the insulin therapy, insulin pen treatment still seems to be an option complying with the patient's requirements because of her rejection of wearing an insulin pump. However, improvement in this area could be at least a pen enabling to transfer data to a mobile app via Bluetooth. As the patient is capable of operating digital technologies, we could also try to shift her to a patch pump therapy, if that would be acceptable for her to wear, rather than the traditional pumps with tubing. She could then effectively reduce nighttime highs using a squared bolus or temporary basal rate settings for the high-fat snacks intake she has a difficulty to control.

A personal account for a Web app connected to a clinician's account for automatic data synchronization would be a matter of course.

Figure 1. Graphical interpretation of 1-day data registrations of the patient from case study 1, visualized by the Diani Web app. In the picture, we can observe patterns, such as the low-carbohydrate intake, high intensity of physical activity, and higher glucose values during the night. CGM: continuous glucose monitoring.



Average blood glucose per day [mmol/L]		Total carbohydrates per day [g]		Total insulin per day [IU]		Activity [steps/day]	
1/31/2018	4.9	1/31/2018	67.0	1/31/2018	7.0	1/31/2018	17811

Case Study 2

Patient Information

A 29-year-old woman has T1DM since 2005, and she has been on continuous subcutaneous insulin infusion (CSII) regimen since 2013. Besides her diabetes, she is not suffering from other diseases or diabetes complications. She is preparing for pregnancy.

Daily Regimen and Self-Management

This patient is specific in her motivation to improve her HbA_{1c} because she is planning for pregnancy. Being a high school teacher, her daily program is stable and regular. Some unexpected changes in her schedule or emergencies can, however, occur occasionally. These events mostly influence her ability to eat regularly and on time. She is used to maintaining a healthy food intake, but to a certain extent, she has to adapt to the menus at the school canteen during lunchtimes.

She likes walking a lot and she goes for a long walk every day, if the time allows her to do so. She is also educated in flexible dosing of insulin and tries to make changes in her insulin dosing herself based upon the collected data. From time to time, she struggles with nighttime hypoglycemia, mostly induced by evening walks.

Patient's Attitude to Technology

Regarding her technical abilities, she can learn how to use any device easily if she gets sufficient instructions and can turn to technical support or a more advanced person when she gets into trouble, for example, with Bluetooth connection or unpaired devices. She is a smartphone user, so any kind of mobile apps do not pose any obstacle for her to install and use.

She is not concerned about how many devices she has to wear or whether they are visible to the people around her. The accuracy of blood glucose measuring devices is more important to her than the design and size of the technology.

She has been on the CGM system full time since November 2017. At the same time, she started to use all the other equipment within the Diani system. She also took advantage of sharing CGM data with her T1DM friend as another motivation to achieve better blood glucose results while being observed by another person.

By wearing the activity tracker, she has been motivated to walk more and compete with friends who track their daily steps as well.

Regarding her manual registrations, she has entered her insulin doses and carbohydrate information into the diary almost daily, but some lack of data within a day or several days with a pause of manual registrations occurs. She reviewed her historical data more frequently at the beginning to identify problems that caused her blood glucose fluctuations. Once she stabilized her glycemia, she started reviewing the data only a few days before the visit to her diabetologist. She always prepares for the visit and downloads the data for the doctor.

The trend indicating her blood glucose improvement and the way she collects the data can be seen in Figures 2 and 3. Compared with Figure 2, we can see that the regular data registrations are reduced after the average blood glucose has stabilized.

Suggestions for the Optimal Combination of Devices

Ideal tailored system for this type of patient would certainly be an insulin pump in combination with a CGM system that would enable her to transfer data to mobile and Web apps. As we know she experiences nighttime hypoglycemia, the flash glucose monitoring would not be beneficial for her, despite the ability to use it in combination with a smartphone. Knowing her strong focus on device accuracy, the most accurate CGM device enabled with alarm and data transfer to a mobile app might be a good option for her blood glucose monitoring. Considering her motivation while sharing data, a device having such a function included would represent another preference point. Regarding the type of a pump, she is not an exacting user and uses its basic settings and functions (normal boluses, temporal basal reduction, and 1 basal profile). The most convenient option would ideally be a pump that can receive data from the CGM device, in addition to the CGM data synchronization with a smartphone. This would ensure both the ability of data sharing and assurance of data transfer to the pump in case the smartphone has weak signal or its battery level is low. If no such device is available to her, she could choose a pump that is at least comfortable to wear, easy to use, enables to export data for a doctor, and has good technical support.

Case Study 3

Patient Information

A 24-year-old woman was diagnosed with T1DM in 1999, and she started with CSII therapy in 2002. She suffers from knee pain because of patellofemoral dysplasia, which she was diagnosed with in 2017. Besides that, she is not suffering from other diseases or diabetes complications.

Daily Regimen and Self-Management

This patient is a university student and, in addition, has a part-time job. Therefore, her daily program is changing frequently, and she is often busy with work until late evening.

As she struggles with a higher insulin resistance and complications with her knees, she tries to reduce her weight by decreasing her total daily carbohydrate intake and incorporating different types of PAs in her daily program. From time to time, she makes an exception in her regular dietary plan and takes a high-carbohydrate food because she is able to anticipate the majority of her postmeal spikes using her knowledge from the CGM data. She is very well educated and able to keep her blood glucose in a tight target range, mostly thanks to her regular attendance of educational courses and CGM monitoring throughout the whole year.

Patient's Attitude to Technology

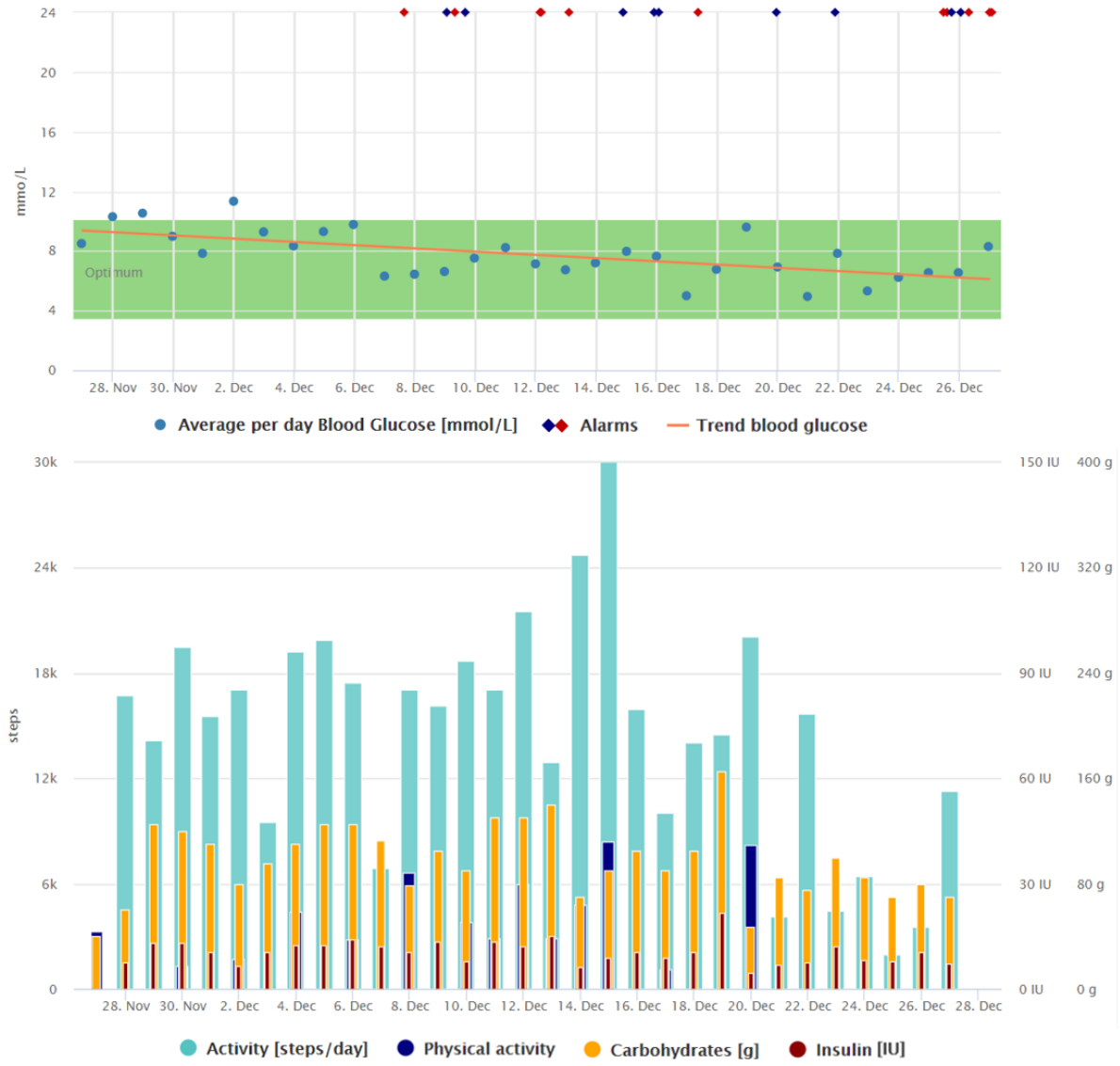
This patient is very interested in new wearable technology not only for diabetes treatment. Wearing any kind of mobile technology, even visible medical devices, is not perceived as a stigma by her.

Being connected fulltime through her CGM device since 2017 and having the motivation to undergo educational courses, she has learned a lot about how to make insulin adjustments based upon the arrow trends and actual glucose readings on her CGM system. Therefore, based on the trends, she gives herself correction boluses or suspends the basal rate often, rather than exactly counting carbohydrates in foods and reacting on upcoming situations too much in advance (see Figure 4).

She is able to register data into the diary properly as far as she has a good reason for doing so (eg, her blood glucose is suddenly, for unknown reasons, out of her control) and has a sufficient motivation (such as being pushed by her diabetes friends).

To keep her blood glucose in a very tight target range, she sets the hypo- and hyperglycemia ranges close to each other. This naturally results in more frequent alarms coming out of the CGM receiver, but it does not disturb her daily activities. However, this becomes a problem during the nights when she often does not hear the alarm and, thus, often does not wake up because of unstable glycemia values. To ensure that she wakes up once the alarm goes off, she started to change the tones in her new receiver settings every week once she got the version enabling that.

Figure 2. Graphical interpretation of 1-month data registrations of the patient from the case study 2, visualized by the Diani Web app. In the picture, we can observe everyday data registrations, high daily step counts, and decreasing trend of average daily blood glucose.



Although she is keen on trying new diabetes-related or fitness devices, she often comes up against technical issues, especially with her mobile phone. She uses many social media apps and games, listens to music, and uses a navigation app when driving a car, so she always needs an extra secure digital card and a phone that enables her to always be *online*. Lack of signal to connected devices is also a frequent issue she faces. Another issue is the fact that she lost some devices in the past, which were too tiny or not well fixed to her body, or the devices simply stopped working because of unknown reasons. Besides that, she is able to figure out most of the technical issues she encounters.

Suggestions for the Optimal Combination of Devices

Knowing all this information, this patient would certainly benefit from CGM technology and rely on its real-time values. Insulin pump is also the most convenient tool for her. However, as we know, losing the Bluetooth signal on her phone is a frequent issue. Therefore, she might benefit a lot from a pump that displays blood glucose values directly on the pump. An even better option would be a combination of displaying the data both on the pump and on the phone (similar to the previous case no. 2), as that would ensure the ability to arbitrarily change the alarm tone on her phone, in addition to receiving the 1-tone alarm from the pump. In connection to her ability to do her correction boluses based upon the glucose values and trends displayed on the pump, she could benefit from using a device that would automatically suspend the dosing before her glucose is predicted to reach a low level. It could help her to reduce hypoglycemia incidents (see Table 2), especially when overdone correction boluses occur. Considering a hybrid closed-loop system, if available in patient's country, this patient might have trouble handling its automatic delivery function because she might tend to manually interrupt its action mostly on high glucose levels to assume control of the insulin corrections and make the action faster.

Figure 3. Graphical interpretation of 1-month data registrations of the patient from case study 2, visualized by the Diani Web app.

Case Study 4

Patient Information

A 27-year-old man has T1DM since 1992, and he has been on CSII regimen since 2002. He started using the Diani system in July 2014, starting with the HbA_{1c} of 78 mmol/mol. Other than a laser operation he underwent because of early manifestations of retinopathy, he is not suffering from other diseases or diabetes complications.

Daily Regimen and Self-Management

Working in an administration office, this patient has a mostly regular working schedule. In his free time, he is physically very active (performing regular PA, such as floorball and volleyball). He is also very creative and likes gaming. He is a very competitive person when it comes to any games or sport matches.

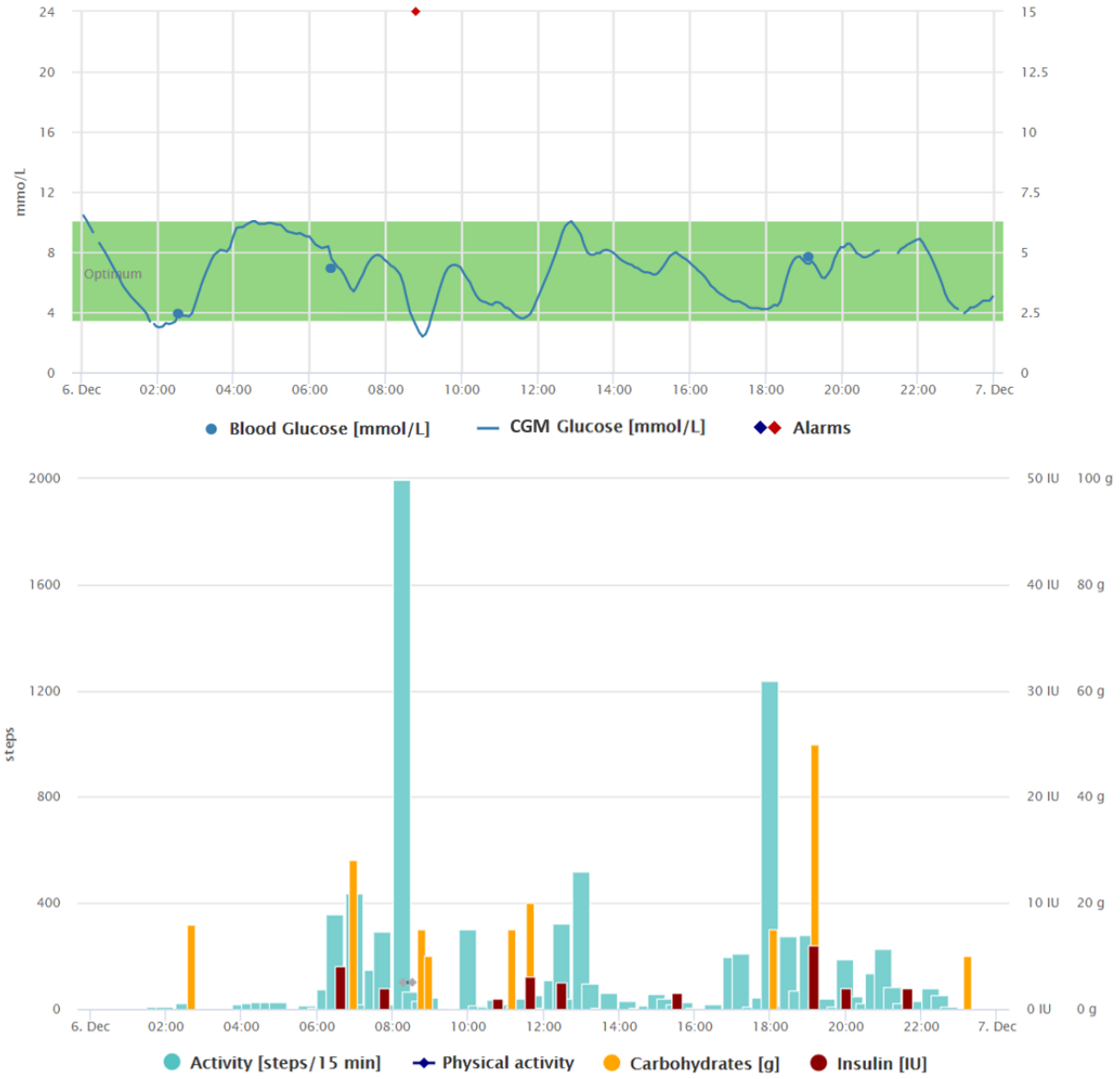
Regarding his eating habits, he often underestimates the timing of insulin injection for meals and sometime takes boluses too late. He also loves beer and is on a bit higher carbohydrate diet, which causes frequent postmeal spikes.

He tries to check his blood glucose regularly, but there are some days with only 1 or no measurements.

Patient's Attitude to Technology

This patient gets the sensor for CGM few times a year, but most of the time, he relies on SMBG alone. He is very competent technically and is able to learn, even intuitively, how to operate new mobile apps or wearables. He is also able to solve common problems with loss of connection and other minor technical complications on his own.

Figure 4. Graphical interpretation of 1-day data registrations of the patient from case study 3, visualized by the Diani Web app. In the picture, we can notice variable activities during the day composed of 1 high-intensity physical activity at around 8 am and then frequent changes between sitting and walking patterns. Regarding food intake, there are very different amounts of carbohydrates throughout the day. Patient´s reaction on blood glucose level made by correction boluses is another typical pattern. CGM: continuous glucose monitoring.



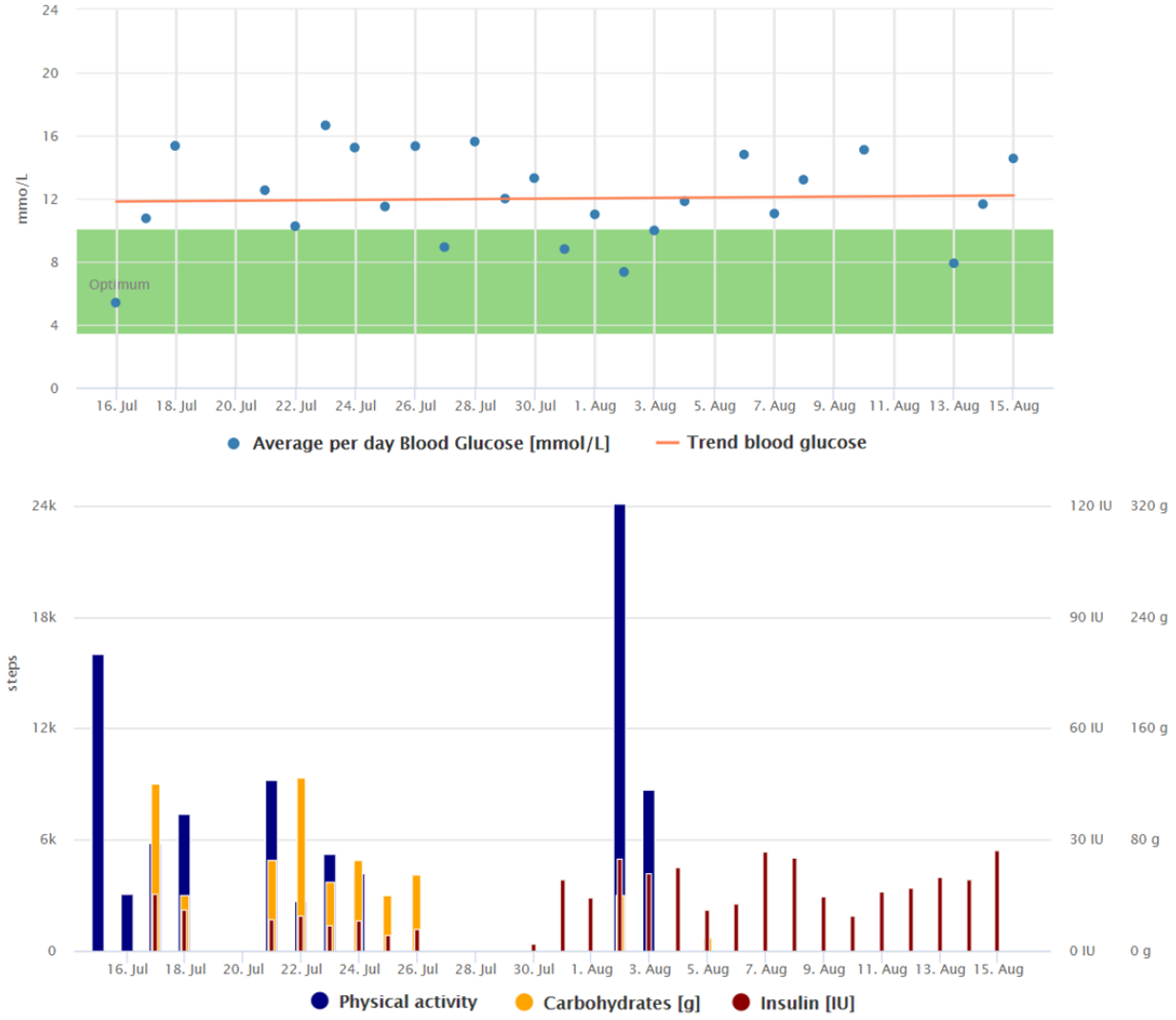
Considering his competitiveness, he is using an activity tracker all the time to set goals and compete with his friends in daily/weekly step counts.

However, it is difficult for him to register data into the diary manually. He is willing to enter more data when he gets motivation from the outside that, in addition, is often updated by some new stimulus. It can be a new tailored version of the app or another app that has a game basis, but it can also be a new device itself (a new *toy* he can play with). With respect to the long-term motivation, the best chance for him to better self-manage his disease is competing with his diabetic friends.

Figures 5 and 6 show the difference between the phase when he was not wearing the activity tracker and the period after he got the new device.

Although he uses just basic functions of his insulin pump, he has no problem to operate any kind of device and could benefit from more advanced functions (eg, square wave or dual wave bolus, bolus wizard) in case he got proper education in diabetes management.

Figure 5. Graphical interpretation of 1-month data registrations of the patient from the case study 4, visualized by the Diani Web app. In the picture, we can observe irregular data registrations and high blood glucose variability.



Suggestions for the Optimal Combination of Devices

Considering all these aspects, patients similar to this one might try to use, for example, a mobile app that is gamesome, includes functions for setting challenges, and enables users to take advantage of coaching services through a certified diabetes educator to increase the level of education in self-management issues. This patient might also be a good candidate for a hybrid closed-loop system, as it could reduce the burden of frequent blood glucose control and reduce the postmeal spikes caused by his eating habits and incorrect bolusing time.

If the hybrid closed-loop system is not accessible, we could consider a pump that suspends before low (it means the insulin delivery is stopped when low blood glucose limit is predicted to be reached within certain time). This could, in addition to other benefits, reduce hypoglycemia incidents, especially during PA. However, if the chosen pump is susceptible to falls and hits, the silicon case should be in place to protect the device while performing competitive sports.

Case Study 5

Patient Information

A 45-year-old man was diagnosed with T1DM in 2014. He has been on an MDI regimen right from the onset of the disease. Apart from diabetes and arterial hypertension, he is not suffering from other diseases or diabetes complications.

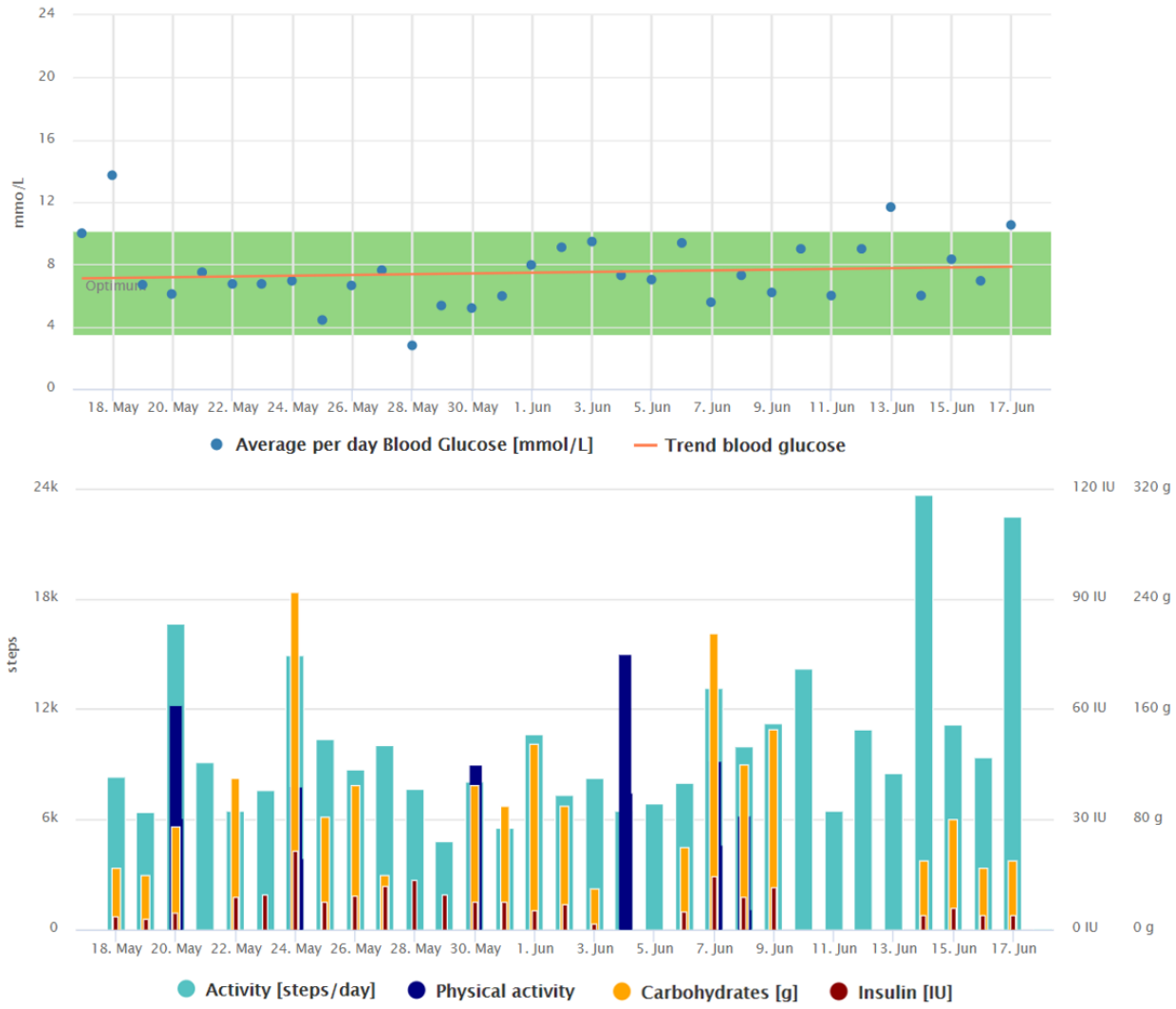
Daily Regimen and Self-Management

The patient has an irregular working regimen because of his frequent nighttime shifts. However, he performs PAs (walking, cycling, and working out) regularly and more than twice a week. He is used to complying with a fixed daily insulin dosing and tries to do proper carbohydrate counting using the nutrition tables on food packages.

Patient's Attitude to Technology

Before starting to use the Diani system, this patient had never used any mobile or Web app for diabetes self-management. Therefore, the only data he could check were the values displayed on his glucometer, which he had never reviewed before.

Figure 6. Graphical interpretation of 1-month data registrations of the patient from case study 4 after the patient got the activity tracker. The frequency of data registrations has increased, and the average blood glucose has decreased significantly compared with the average blood glucose trend in Figure 5.



However, he had no problem with handling the smartphone and learning how to work with the mobile app and make data registration. He only had some minor issues when connecting the smartwatch to his phone at the very beginning, which he was able to manage on its own quickly once he got the proper instructions for the device pairing process.

The diabetes diary mobile app was the most beneficial tool for him as it was very easy to operate, the data were displayed in a well-arranged way, and the app was in his native language. Reviewing his data, he was motivated to achieve better results (changes in average blood glucose trends can be observed when comparing Figures 7 and 8). He was very happy about the automatic transfer of data from the glucometer to his phone. Insulin doses were, with the exception of a few PA comments, the only data manually registered by him (see Figures 7 and 8). On the basis of the last consultation, this patient feels much better both physically and mentally, and his quality of life has improved appreciably. He would also be willing to pay a monthly fee for the telemedicine service.

Suggestions for the Optimal Combination of Devices

As we can see, the patient was satisfied with the set of devices he was equipped with when using the telemedicine system. As an improvement, we could suggest to him to use an insulin pen that enables automatic transfer of data to the same mobile app into which the data from his glucometer are sent. Potentially, we could discuss how acceptable it would be for him to switch to an insulin pump that would be connected to a blood glucose meter and transfer the measured data to a user-friendly mobile app. The app should also have a bolus calculator and connected food database included to help him to better manage the carbohydrate counting.

Figure 7. Graphical interpretation of 1-month data registrations of the patient from case study 5, visualized by the Diani Web app. We can observe the decreasing trend of average daily blood glucose during the first month of using the telemedicine system.

Case Study 6

Patient Information

An 87-year-old man was diagnosed with T1DM in 1982, and he is still on an MDI regimen and SMBG measurement only. He suffers from diabetic peripheral polyneuropathy because of which his hands shake slightly, and he complains of leg pains, for which he takes the prescribed pills. He also suffers from diabetic retinopathy, proteinuria, corrected arterial hypertension, and hypercholesterolemia.

Daily Regimen and Self-Management

This patient is retired and as such has a very regular daily regimen and lots of free time he can spend on his hobbies and on the diabetes self-management. He is extremely motivated to learn new things and still has lots of energy to try or read about new methods in diabetes care. Thanks to his caring wife and his own carefulness and sense of precision, he has been keeping his paper-based diabetes records since the onset of his disease. He has read most of the diabetes books available in his native language and made notes about any unusual information that could help him to better self-manage the disease. He also performs daily PA (everyday walking, gardening, and working in his workshop). He was not used to checking his blood glucose regularly before he started to use the telemedicine system (1.7 times per day on average, calculated from 3-month records in his glucometer measured before he started to use the telemedicine system).

Figure 8. Graphical interpretation of 1-month data registrations of the patient from case study 5 after 2.5 months of using the telemedicine system. We can see the data registrations are more regular than those in Figure 7, and the average blood glucose has decreased and stabilized.

Patient's Attitude to Technology

He has already tried multiple types of activity trackers in the past. The device motivates him to maintain regular PA (walking or gardening). He is also able to use a personal computer to a certain extent, that is, for surfing on the internet, sending emails, and using Skype.

For him, the biggest problem he faced with the telemedicine system was that he had never used a smartphone before. Therefore, he first got the phone only to learn how to switch it on and off and how to open the diabetes diary app and use it. After a month, he came back to get the rest of the devices. As he only had a cable internet connection at home, he also got a subscriber identity module (SIM) card with prepaid data with the phone. Despite his efforts to handle the phone, he often had problems with operating, charging the devices, and losing the internet connection.

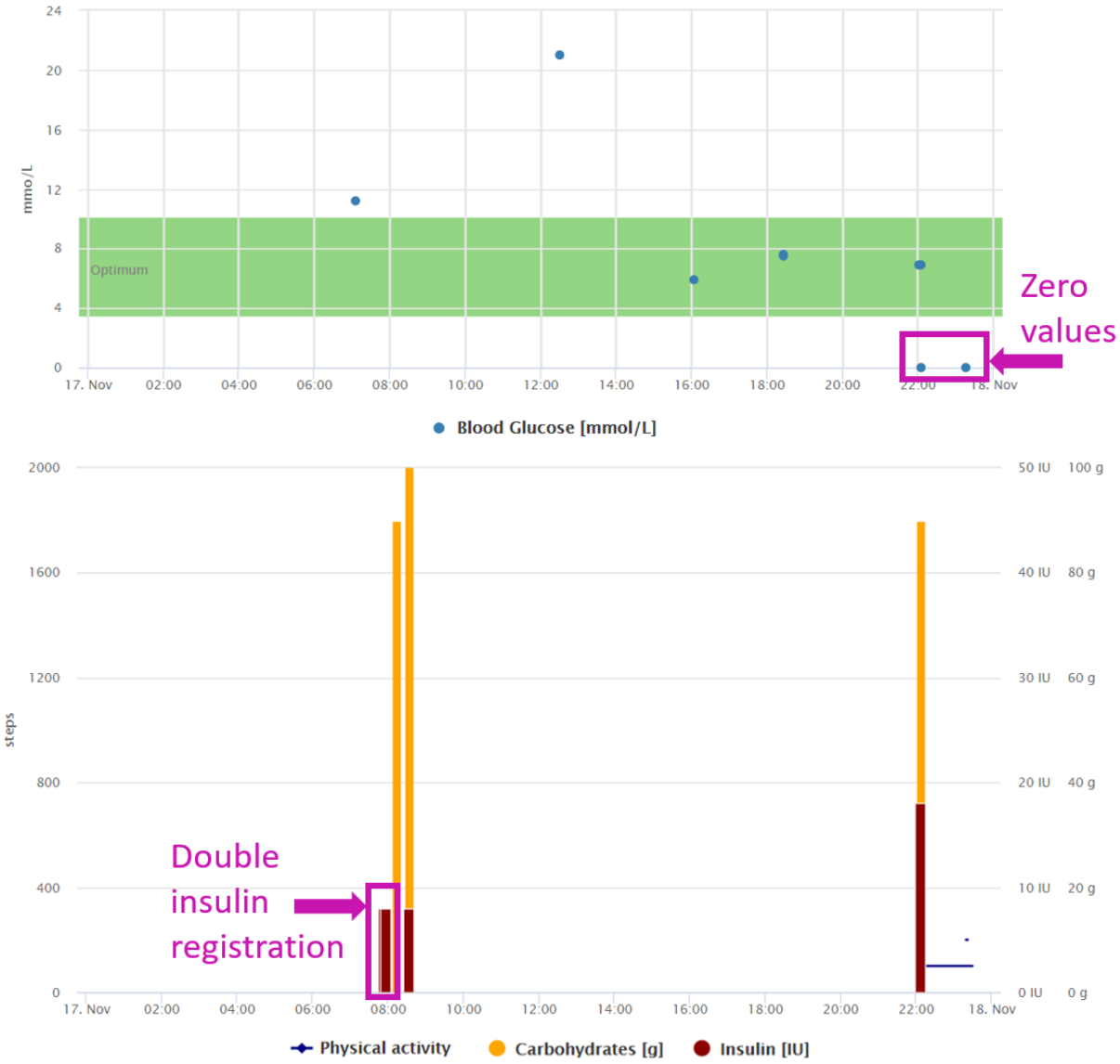
As he suffered from neuropathy, it was also difficult for him to handle the touchscreen because his hands were shaking, and he often clicked on more than 1 button at the same time or on the wrong one. This led to a wrong data entry (see Figure 9) or frequent calls to the technical support when getting to a page he did not know how to get out of. Thus, he spent more time dealing with technical issues than using the system effectively.

Suggestion for the Optimal Combination of Devices

In summary, besides the activity tracker that is simple to use even for an elderly person, the rest of the system is not a suitable solution for such a patient.

Another possible help could be occasional phone call checkups made by some diabetes educator to increase his adherence to regularly checking his blood glucose or connection to a remote assistance service that would track and control the patient via a smart device (SIM card and global system for mobile communication module based) and react in case of emergency.

Figure 9. Graphical interpretation of 1-day data registrations of the patient from case study 6. We can see some accidentally duplicated or zero values because of the patient's inability to operate the mobile app.



Discussion

Principal Findings

It is obvious, based on the case studies presented here, that there is no *one-size-fits-all* diabetes self-management tool, which would fully satisfy the needs of each particular patient.

To be able to give proper advice about the type of device that would be the most suitable for a given patient, specific information about the person is required. Such information includes, in particular, the patient's personality, his/her technical skills, daily regimen, his/her attitude to diabetes, obstacles in diabetes management, preferences in data visualization and devices' functionalities, willingness to learn new things, and motivational means that could help him/her use any system effectively and on a long-term basis.

From the case series, we could learn that a physically very active patient, who tends to conceal the disease from public, could only benefit from a technology that would not represent an obstacle when performing PA and would not be visible from the outside. On the contrary, there are patients who do not have any problems wearing any kind of devices and of any size, as far as the system is reliable and sufficiently accurate.

Although some patients would benefit from automatic functions of the most advanced pumps that suspend the insulin delivery, or work in hybrid mode, enabling them to reduce their hypoglycemia incidents and correcting their *mistakes* in bolusing, there are other patients for whom this system could be rather burdensome. These are patients who need to have their dosing under control, do not trust the system, and do not have the will to wait until the system corrects their blood glucose spikes.

Technical abilities, educational level, and age can also play a dominant role in technology acceptance and its use. Obviously, there are certain limits indicating that a given patient would not be able to operate some systems, even if proper education and technical support were provided.

Motivational tool embedded into technology is more related to a patient's personality. It can be, for example, the ability to share data with other patients/users or compete with friends who constantly push a patient to achieve good results, a function that is gamesome, or even just the ability to review data from the given device that proves to the patient that he or she is doing well or has achieved exceptional results.

It is also very effective to observe how patients handle a given technology in the present and after they get a new one and to check the data they collect regularly to learn more about their daily regimen, self-management, and potential changes in data entry and frequency of data registration over the long term.

With respect to the effect of the telemedicine system on patients' self-management and blood glucose value improvements, we can see a reduction in HbA_{1c} values in all but 1 of the 6 patients. However, because the patients were using the system in different periods of time, and because there could also be other factors that were not tracked but could have an impact on HbA_{1c} reduction, we cannot attribute this effect to our system only.

Conclusions

We believe this paper can provide relevant guidance on how to help particular patients to choose the best technology that is likely to suit them the most based on specific patient information we are able to obtain.

The input information we get about a patient represents one of the sources clinicians or educators can use to help a given patient to find the optimal combination of devices for diabetes self-management. Furthermore, clinicians or educators should be aware of available technologies a given patient can choose from. In addition, to achieve an effective use of chosen devices, there is a substantial need for proper education of the patients before they start using them.

Furthermore, with the rapid development of new and more advanced technological solutions (ie, hybrid and closed-loop systems), educators specialized in technical-related areas of diabetes management are needed to help with such customization and technical support of patients.

Acknowledgments

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Authors' Contributions

AH, MV, and JM were involved in technical education and support, patients' interviews, data collection, and monitoring. JB contributed to the patient interviews and clinical supervision. All authors contributed to the data analysis and its interpretation and to the editing of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Screenshots of the Diani Web application.

[PDF File (Adobe PDF File), 386KB - mhealth_v7i7e11527_app1.pdf]

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Abbreviations

CGM: continuous glucose monitor
CSII: continuous subcutaneous insulin infusion
HbA_{1c}: glycated hemoglobin
MDI: multiple daily injection
PA: physical activity
SIM: subscriber identity module
SMBG: self-measured blood glucose
T1DM: type 1 diabetes mellitus

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Short Paper

Real-World Use of Do-It-Yourself Artificial Pancreas Systems in Children and Adolescents With Type 1 Diabetes: Online Survey and Analysis of Self-Reported Clinical Outcomes

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Abstract

Background: Patient-driven initiatives have made uptake of Do-it-Yourself Artificial Pancreas Systems (DIYAPS) increasingly popular among people with diabetes of all ages. Observational studies have shown improvements in glycemic control and quality of life among adults with diabetes. However, there is a lack of research examining outcomes of children and adolescents with DIYAPS in everyday life and their social context.

Objective: This survey assesses the self-reported clinical outcomes of a pediatric population using DIYAPS in the real world.

Methods: An online survey was distributed to caregivers to assess the hemoglobin A_{1c} levels and time in range (TIR) before and after DIYAPS initiation and problems during DIYAPS use.

Results: A total of 209 caregivers of children from 21 countries responded to the survey. Of the children, 47.4% were female, with a median age of 10 years, and 99.4% had type 1 diabetes, with a median duration of 4.3 years (SD 3.9). The median duration of DIYAPS use was 7.5 (SD 10.0) months. Clinical outcomes improved significantly, including the hemoglobin A_{1c} levels (from 6.91% [SD 0.88%] to 6.27% [SD 0.67]; P<.001) and TIR (from 64.2% [SD 15.94] to 80.68% [SD 9.26]; P<.001).

Conclusions: Improved glycemic outcomes were found across all pediatric age groups, including adolescents and very young children. These findings are in line with clinical trial results from commercially developed closed-loop systems.

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KEYWORDS

artificial pancreas; do it yourself; open source; mobile health; diabetes; type 1 diabetes; pediatric diabetes; closed loop; automated insulin delivery

Introduction

Over 30 years ago, the Diabetes Control and Complications Trial showed benefits of intensive diabetes management in delaying the onset and reducing the severity of diabetes-related complications [1]. People diagnosed at a young age are particularly at risk for developing long-term complications and comorbidities during childhood and later throughout life. Owing to this, therapeutic guidelines recommend tight glycemic control, with a target hemoglobin A_{1c} (HbA_{1c}) level<7.0% (53 mmol/mol) for all people with diabetes [2]. For children, adolescents, and young adults, guidelines even recommend the lowest achievable HbA_{1c} without undue exposure to severe hypoglycemia, balanced with quality of life and burden of care [3]. Today, despite significant advances in therapy and technological developments, only 17% of all children and adolescents with diabetes achieve an HbA_{1c} level<7.5% (58 mmol/mol) [4].

Multiple clinical trials have shown that closed-loop insulin delivery systems (also known as automated insulin delivery systems or "artificial pancreas") designed for commercial use are safe and effective in reducing hyper- and hypoglycemia in people of all age groups with diabetes, including adolescents and children [5-9]. Closed-loop systems are characterized by automated insulin delivery in response to the user's glucose level. Although commercial systems are under development and some have recently become available in a limited number of countries, they are not universally available, accessible, or affordable. Behind the hashtag #WeAreNotWaiting, a community of people with diabetes and their families have created new tools and systems, in addition to the existing, already approved medical devices, and shared them via open source platforms in order to help others with diabetes better utilize their devices and data. One of the most significant innovations to emerge through this movement is the Do-it-Yourself Artificial Pancreas System (DIYAPS). In DIYAPS, commercially available and approved medical devices such as insulin pumps and continuous glucose monitoring sensors are connected and remotely controlled by systems using open-source algorithms to automate insulin delivery. While these systems are cocreated by the DIYAPS community, each user has to build his/her own system and use it at his/her own risk. This includes children and adolescents whose caregivers build and maintain these systems on their behalf.

Initial observational studies have shown significant improvements in glycemic control, quality of life, and sleep quality in adult DIYAPS users [10-12]. A Czech pilot study was the first to report findings in a pediatric population and showed that AndroidAPS (an Android-based DIYAPS) was a safe and feasible alternative to a commercially available system, with predictive low glucose suspension during a winter sports camp [13]. There remains, however, a lack of research examining outcomes of children and adolescents with DIYAPS in everyday life and their social context. This survey assesses the self-reported clinical outcomes of this specific user group.

Methods

An online survey was distributed to caregivers using DIYAPS through the Facebook groups "Looped" (>11,500 members as of May 2019) and "AndroidAPS users" (>2800 members as of May 2019), other regional subgroups on Facebook, and Twitter. In this context, a caregiver was either a family member or another person who regularly looked after the child or adolescent with diabetes. Demographics and socioeconomic status of the study population were assessed. Participants were also asked for their child's last three HbA_{1c} measurements and mean time in range (TIR; sensor glucose level between 70 mg/dL or 4.0 mmol/L and 180 mg/dL or 10.0 mmol/L) before and after DIYAPS commencement. In an open-ended question, we asked respondents if they experienced difficulties in making the transition to DIYAPS.

The survey was designed by an interdisciplinary team of medical doctors, social scientists, public health researchers, and patient innovators. Participants were able to choose between two languages (English and German). Data were collected, managed, and analyzed using the secure REDCap electronic data capture tools hosted at Charité - Universitaetsmedizin Berlin [14]. Arithmetic mean, SD, and two-tailed heteroscedastic *t* test were used to perform the statistical analysis. The survey was approved by the Charité ethics committee (EA2/140/18).

Results

Overall, 209 participants from 21 countries (74.3% from Europe, 12.0% from North America, 6.9% from Asia, and 6.9% from Australia) responded to the survey (Table 1). Of the total, 47.4% children were female, with a median age of 10 years (range: 3-20 years), and 99.4% had type 1 diabetes. The median duration of diabetes was 4.3 (SD 3.9) years, and various types of DIYAPS (AndroidAPS, 48.0%; OpenAPS, 28.4%; Loop, 28.4%; other, 3.4%; and several systems over time, 7.5%) were used. The group had used these systems for a median of 7.5 (SD 10.0) months. Analysis of caregivers' socioeconomic status indicated that the cohort was evenly distributed across a range of income groups. The responding caregivers' employment rate was 91.4%, with 58.4% working full-time and 31.8% working part-time. Analysis of the education level showed that 65.2% had an academic or professional degree.

Table 1. Demographic data of children and adolescents using Do-it-Yourself Artificial Pancreas Systems, who participated in this survey.

Demographic	n (%)
Child's gender	
Female	83 (47.4)
Male	92 (52.6)
Child's age (years)	
3	6 (3.4)
4	11 (6.3)
5	14 (8.0)
6	14 (8.0)
7	12 (6.9)
8	12 (6.9)
9	15 (8.6)
10	20 (11.4)
11	9 (5.1)
12	19 (10.9)
13	11 (6.3)
14	10 (5.7)
15	12 (6.9)
16	2 (1.1)
17	2 (1.1)
18	2 (1.1)
20	4 (2.3)
Child's type of diabetes	
Type 1	174 (99.4)
Type 2	0 (0.0)
Other/Unknown	1 (0.6)
Type of DIYAPS[a] used	
OpenAPS	43 (28.4)
AndroidAPS	71 (48.0)
Loop	42 (28.4)
Other/Unknown	5 (3.4)
Region (country of residence)	
Europe	130 (74.3)
Austria	3 (1.7)
Bulgaria	9 (5.1)
Croatia	2 (1.1)
Czech Republic	12 (6.9)
Denmark	2 (1.1)
Finland	8 (4.6)
France	1 (0.6)
Germany	46 (26.3)
Greece	2 (1.1)
Ireland	3 (1.7)

Demographic	n (%)
Luxembourg	1 (0.6)
Poland	2 (1.1)
Slovakia	4 (2.3)
Spain	3 (1.7)
Sweden	8 (4.6)
Switzerland	1 (0.6)
United Kingdom	23 (13.1)
North America	21 (12.0)
Canada	5 (2.9)
United States	16 (9.1)
Asia	12 (6.9)
South Korea	12 (6.9)
Australia/Western Pacific	12 (6.9)
Australia	12 (6.9)
Caregiver's occupational status	
Full-time	101 (58.4)
Part-time	55 (31.8)
Unemployed	10 (5.8)
Retired	0 (0.0)
Student	2 (1.2)
Other/Unknown	5 (2.9)
Caregiver's household annual net income (US $)	
<20,000	19 (12.0)
20,000-34,999	12 (7.6)
35,000-49,999	19 (12.0)
50,000-74,999	33 (20.9)
75,000-99,999	24 (15.2)
≥100,000	40 (25.9)

[a]DIYAPS: Do-it-Yourself Artificial Pancreas Systems.

On an average, the cohort already had a baseline glycemic control level below the target HbA_{1c} recommended by the International Society for Pediatric and Adolescent Diabetes [11]. Nevertheless, a significant HbA_{1c} improvement of –0.64 percentage points, from a mean HbA_{1c} of 6.91% (SD 0.88%; or 52.0 mmol/mol) to 6.27% (SD 0.67; or 45.0 mmol/mol) after commencing DIYAPS was reported (P<.001; Figure 1). The mean TIR increased from 64.2% (SD 15.94%) to 80.68% (SD 9.26; P<.001; Figure 2). Participants also reported a continuous HbA_{1c} improvement over time, starting from a mean HbA_{1c} of 6.39% (SD 0.65%; or 46.3 mmol/mol) as their first result after commencement, which equals an improvement of –0.52 percentage points compared to the baseline level, gradually improving to a mean HbA_{1c} of 6.26% (SD 0.69%; or 44.9 mmol/mol) as their second result and a mean HbA_{1c} of 6.06% (SD 0.66%; or 42.7 mmol/mol) as their third result, which equals an improvement of –0.85 percentage points. Users of all DIYAPS systems and all age groups showed similar results (Table 2).

Among the relatively few respondents who indicated difficulties with DIYAPS (n=29), the primary challenge was sourcing the necessary devices and setting up the closed loop. In both cases, successful solutions were primarily found online, although for some, this was a time-consuming process.

Figure 1. Mean last HbA_{1c} levels of children and adolescents before (black) and after (white) the initiation of Do-it-Yourself Artificial Pancreas Systems. HbA_{1c}: hemoglobin A_{1c}.

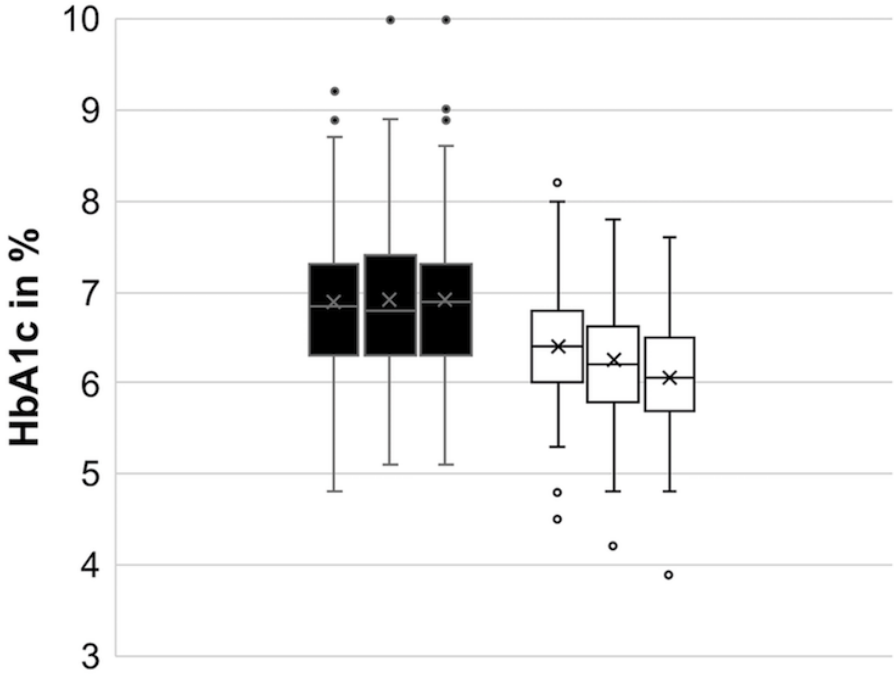

Figure 2. Mean time in range for sensor glucose levels of children and adolescents before (black) and after (white) the initiation of Do-it-Yourself Artificial Pancreas Systems.

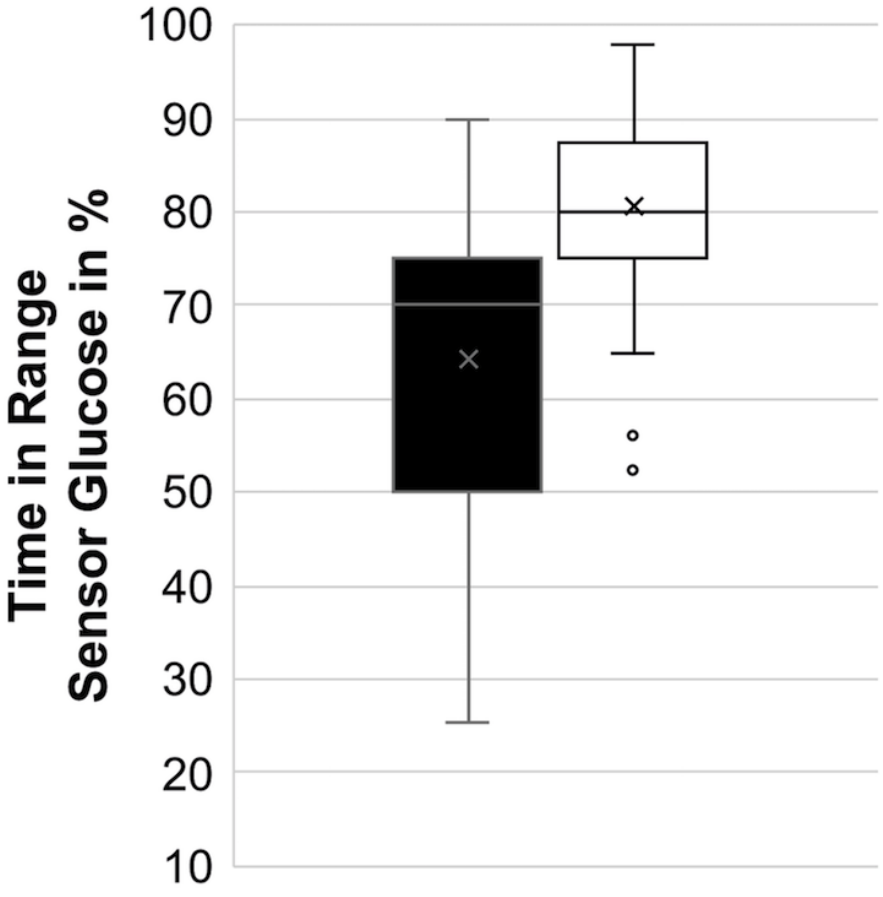

Table 2. Clinical outcomes in children and adolescents before and after initiation of Do-it-Yourself Artificial Pancreas Systems.

Outcomes and users	Mean (SD)
All DIYAPS[a] users	
HbA_{1c}[b]	
Before	6.91 (0.88)
After initiation	6.27 (0.67)
Time in range	
Before	64.2 (15.94)
After initiation	80.68 (9.26)
OpenAPS users	
HbA_{1c}	
Before	7.10 (0.75)
After initiation	6.36 (0.72)
Time in range	
Before	67.1 (14.4)
After initiation	81.7 (7.7)
AndroidAPS users	
HbA_{1c}	
Before	6.85 (0.79)
After initiation	6.24 (0.73)
Time in range	
Before	63.8 (15.0)
After initiation	79.5 (7.9)
Loop users	
HbA_{1c}	
Before	6.99 (1.00)
After initiation	6.39 (0.61)
Time in range	
Before	64.2 (15.4)
After initiation	79.1 (8.4)
Children (3-9 years)	
HbA_{1c}	
Before	6.89 (0.80)
After initiation	6.31 (0.59)
Time in range	
Before	66.5 (15.9)
After initiation	79.2 (8.4)
Adolescents and young adults (10-20 years old)	
HbA_{1c}	
Before	6.93 (0.95)
After initiation	6.23 (0.75)

Outcomes and users	Mean (SD)
Time in range	
Before	62.2 (15.9)
After initiation	80.1 (9.3)

[a]DIYAPS: Do-it-Yourself Artificial Pancreas Systems.

[b]HbA_{1c}: hemoglobin A_{1c}.

Discussion

This survey is currently the largest study of DIYAPS users on a global level and provides new evidence about real-world use of these systems in children and adolescents. Improvement of glycemic control was consistently reported across all pediatric age groups, including adolescents and very young children. Thus, the beneficial effects observed in adult users appear to apply to the pediatric population with no age limitations. These findings are in line with clinical trial results and improvements seen in commercially developed closed-loop systems [5-9].

The occupational and educational level of the responding caregivers was well above the population level; however, the household income levels varied. This finding suggests that DIYAPS may be financially accessible to a variety of socioeconomic groups. Further investigations on the role of all household caregivers' socioeconomic status and barriers to scaling up use of these systems would be of interest.

Although studies investigating DIYAPS consistently have demonstrated significant improvements in a variety of clinical and patient-reported outcomes, with no accompanying severe adverse events, various stakeholders continue to view the use of DIYAPS with skepticism. Ethical and legal questions have been raised, especially for the vulnerable group of children and adolescents. The off-label use of unregulated medical devices as well as the role of the caregiver taking the decision independently from doctors is the subject of intense debate [15]. Children are dependent on their caregivers' technological and medical knowledge and skills, both of which are prerequisites of understanding, building, and maintaining a DIYAPS. Moreover, a limited number of diabetes specialists are familiar with DIYAPS and their in-built safety mechanisms. Knowledge is also limited because research focusing on pediatric cohorts have tended to lag behind the adult population. Studies such as this one may therefore help alleviate concerns of health care providers as they are increasingly confronted with caregivers who have opted for DIYAPS for their child's diabetes management in their day-to-day clinical practice.

This study has several limitations. Outcomes were self-reported by caregivers. Until recently, self-reported data have not been commonly used in clinical research. However, a Norwegian study previously found that self-reported outcomes showed good concordance with data from patient registries reported by health care professionals [16]. Continuous glucose monitoring data were not directly captured in this survey. Therefore, time in hypoglycemia was not assessed. Time spans between HbA_{1c} measurements and TIR as well as DIYAPS versions, settings, and targets might differ individually. With a median DIYAPS experience of 7.5 months, some participants were unable to provide all three HbA_{1c} measurements. With education level and occupational status above the average population level and previous baseline glycemic outcomes below the target, the cohort or DIYAPS community may, in general, not be representative of all families having children with diabetes. To fully evaluate both the benefits and risks of DIYAPS, safety and efficacy trials for all age groups are needed.

The growing #WeAreNotWaiting movement globally is indicative of a paradigm shift whereby traditional, top-down health care solutions are increasingly being complemented by bottom-up and patient-led initiatives. This survey, novel in both its sample size and international scope, provides new evidence that DIYAPS can offer substantial improvements in clinical outcomes for children and adolescents, even in a population that already has achieved glycemic outcomes below the target. However, more research is needed to examine the mechanisms by which these results are achieved; lived experiences of DIYAPS users; adverse events; and what can be learned from this movement in order to accelerate the diffusion of APS technology across the population.

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Authors' Contributions

KB, DL, and KR performed the literature search. KB, SO, BC, AT, DL, BH, IW, and KR designed the survey. KB and KR collected the data. KB, SO, BC, AT, DL, BH, IW, and KR performed the data analysis and interpretation. KB, SO, KR, BC, IW, and DL wrote the article. All authors read and approved the article.

Conflicts of Interest

KB reports grants from the Berlin Institute of Health (BIH) Clinician Scientist program; fees for medical consulting from Medtronic Diabetes as a member of the Advisory Board "Impact"; medical consulting fees from Roche Diabetes Care; and paid talks for Dexcom, Medtronic Diabetes, and Bertelsmann Stiftung outside the submitted work. AT reports personal fees from Dexcom, Roche Diabetes Care, IME-DC, and Ypsomed; nonfinancial support from Sooil; and personal fees from Gruber-Debong GmbH outside the submitted work. DL reports grants from Robert Wood Johnson Foundation and personal fees from Lilly, Diabeloop, Roche Diabetes Care, Novo Nordisk, and Tandem outside the submitted work. BH reports personal fees from Roche Pharma, Roche Diabetes Care, Novo Nordisk, LifeScan, Bayer AG, and Medtronic Diabetes outside the submitted work. KR is advisory board member of Lilly Diabetes Care and Abbott Diabetes Care outside the submitted work. The remaining authors declare no conflicts of interest.

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Abbreviations

DIYAPS: Do-it-Yourself Artificial Pancreas Systems
HbA_{1c}: hemoglobin A_{1c}
TIR: time in range

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Original Paper

Barriers and Facilitators to the Implementation of a Mobile Insulin Titration Intervention for Patients With Uncontrolled Diabetes: A Qualitative Analysis

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Abstract

Background: In 2016, a short message service text messaging intervention to titrate insulin in patients with uncontrolled type 2 diabetes was implemented at two health care facilities in New York City.

Objective: This study aimed to conduct a qualitative evaluation assessing barriers to and the facilitators of the implementation of the Mobile Insulin Titration Intervention (MITI) program into usual care.

Methods: We conducted in-depth interviews with 36 patients enrolled in the MITI program and the staff involved in MITI (n=19) in the two health care systems. Interviews were transcribed and iteratively coded by two study investigators, both inductively and deductively using a codebook guided by the Consolidated Framework for Implementation Research.

Results: Multiple facilitator themes emerged: (1) MITI had strong relative advantages to in-person titration, including its convenience and time-saving design, (2) the free cost of MITI was important to the patients, (3) MITI was easy to use and the patients were confident in their ability to use it, (4) MITI was compatible with the patients' home routines and clinic workflow, (5) the patients and staff perceived MITI to have value beyond insulin titration by reminding and motivating the patients to engage in healthy behaviors and providing a source of patient support, and (6) implementation in clinics was made easy by having a strong implementation climate, communication networks to spread information about MITI, and a strong program champion. The barriers identified included the following: (1) language limitations, (2) initial nurse concerns about the scope of practice changes required to deliver MITI, (3) initial provider knowledge gaps about the program, and (4) provider perceptions that MITI might not be appropriate for some patients (eg, older or not tech-savvy). There was also a theme that emerged during the patient and staff interviews of an unmet need for long-term additional diabetes management support among this population, specifically diet, nutrition, and exercise support.

Conclusions: The patients and staff were overwhelmingly supportive of MITI and believed that it had many benefits and that it was compatible with the clinic workflow and patients' lives. Initial implementation efforts should address staff training and nurse concerns. Future research should explore options for integrating additional diabetes support for patients.

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KEYWORDS

type 2 diabetes; telemedicine; implementation science

Introduction

Over 30 million people in the United States have diabetes [1], and approximately 30% of adults with diabetes take insulin to regulate their blood sugar [2]. The process of finding the correct dose of insulin often requires frequent visits to a clinician to review daily fasting blood glucose (FBG) logs and adjust doses until the patient reaches a desired FBG level. This insulin titration process is demanding for both patients and health care systems. For patients, it requires daily FBG testing and tracking. Patients must also devote considerable time and effort to make medical appointments, potentially contributing to lost wages or absence in school and extra childcare costs [3,4]. For health care systems, it requires the availability of appointments and clinician time for titration visits. This can be especially challenging for public and safety net hospitals that care for large numbers of patients with diabetes [5].

Mobile health (or mHealth) interventions have been promoted as a means to overcome barriers to health care in general and safety net populations. These interventions use mobile devices, such as mobile phones, to provide patient education and care support in between health care visits. Through the use of phone calls, text messaging, and/or smartphone apps, mHealth interventions may alleviate the barriers to health care access by eliminating costs of commuting to medical visits, difficulties finding childcare to attend medical visits, difficulties taking time off for health care visits, and limits in appointment availability. Previous studies have supported the effectiveness of mHealth interventions for diabetes self-management [6]; however, there are no mobile programs to assist patients with type 2 diabetes with the process of insulin titration.

In recognizing the power of mHealth to help vulnerable populations access care, Bellevue Hospital (part of NYC Health + Hospitals in New York City) developed a remote insulin titration program called the *Mobile Insulin Titration Intervention* (MITI). With MITI, an automated system sends a text message every week day to patients who have uncontrolled type 2 diabetes and need an adjustment of their basal insulin by asking for their FBG levels. A nurse monitors incoming FBG texts from patients, and nurses call patients once weekly to advise on insulin dose titration. The hospital also supplies uninsured patients with free FBG testing supplies. The goal of MITI is to find the dose of insulin that achieves an FBG level of 80 to 130 mg/dL [7]. In a randomized controlled trial (RCT), 88% (29/33) of MITI patients (vs 37% [10/27] of patients receiving the usual care) were able to find their optimal insulin dose (OID) in an average of 3 weeks [8].

On the basis of the success of the RCT, Bellevue Hospital and a second NYC Health + Hospitals facility (Gouverneur Health) implemented the MITI program into routine care. To accelerate the future translation of MITI in other settings, we conducted a mixed-methods hybrid effectiveness implementation study evaluating the implementation of MITI as it moved from the RCT into usual care [9,10]. The study's quantitative analysis showed that MITI was effective as routine care, with 84% of MITI patients reaching their OID in an average of 24 days [9].

This paper describes the study's qualitative analysis assessing barriers and facilitators to implementing MITI into routine care.

Methods

Setting

The study took place at two ambulatory care facilities within NYC Health + Hospitals: Bellevue Hospital and Gouverneur Health. Bellevue is the nation's oldest public hospital, providing over 60,000 primary care continuity visits per year to 33,000 active patients. Gouverneur Health is NYC Health + Hospitals' largest ambulatory care facility, providing over 267,000 outpatient visits per year. Each site cares for approximately 5000 patients with diabetes annually and serves a multiethnic, multiracial patient population. Most patients (65% at Bellevue and 75% at Gouverneur) either have Medicaid or are uninsured. This study was approved by the New York University institutional review board (IRB).

Routine Insulin Titration Care

The patients with diabetes needing titration of basal insulin have the option of self-titration [11]. The patients who are not comfortable with self-titration are asked to keep a daily log of their FBG level and return to the clinic to review the FBG log in person with a provider to identify the need for a change in their insulin dose. The frequency and the timing of in-person visits to check the FBG logs can vary based on patient needs.

Mobile Insulin Titration Intervention Program

Physicians could refer patients with uncontrolled diabetes who needed adjustment of their basal insulin to MITI during a routine clinical visit (full patient eligibility criteria are described elsewhere [10]). At Bellevue, physicians referred the patients to MITI by paging an onsite program coordinator who met the patient to complete enrollment. At Gouverneur, physicians referred the patients to their regular team nurse who completed enrollment as part of the routine outtake process. Each week day, enrolled patients received a text message from a secure Web portal [12] asking "What was your fasting blood sugar this morning?", and patients texted back the value. Every week day, a nurse monitored incoming values for alarming values or anomalies. If a patient texted on a weekend or afterhours, he or she received an automated text message stating the following:

> *There is no one available to review this text at this time. Your message will be reviewed on the next day, usually from Monday to Friday.*

Every Thursday afternoon a nurse would call each MITI patient to provide dosing instructions using an algorithm [8,10] developed by the MITI clinical director (NL). At Bellevue, the daily FBG monitoring and Thursday titration calls were completed by the clinic's two diabetes nurse educators (DNEs) who had protected time to deliver the MITI intervention. At Gouverneur, these procedures were performed by the team nurses who enrolled the patient in MITI without protected time. Patients remained in MITI for up to 12 weeks and were discharged when they (1) achieved their OID either by reaching an FBG level within 80 to 130 mg/dL or by reaching the maximum dose of 50 units, (2) had to be terminated early

because a nurse was unable to reach them by phone after 3 consecutive weeks to provide titration instructions, or (3) had been in the program for 12 weeks without reaching their OID.

Implementation Process

The MITI team used a combination of evidence-based strategies to implement MITI at each site [13]. Before implementation, an advisory committee was formed at each site comprising physician and nursing representatives who helped decide how MITI would function as routine care in their clinic (eg, staffing model and referral process). Once MITI was ready to start, the team disseminated educational materials and conducted educational activities with providers and nurses. These activities included group and individual training sessions with the nurses delivering MITI on how to enroll, monitor, and titrate patients. The team also presented the program and distributed MITI materials to physicians at regular staff meetings. After implementation, the MITI team met with physicians and nurses at routine staff meetings to provide program updates and hear clinician feedback. The MITI team performed an individual educational outreach to new physicians and nurses as needed. The MITI coordinator was also available to assist the nurses if they were having challenges with the texting platform or other program elements.

Interview Participants and Recruitment

Patients

We were interested in interviewing 50 patients enrolled in MITI (25 per site). During our interview recruitment period, all patients enrolled in the MITI program as part of their routine care were invited to participate in an interview at the end of their MITI enrollment visit. After completing the MITI enrollment process, the enrolling MITI team member told patients about the study, assessed patient interest in completing an interview, and requested patient permission to page an onsite member of the study team. The study team member arrived to provide the patient with more information about the study and obtain participants' written informed consent using an IRB-approved consent form.

Staff

We were interested in interviewing 20 staff members (10 per site). Our staff sampling frame was the staff at each site who had a role in MITI: physicians referring patients to MITI, nurses performing titration monitoring and giving instructions, and clinic administrators who were involved in implementing MITI. We used purposeful criterion sampling [14] to recruit the staff for interviews. Factors that informed our sampling approach included gender, staff role (provider—physician, nurse practitioner, or physician assistant; registered nurse; and administrator), site, and whether they had referred at least 1 patient to MITI (for providers) or assisted at least 1 patient through the MITI program (for nurses). The staff were invited to participate via institutional email and sign-up lists distributed during regular staff meetings. The staff had signed an IRB-approved consent form before interview procedures began.

Interview Procedures

Conceptual Framework

Our interview and analytic approach was guided by the Consolidated Framework for Implementation Research (CFIR) [15]. The CFIR specifies 39 constructs mapping to 5 major domains that delineate the potential barriers and facilitators of implementation outcomes: (1) the *characteristics of an intervention*, (2) the *outer setting* of the organization in which the intervention is being implemented, (3) the *inner setting* of the organization, (4) the *characteristics of individuals* involved in the intervention, and (5) the *implementation process*. We conceptualized the *inner setting* for patients as being their personal setting (eg, home and work) where they would perform their MITI activities.

Patients

Patients were asked to complete 2 interviews—an interview immediately after the MITI enrollment and another 12 weeks later or when they were discharged from MITI (whichever occurred first). Patients had the option to complete the interviews in English or using a translator phone. Enrollment interviews were conducted in private, closed offices located in the primary care clinics at each site. Patients could complete the follow-up interview at the hospital or over the phone. The interviews were conducted by 3 study team members (ESR, SA, and DM) using an interview guide (Multimedia Appendix 1) informed by the CFIR that included structured questions with follow-up probes to assess patient perceptions of the MITI program, including how it compared with other options for insulin titration and factors that might enhance or impede their use of MITI. Follow-up interviews assessed patient experiences of actually using MITI, including challenges encountered and recommendations for improving the program. All interviews were audio-taped. When a translator phone was used during interviews, the translator phone was recorded. The patients received US $20 in cash for each completed interview.

Staff

The staff were asked to complete 2 interviews—an interview during the early implementation period (first 5 months) at their site and another approximately 6 months later. The staff interviews were conducted in their private offices by the same team members who conducted the patient interviews. The interviewers followed a guide (Multimedia Appendix 2) informed by the CFIR to assess the staff perceptions of MITI, including how it compares with usual care, how it worked within the regular clinic workflow, and factors that might enhance or impede the staff and patient use of MITI. Follow-up interviews further assessed staff experiences using MITI, challenges encountered, and recommendations for improving the program in the future. Interviews were audio-taped. The staff received a US $20 gift card for each interview completed.

Data Analysis

Interview audio files were transcribed verbatim, removing identifiers at the time of transcription. For interviews conducted using the translator phone, the English portion of the interviews was transcribed (ie, the interview questions as asked by English-speaking interviewers and the participant responses as

translated into English by the translators). Transcribers reviewed each audio file twice to confirm transcription accuracy. A total of two study team members (ESR and RF) used both deductive (CFIR theory–driven) and inductive (open coding) approaches to code the transcripts using Atlas.ti software (Scientific Software Development GmbH). An initial codebook was created that included all 39 CFIR constructs as codes. The codebook included a definition of each domain/code and its inclusion/exclusion criteria. The two coders independently coded 5 transcripts deductively using the CFIR codebook and with open coding to create preliminary codes specific to the study that were then mapped to the CFIR constructs. The coders met to discuss agreement and disagreement in the first round of coding and to collapse the preliminary codes to limit redundancy. Once they finalized the codebook (Multimedia Appendix 3), they completed independent coding of the remaining transcripts. Differences in coding were resolved via discussion. Once coding was complete, the coders met to identify themes (using memoing and reading of quotations to identify themes within codes and using frequency of code occurrence in the Atlas.ti dataset) and relationships among codes.

Results

Patient Participant Characteristics

Owing to delays in obtaining IRB approval for interviews at Gouverneur, our interview recruitment period was shorter than planned and we were only able to offer interview participation to 45 patients (39 of whom agreed to participate). The most common reason given for not participating was that the patient did not have time to stay for the interview. One patient did not want to be audio-taped and was not enrolled. The sociodemographics and program outcomes of the patient interview sample are shown in Table 1. The characteristics of the interview sample were similar to those in the broader MITI sample [10]. Participants at both sites were predominantly male, on average aged 49 to 51 years, and most reported Hispanic ethnicity. As was found in the general MITI population, participants in the interview sample were highly responsive to the program's text and titration call procedures, and most graduated from MITI finding their OID with an FBG level within the goal of 80 to 130 mg/dL.

Table 1. Characteristics and Mobile Insulin Titration Intervention program outcomes of the patient interview sample.

Demographic characteristics	Bellevue (n=24)	Gouverneur (n=15)	Total (N=39)
Female gender, n (%)	8 (33)	6 (40)	14 (36)
Age (years), mean (SD)	51 (11)	49 (10)	50 (11)
Race, n (%)			
White	4 (17)	2 (13)	6 (15)
Black or African American	5 (21)	1 (7)	6 (15)
Asian	2 (8)	1 (7)	3 (8)
Native American/Alaskan Native	1 (4)	1 (7)	2 (5)
Other[a]	12 (50)	10 (67)	22 (56)
Hispanic ethnicity, n (%)	16 (67)	13 (87)	29 (74)
Has health insurance, n (%)	10 (42)	12 (80)	22 (56)
Had a visit copay, n (%)	9 (38)	4 (27)	13 (33)
Unemployed, n (%)	12 (50)	4 (27)	16 (41)
Preferred Spanish language for texts, n (%)	11 (46)	8 (53)	19 (49)
Mobile Insulin Titration Intervention program outcomes, %			
Text response rate	97	96	97
Call connection rate	74	95	82
Program termination status, n (%)			
Achieved OID[b]	21 (88)	13 (87)	34 (87)
Achieved 80-130 FBG[c]	18 (75)	12 (80)	30 (77)
Reached maximum dose without reaching FBG goal	3 (13)	1 (7)	4 (10)
Programmed terminated early	0 (0)	1 (7)	1 (3)
Reached 12 weeks without OID	3 (13)	1 (7)	4 (10)

[a]All patients who checked the *Other* race option said they were Hispanic.

[b]OID: optimal insulin dose.

[c]FBG: fasting blood glucose.

In total, 25 patients (n=15 Bellevue and n=10 Gouverneur) completed a follow-up interview. The characteristics of follow-up respondents were similar to the full interview sample (mean age 51.5 SD [11.5] years; 36% female; 70% Hispanic; 60% with health insurance; 44% unemployed; 44% requested Spanish texts; and 80% achieved their OID).

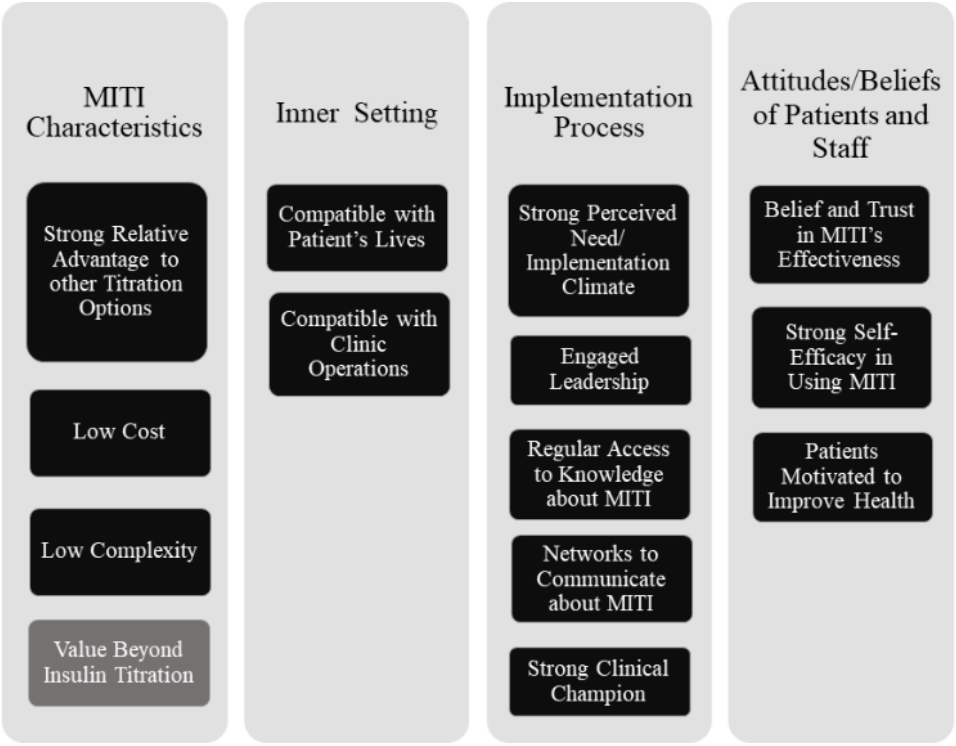
Staff Participant Characteristics

The study coordinator reached out to 32 staff to offer an interview. At Bellevue, 25 physicians, the 2 DNEs working on MITI, 2 physician assistants, 2 nurse practitioners, and 1 administrator were invited. At Gouverneur, 6 physicians, 17 nurses, and 1 administrator were invited. In total, 19 staff agreed to participate. Only 1 staff member actively refused participation; the other staff members could not be reached after multiple attempts. The final staff sample at Bellevue included 6 physicians (3 men and 3 women), 1 physician assistant (woman), and 1 clinic administrator (woman). The final staff sample at Gouverneur included 4 physicians (3 men and 1 woman), 6 nurses (5 women and 1 man), and 1 nursing administrator (woman). A total of 14 staff (n=7 per site) completed a follow-up interview.

Facilitators

Figure 1 displays the implementation facilitators organized around the main domains of the CFIR that emerged during the interviews. Facilitators in black boxes were deductively derived from the 39 CFIR constructs. Facilitators in gray boxes were derived from inductive open-coding and then mapped to the main domains of the CFIR. Multiple themes emerged identifying the *characteristics of MITI*, characteristics of the *inner setting*, *beliefs and attitudes of the patients and staff*, and characteristics of the *implementation process* that facilitated provider referrals, patient enrollments, and patient use of MITI. Of note, the same themes emerged during baseline and follow-up interviews; so, we have combined them in the Results section.

Figure 1. Themes related to factors that facilitated the implementation of Mobile Insulin Titration Intervention (MITI) at the two clinics.



Facilitators: Mobile Insulin Titration Intervention Characteristics

Strong Relative Advantage to Other Titration Options

All patients spoke about the advantages of MITI compared with in-person insulin titration options, which contributed to their decision to enroll and stay in the MITI program. Advantages included MITI's convenience and ability to save patients time by not having to go to the hospital. One patient described it as follows:

> *[MITI] makes my life much easier. I'm a security guard. I do 60-something hour weeks. I don't have the time to burn a day off to come down here. So, [MITI] makes my life much easier.* [B17, English-speaking patient at Bellevue]

Additional advantages for patients relative to in-person titration included the ability of the MITI texting platform to keep a record of FBG levels so that patients do not have to keep track themselves and the included the perception that the frequent text-based contact with providers was a better way to communicate with their health care team. When asked about the option to create MITI as a secure website or smartphone app, most patients either preferred MITI to remain a texting program or were neutral. Some patients stated that they did not have access to (or had limited comfort with) the internet and/or phone apps, whereas some patients reported that texting was simply easier or faster than logging into an app or a Web-based program.

Similar to patients, all the staff saw advantages to the MITI program compared with in-person titration. These advantages

drove their decision to refer the patients to MITI. Perceived advantages of MITI included its convenience for the patients. A physician assistant at Bellevue shared the following:

> *MITI is extremely convenient and great for patients because our patients unfortunately have a lot of barriers when it comes to seeking care…the fact that they can receive optimal care just by text messaging is very efficient, cost-effective, and a great idea for the patient.* [B209]

The staff reported additional advantages to in-person care including MITI's ability to speed-up the titration process because patients do not need to wait months just to have their FBG logs reviewed:

> *With MITI patients get seen faster. Patients get the equivalent of three nursing visits in weeks as opposed to months.* [B202, Bellevue physician]

The staff further perceived that there were nonpatient advantages of MITI, including its ability to reduce the burden of titration visits on providers. A clinic administrator suggested that MITI had advantages to non-MITI patients and to the health care system more broadly by reducing the number of visits for insulin titration:

> *[With MITI] the waiting time for all patients here would reduce because there are less patients in the waiting room just for finger sticks. This improves satisfaction and retention.* [B205, Bellevue]

Low Cost

The free cost of MITI and the free daily testing strips were important to all patients interviewed. However, the patients had mixed opinions on whether they would have enrolled in MITI if there was a cost associated with the program. A total of 15 patients would not have enrolled, as one woman described:

> *I live by myself on a budget and even my medication, to be honest with you, some of the medication, I was calling the providers and companies to see if I can get coupons. So, I don't think I would sign up [for MITI] if I had to pay.* [G114, English-speaking patient at Gouverneur]

On the contrary, 9 patients were unsure if they would enroll with a cost or said it would depend on the amount of cost. A total of 12 patients said they would have enrolled even if there were a charge, because MITI was ultimately beneficial for their health.

Low Complexity

All patients valued MITI's simplicity and ease of use. Only 1 patient reported challenges using MITI but noted that it got easier over time. One patient said:

> *It was easy. It takes messaging, y'know, with these smart phones and the ability to make a noise and then you just get up and do your test and then put that information back in there.* [B11, English-speaking patient at Bellevue]

Similarly, all staff believed that MITI would be easy for patients to use, in particular because MITI requires little of the patient and uses the familiar, easy technology of texting. This perception of MITI's ease for patients contributed to physician motivations for referring patients to the program.

Perceived Value Beyond Insulin Titration

Interviews also showed that some patients experienced MITI as having value beyond insulin titration. A total of 10 patients discussed how MITI made them more aware of their diabetes and reminded them to check their FBG levels and to take their medication. As one patient noted:

> *I'm going to do a lot better because now I'm going to be reminded to [check my sugar], and at the same time, it's going to remind me to take my medication.* [B34, Spanish-speaking patient at Bellevue]

Most patients also expressed that even though MITI did not address healthy eating directly, the process of being reminded to check their sugar motivated them to eat well or engage in other healthy behaviors. One female patient noted that*:*

> *[MITI] reminded me about my sugar, so I have to control what I eat. Every time you text me, I remember okay, you can't eat this, you can't eat that.* [G127, English-speaking patient at Gouverneur]

Finally, 4 patients reported that the daily text messages and weekly phone calls from a nurse felt like a needed source of personal support. In the words of one patient:

> *I know the program will help me and I will get support, and that's what I think I need: the support.* [B39, English-speaking patient at Bellevue]

Most staff also saw value in MITI beyond insulin titration, including MITI's ability to engage with patients in between visits and potentially increase medication adherence by reminding the patients to attend to their diabetes and use their insulin daily. A physician also felt that by making the insulin titration process easy, MITI might reduce the burden on patients of starting insulin. In his words:

> *Starting insulin is always kind of like the biggest hurdle to overcome in a diabetic. I think having this program where they don't have to come in to the clinic, it's not a big intrusion, like a big change to their routine.* [G301, Gouverneur physician]

Facilitators: Inner Setting

Compatibility of Mobile Insulin Titration Intervention With Patients' Lives

At enrollment, all patients felt that MITI would fit well with their regular routines at home and that they would need to make minimal, if any, changes to be able to send the daily text messages. The follow-up interviews confirmed that this expectation was accurate for most patients, who expressed that they had no challenges in sending the daily text. In addition, related to the *relative advantage* findings discussed above, MITI was more compatible with patients' lives than in-person care. One patient noted that:

> *Part of the reason why I went missing for a year from the hospital is because I have to come down here…Whereas with MITI I can get a text message*

> *and then get a weekly phone call. I'm more likely to stay on top of it, because I can fit it into my schedule versus having to fit someone else's schedule.* [B17, English-speaking patient at Bellevue]

All staff similarly viewed MITI as being compatible with patients' lives, which contributed to their decision to refer patients. A physician said:

> *MITI is part of [patients'] routines because they're already going to get up and check [their FBG] in the morning.* [G302, Gouverneur]

Compatibility of Mobile Insulin Titration Intervention With Clinic Operations

Most nurse interviews at Gouverneur (where nurses did not have protected time for MITI patients) revealed that managing the MITI patients worked well with the regular clinic work flow. Physician interviews at both sites also found that the process of referring the patients to MITI was easy:

> *MITI referral is almost entirely similar to what I do now, so it's no problem.* [G304, Gouverneur physician]

Facilitators: Beliefs and Attitudes of Patients and Staff

Trust in Mobile Insulin Titration Intervention's Effectiveness

Interviews revealed that most patients believed in the effectiveness of MITI at the time they enrolled. They were confident that MITI would help them improve their health and their diabetes management, which contributed to their decision to enroll. One patient told us:

> *There's a good chance that I can probably get my diabetes under control and live a good healthy life. That's what I'm looking forward to.* [B11, English-speaking patient at Bellevue]

Physicians also trusted and perceived the evidence supporting MITI's potential effectiveness to be of high quality. Most interviewees were aware of the previous pilot RCT showing MITI to be efficacious compared with usual care. The staff also reported that the data and feedback that they received from the MITI program regarding the successes of patients whom they referred to MITI supported their decision to continue referring.

Strong Patient Self-Efficacy in Using Mobile Insulin Titration Intervention

There were a few patient concerns about their ability to use MITI (concerns are described in the *Barriers* section). All patients were highly confident in their ability to use MITI and send the daily text message. Patients reported that their high confidence was related to the simplicity of MITI and how well it fit with their routine:

> *It's easy to text somebody…you know…that's all you do all day… is text.* [B24, English-speaking patient at Bellevue]

Patients Motivated to Improve Health

Finally, some patients were highly motivated to improve their health. This motivation contributed to their decision to enroll in MITI and stay engaged in the program once enrolled. A woman told us:

> *I was very interested in [MITI] to get my blood sugar down, cause it's been high for a long time…I'll do anything that can help.* [B24, English-speaking patient at Bellevue]

A man similarly shared:

> *I've been a diabetic for better part of 20-25 years, when I really found out about it. Probably longer than that and I never paid attention to it. Now it's getting down to that point where it needs to be a big concern.* [B11, English-speaking patient at Bellevue]

Facilitators: Implementation Process

Strong Perceived Need for Mobile Insulin Titration Intervention And Strong Implementation Climate

When it came to the process of implementing MITI, most staff reported that there was strong support among clinicians for the implementation of MITI. They recognized that this new service was meeting the needs of patients who could not attend frequent clinic appointments. A physician at Bellevue said:

> *There's been overwhelming support for [MITI] because it really does facilitate the care of our patients. It's a good alternative to regular clinic visits because it can be difficult to fit in regular clinic visits for something like insulin titration.* [B207]

Regular Staff Access to Knowledge About Mobile Insulin Titration Intervention

In addition, all staff interviewees were aware of MITI, and most reported that they had regular access to information about MITI. They reported receiving initial trainings and educational outreach for MITI. Most providers felt that the information provided to them about MITI was comprehensive and easy to understand. Gouverneur staff reported that there were information packets about MITI in the shared precepting and break rooms that were updated regularly. Nurses also appreciated the ongoing support provided by the MITI team when they had questions about the texting platform or other procedures. A nurse reported that:

> *[The MITI coordinator] would tell us that if anyone wants to practice enrollments or the texting program to come see her for a little bit. She would help whoever felt uncomfortable doing it on their own and practice with them.* [G302, Gouverneur]

Formal and Informal Networks to Communicate About Mobile Insulin Titration Intervention

All staff described that each clinic had opportunities for formal discussion about MITI, including regular staff meetings and emailed distribution of MITI information. The staff also reported that there was informal communication about MITI within the clinic, such as physicians hearing about MITI from colleagues or sharing patient successes. These formal and informal communication opportunities facilitated the sharing of information about MITI during and after implementation.

Strong Clinical Champion

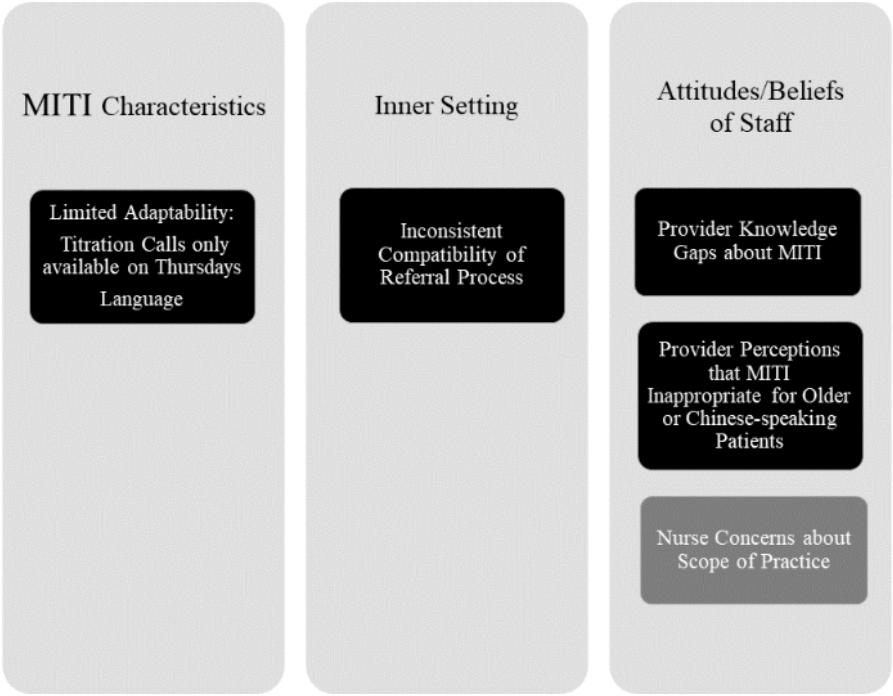
Finally, 3 staff reported that the MITI coordinator and medical director (whom most interviewees knew by name) were strong champions for the program, which facilitated implementation. A Bellevue physician noted:

> *I'm impressed with everything accomplished, with overcoming bureaucratic hurdles with the texting and the patient protection of health information issues. It's a real testament to the ability of [the MITI medical director]. It takes a champion.* [B201]

Barrier Themes

Figure 2 displays the themes related to the implementation barriers organized around the main domains of the CFIR that emerged during interviews. Barriers in black boxes were deductively derived from the 39 CFIR constructs. Barriers in gray boxes were derived from inductive open-coding and then mapped to the main domains of the CFIR. A few barriers were discussed by the patients or staff. Those identified were related to the *characteristics of MITI*, *characteristics of the inner setting*, and *beliefs or attitudes of the staff*, which limited provider referrals or impeded patient use of MITI. These are described in detail below.

Figure 2. Themes related to barriers toward the implementation of Mobile Insulin Titration Intervention (MITI) at the two clinics.



Barriers: Characteristics of Mobile Insulin Titration Intervention

Limited Adaptability

Titration Calls Only Available on Thursdays

Some patients expressed concern at being able to take the Thursday titration calls, because they had work commitments or other activities that would make it difficult to receive a call on Thursdays. They requested more flexibility in the ability to pick the day of week or time of day during which they would receive the titration calls.

Language Limitations

Multiple staff pointed out that MITI was not appropriate for their patients who could not text in English or Spanish, which could comprise a significant portion of patients at the program's two safety net sites. A physician noted:

> *One aspect [of concern] was definitely language. I think MITI [only] included English and Spanish, so language can be a barrier for some.* [G301, Gouverneur]

Barriers: Inner Setting

Limits to Clinic Compatibility (Referral Process)

Once MITI launched at Bellevue, the process of paging the MITI coordinator was described as unusual by some staff because the clinical referral process typically happens through the electronic health record (EHR). Physicians requested the ability to refer via the EHR. At Gouverneur, interviewees noted that their team nurses were not always available to immediately enroll an MITI patient. Gouverneur nurse interviewees also suggested that physicians were often too busy to identify the patients who would be potentially eligible for MITI and offered to identify the potential MITI patients themselves.

Barrier: Beliefs or Attitudes of Staff

Initial Staff Knowledge Gaps About Mobile Insulin Titration Intervention

Interviews conducted in the early implementation period identified some staff knowledge gaps about MITI. Some staff were not aware of what MITI offered and did not offer (eg, insulin refills) or who to contact with questions about MITI.

Some staff also thought that MITI was still being tested as part of a clinic trial, were not aware that MITI was offered in Spanish, or were not aware that the Chinese-speaking patients could be referred to MITI as long as they were able to text in English or Spanish. Finally, nurses at Gouverneur reported that initially they were not sure how many times they should try to a reach a patient for weekly titration instructions. Of note, the MITI team responded to these knowledge gap findings by updating educational materials for the clinicians and clarifying MITI protocols. Follow-up interviews did not identify remaining knowledge gaps among the staff.

Nurse Concerns About Scope of Practice and Liability

In the early implementation period, all the interviewed nurses at Gouverneur were initially concerned about how their MITI responsibilities would fit with their regular workload and scope of practices, which were eventually modified to incorporate MITI. In addition, nurses were concerned about the need to frequently monitor and immediately respond to the patients or alarming FBG levels during busy clinic operations. A Gouverneur nursing administrator described these initial concerns and how the MITI team responded:

> *I think [the nurses'] biggest concern was if the patients contact the nurses and they can't immediately respond back, or if there was a really grossly high or low blood sugar, that they would put the patient in danger by not being as attentive as they would want to be. What ultimately happened, which was really good, was the MITI lead explained that this kind of situation is [rare]. Once the nurses got those reassurances, and once they knew that I was here and the MITI team was consistent in showing up to provide support, it wasn't that big of a lift.* [G304]

Physician Perceptions That Mobile Insulin Titration Intervention is Inappropriate for Some Patients

Some staff suggested that MITI is not appropriate for some of their patients, such as older patients or those who are not comfortable with texting. Some providers also perceived that their Chinese-speaking patients do not regularly text or have texting plans. Interviews revealed that these concerns about patient appropriateness of MITI impacted physician referral decisions. One Bellevue physician discussed his concerns:

> *Some of our patients also, even though they have a phone and they have text messaging available to them, they're not high utilizers of that kind of technology, so sometimes I think the idea of using their smart phone to text is a bit new to them and also they may not be their primary mode of communicating so they may not be as comfortable with the idea of talking to someone about something like medication changes.* [B201]

Additional Noteworthy Findings

There were 3 additional findings from the interviews that were not implementation barriers or facilitators but were noteworthy, nonetheless.

Patient and Staff Desire for Mobile Insulin Titration Intervention to Last Longer

Some patients and staff felt that patients needed a longer-term program than MITI. Patients and staff felt that being discharged from MITI after only one low FBG value was too soon, as patients might not be able to maintain the low value without ongoing support. In the words of one patient:

> *Let [MITI] go longer. Even though I got my numbers back in a short period of time, I still would like to see the program go longer just to make sure there's no relapse. 'Cause I'm a diabetic, so of course I can relapse at any time.* [G132, Spanish-speaking patient at Gouverneur]

Similarly, some providers wanted MITI to last longer because the patients might have lifestyle factors or varying eating habits that caused fluctuating blood sugar:

> *It was a little unfortunate that as long as you just get one [low FBG value], then you're out of the program. Sometimes people might have life factors, like they didn't eat and then all of a sudden their sugar is low one time, but then the next day they're back to their normal eating schedule and their sugar is 160. That might be an issue. We would usually tell people, even if [your sugar is] low one time, you keep the same dose and you keep on checking, and then if the next couple days it's back to a higher level, you would still go up [in insulin] as opposed to just stopping where you were.* [G301, Gouverneur physician]

Unmet Need for Additional Diabetes Support

There was also a theme identified that MITI addressed just 1 component of diabetes care (insulin titration) and there was an unmet need for additional diabetes support more broadly in the population. In particular, 4 physicians noted the need for more services related to nutrition and exercise education and compliance. A Bellevue physician noted that:

> *In general, the diabetics who need insulin, they tend to be people who have very little control over when they eat…one of the big needs is lack of knowledge of diet and really a desire to know more about eating.* [B205]

Physician Desire to Expand Mobile Insulin Titration Intervention to Other Conditions

Finally, most providers discussed that they would like to see MITI expanded to other conditions, such as hypertension. One Bellevue physician noted that:

> *The broad idea of using mobile technology to adjust something like insulin is a new direction for care of chronic conditions. Seeing this apply to other things, like blood pressure, would be great in the future.* [B105]

Discussion

Principal Findings

This study was designed to understand the perspectives of patients and staff regarding potential barriers and facilitators to implementing the first mobile text message–based intervention for insulin titration (called MITI) into routine ambulatory care. The interviews revealed that the patients had highly favorable perceptions of the MITI program and positive experiences using the program, which contributed to their decision to enroll in and complete the program. Patients reported multiple advantages of MITI compared with in-person visits, especially its convenience. Patients also found the program easy to use and mostly compatible with their lives, which we believe is related to MITI's simplicity (our *low complexity* finding). MITI is also a short program (most patients graduated in 2-3 weeks); thus, requiring no long-term engagement with the program and limiting the potential for message fatigue [16]. These findings are consistent with mHealth usability research suggesting that simplicity should be a primary feature of user-centered design [17]. However, these results also found that many patients and staff wanted MITI to last longer and expand to other chronic conditions. Therefore, future research should balance designing for simplicity and limiting message fatigue with the need to address the long-term nature of diabetes and other chronic diseases.

Diabetes-related distress is common in people with type 2 diabetes and can encompass many factors, such as the overwhelming emotional burden of having a serious medical condition, the burden of the diabetes regimen (eg, taking medications, checking FBG levels, and eating well), interpersonal distress, and stress associated with interacting with one's health care providers [18]. This study found that patients valued MITI beyond insulin titration because MITI reminded and motivated them to achieve health goals and provided them with personal support. This was surprising, given that MITI involves a single daily text message asking for their FBG level and a weekly call focused solely on insulin instructions. Consistent with user-centered models supporting the power of simplicity, our results suggest that short, proactive communications with patients who have type 2 diabetes may be effective in alleviating diabetes-related distress and encouraging healthy behavior change, which can be assessed in future randomized trials.

Low adoption by providers can be one of the greatest barriers to implementation of mHealth interventions. This study found that the staff had favorable views about and experiences using MITI, which facilitated physician decisions to refer patients to the program and facilitated nurses' work while executing the program. The staff results also suggest that physician adoption of MITI was determined primarily by their perceptions of MITI's effectiveness and benefits to the patients—consistent with the research identifying factors that influence provider adoption of new telehealth interventions [19,20]. Future projects implementing MITI or other mHealth interventions may focus on communicating the interventions' effectiveness and benefits to the patients to enhance provider adoption.

There was a notable strong concordance between most staff and patient perceptions of MITI. In particular, the patients and staff similarly believed MITI had advantages to in-person titration care, was compatible with the patient's regular routines, was easy to use, and had value beyond insulin titration. The patients and staff also shared a desire for MITI to last longer. These shared perceptions might have synergistically facilitated MITI implementation and sustainability. In addition, future adaptations of MITI responding to this shared feedback would likely have high acceptability by both the patients and staff. Of note, there was also strong agreement in interview results at the two sites (which led us to combine site findings for this report), despite the two hospitals serving somewhat different patient populations and using a different MITI staffing model (ie, a MITI coordinator and DNEs with protected time at Bellevue; team nurses without protected time at Gouverneur). These results support the generalizability of MITI in different safety net settings and the ability of the two staffing models to function smoothly.

The interview findings differed between the patients and staff mostly when it came to discussing barriers. Although the patients and staff did not disagree about barriers, they experienced different barriers. On the patient side, some patients reported challenges taking the Thursday titration calls. As program flexibility can be a strong determinant of telehealth acceptability and adoption by patients [21], the MITI team is testing potential methods for improving patient-centeredness of the call process, including letting the patients pick the day and time of the week to receive a call if needed and sending titration instructions via text for low-risk patients. With regard to the staff, barriers reported by the staff were mostly encountered during early implementation, including staff knowledge gaps about MITI and nurse concerns about the new responsibilities and scope of practice. The MITI team was able to quickly address these initial challenges, and future sites should plan for them before or shortly after MITI implementation.

However, the staff interviews also identified 3 reasons providers might not have referred some patients to MITI: older age, non-English or Spanish language, and Chinese nationality. Although older adults are less likely to own a cell phone, ownership rates in people aged above 65 years are near 80%, and 90% of cell phone owners aged above 65 years use text messaging [22-24]. Therefore, age alone should not be a reason for not offering MITI to patients, and future MITI implementation work should address provider misperceptions about cell phone and text usage in older patients. We also heard from the staff that some patients were unable to understand English or Spanish texts, so the MITI team is exploring the translation of MITI's text messages. Finally, a small number of the staff discussed that the Chinese-speaking immigrant patients might not use text messaging. However, the use of text messaging is widespread in China, and research supports the use of text messaging–based health interventions in China [25]. Nonetheless, reports suggest that the use of SMS text messaging has been declining in China, replaced by cheaper internet-based messaging services, such as WeChat [26]. In addition, in the United States, there is a growing popularity in smartphone apps

and apps for diabetes care [27]. Future research should examine the acceptability, feasibility, and effectiveness of offering MITI using smartphone-based and Web-based messaging platforms. Of note, this study found that some patients would not have been able to use MITI if it were offered as a Web-based or smartphone program, because they lacked a smartphone or data plans. Therefore, to continue to serve very low-income populations, mHealth developers using smartphone technology should seek ways to increase patient access to smartphones and data plans or offer their programs in an SMS-based version when needed.

Limitations

We were unable to interview the two diabetes nurses performing FBG monitoring and titration calls at Bellevue Hospital. We also did not interview patients with diabetes who were *not* enrolled in MITI. Therefore, results only reflect the perceptions of patients who were offered MITI by their physician, accepted the referral, and ultimately enrolled in the program. In addition, we were only able to conduct follow-up interviews with 25 of 39 patient participants, so there might be some bias in our findings related to the actual patient use of MITI. However, as described in the methods, the characteristics of follow-up respondents were similar to the general interview sample. Finally, some interviews were conducted using a translator phone, resulting in language discordance during the interview and the analysis process, which might have impacted the validity of qualitative results [25]. Additional language-concordant work should be conducted to further understand the perspectives of non–English-speaking patients.

Conclusions

MITI is the first mHealth intervention designed to help patients with type 2 diabetes who need insulin adjustment. Our previous quantitative analysis showed MITI to be effective in helping patients find their OID, a lower FBG level, and a lower hemoglobin A_{1c} level in a short period of time [9]. These qualitative findings complement the quantitative results by showing that MITI patients and the staff were overwhelmingly supportive of MITI, believed it had many benefits, and encountered a few barriers to its use. Health care systems can use these results to design strategies for implementing MITI into their clinic workflows.

Acknowledgments

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Authors' Contributions

NL was the principal investigator. ESR was a co-investigator, designed the qualitative study methods, conducted interviews, and led data analysis and paper preparation. NAO was the MITI program coordinator. SA and DNM conducted interviews. RF coded and analyzed interviews. LU, ATL, and MAS were co-investigators and contributed to data interpretation. All authors contributed to data interpretation and paper preparation.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Patient interview guide.

[DOCX File, 26KB - mhealth_v7i7e13906_app1.docx]

Multimedia Appendix 2

Staff interview guide.

[DOC File, 71KB - mhealth_v7i7e13906_app2.doc]

Multimedia Appendix 3

Codebook.

[DOCX File, 36KB - mhealth_v7i7e13906_app3.docx]

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Abbreviations

CFIR: Consolidated Framework for Implementation Research
DNE: diabetes nurse educator
EHR: electronic health record
FBG: fasting blood glucose
IRB: institutional review board
mHealth: mobile health
MITI: Mobile Insulin Titration Intervention
NYC: New York City
OID: optimal insulin dose
RCT: randomized controlled trial
SMS: short message service

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Original Paper

Tracker-Based Personal Advice to Support the Baby's Healthy Development in a Novel Parenting App: Data-Driven Innovation

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Abstract

Background: The current generation of millennial parents prefers digital communications and makes use of apps on a daily basis to find information about child-rearing topics. Given this, an increasing amount of parenting apps have become available. These apps also allow parents to track their baby's development with increasing completeness and precision. The large amounts of data collected in this process provide ample opportunity for data-driven innovation (DDI). Subsequently, apps are increasingly personalized by offering information that is based on the data tracked in the app. In line with this, Philips Avent has developed the uGrow app, a medical-grade app dedicated to new parents for tracking their baby's development. Through so-called insights, the uGrow app seeks to provide a data-driven solution by offering parents personal advice that is sourced from user-tracked behavioral and contextual data.

Objective: The aim of this study was twofold. First, it aimed to give a description of the development process of the insights for the uGrow app. Second, it aimed to present results from a study about parents' experiences with the insights.

Methods: The development process comprised 3 phases: a formative phase, development phase, and summative phase. In the formative phase, 3 substudies were executed in series to understand and identify parents' and health care professionals' (HCPs) needs for insights, using qualitative and quantitative methods. After the formative phase, insights were created during the development phase. Subsequently, in the summative phase, these insights were validated against parents' experience using a quantitative approach.

Results: As part of the formative phase, parents indicated having a need for smart information based on a data analysis of the data they track in an app. HCPs supported the general concept of insights for the uGrow app, although specific types of insights were considered irrelevant or even risky. After implementing a preliminary set of insights in a prototype version of the uGrow app and testing it with parents, the majority of parents (87%) reported being satisfied with the insights. From these outcomes, a total of 89 insights were implemented in a final version of the uGrow app. In the summative phase, the majority of parents reported experiencing these insights as reassuring and useful (94%), as adding enjoyment (85%), and as motivating for continuing tracking for a longer period of time (77%).

Conclusions: Parents experienced the insights in the uGrow app as useful and reassuring and as adding enjoyment to their use of the uGrow app and tracking their baby's development. The insights development process we followed showed how the quality of insights can be guaranteed by ensuring that insights are relevant, appropriate, and evidence based. In this way, insights are an example of meaningful DDI.

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KEYWORDS

data analytics; data-driven science; mHealth; mobile apps; infant development; infant health; parenting

Introduction

New Parents

The transition to parenthood, from being partners to also being parents, often represents an exciting but challenging phase. Most new parents are looking for knowledge about and advice on how to best take care of the new family member [1]. They might experience a need for more information when it comes down to the practical side of caring for an infant. Learning how to read their infants, interpret what their needs are, and correctly act upon this can feel as daunting tasks [2-4]. This was shown by, for example, Moran et al [5], who studied primipara and multipara women. They investigated on which baby care– and self-care–related topics these mothers desired information for after childbirth. Of the first-time mothers in the sample, up to 87% liked to receive more baby-care information, for example, on baby's illness, baby's schedule, and on how to soothe their baby when their baby was crying.

Changing Ways of Finding Parenting Information

Traditionally, parents have turned to their own parents or other close relatives and friends for information about infant care and parenting. However, over the last few decades, parents have found this traditional source of information increasingly difficult to rely on. First of all, because of globalization and increased mobility of the world population, young parents may live across the country, or even abroad, and thus they may be physically further removed from their loved ones than 30 to 40 years ago [6,7]. Moreover, as a study by O'Connor & Madge [1] showed, young parents experienced the child-rearing knowledge of their parents to be out of date and not reflecting current childcare practices. Therefore, nowadays, new parents often turn to other sources of information, such as books and the internet [1,6,8-11].

New Trends for Finding Parenting Information

Another trend is the widespread use of mobile phones, which enables new parents to look up child-rearing information even quicker. With their capacity to install and launch countless apps, mobile phones contribute to a lifestyle in which the population is always on the Web [12]. This especially holds for the so-called Millennial Generation that refers to the group of individuals who were born between 1981 and 1999. When growing up, a majority of them had access to personal computers, pagers, or cell phones. They are thought to enjoy utilizing technologies and have high expectations of the usefulness and availability of these technologies in all settings [13]. Millennial parents have been found to prefer digital communications (eg, through Facebook, email, and short message service text messages) [14] and make use of apps on an almost daily basis to find information about caring for their infants [15,16].

Parenting Apps

Unsurprisingly, more and more parenting apps have become available to support new parents; a quick search for parenting apps in the Google Play Store easily yields more than 50 hits within a second. These apps are becoming ever smarter, in that they do not only contain information about child-rearing topics but they also allow users to track the infants' development with increasing completeness and precision [16]. The often large amounts of contextual and behavioral data (referred to as big data) that are collected in (and in function of) the process provide ample opportunity for data-driven innovation (DDI) [17]. By means of different techniques—artificial intelligence, machine learning, data mining, and classification algorithms—the collected contextual and behavioral data can be analyzed and turned into meaningful, new information for the infant's parents or caregivers [18,19]. Given this, more apps are increasingly personalized by offering tailored information and personal advice on the basis of tracked app data [20]. Moreover, according to Johnson [20], apps are designed to be performative, that is, they induce or elicit users to act, for example, to change certain behaviors.

Insights

In line with these trends, Philips Avent has developed the uGrow app, a medical grade app dedicated to new parents for tracking their baby's development. It seeks to provide a data-driven solution by offering parents personal advice that addresses their needs and wishes, on the basis of behavioral and contextual data users have tracked in the app. To achieve this, the uGrow team has developed so-called insights. Insights refer to small pieces of text that are shown in the uGrow app on the basis of a technical rule. This rule analyses the data that parents have tracked in the app and defines when an insight text is presented to the user. For example, if a mother is keeping track of her baby's breastfeeds, an insight could be the following: *based on your tracked data, your left breast appears to steal the spotlight a little*. In this way, insights provide personal advice, tips, and information tailored to the unique situation of the parent and the baby. In Multimedia Appendix 1 a screenshot of uGrow can be found including an example of an insight.

Evidence-Based

In addition to being personal, the insights are evidence-based, that is, content is based on scientific publications, guidelines of prominent institutions, such as the American Academy of Pediatrics (AAP), and discussions with experts. This is an important requirement, as research has shown that only few apps contain information that corresponds to guidelines or are supported by scientific evidence. For example, a systematic review of quality of information on infant feeding apps showed that the information studied lacked credibility and reliability [21-26]. This lack of a solid evidence base can lead to misinforming users in the best case, and it can lead to adverse health outcomes in the worst [25,26]. Thus, to ensure quality and prevent providing parents with incorrect or unsubstantiated information, we set up and adhered to a controlled and systematic development process for the insights.

Goals of This Study

The aim of this study was twofold. The first was to give a description of the development process of insights for the uGrow app, that is, we reported on the steps that were taken from defining parents' and health care professionals' (HCPs) needs to the development of high-quality insights supporting parents in their parenting role. The second was to present results from a user study about parents' experiences with the insights and their opinion on whether insights are supportive, insightful, and help reassure that their infants are developing in a healthy way.

Methods

Study Phases

This study comprised 3 phases: a formative phase, development phase, and summative phase. The study started with a formative phase that had 2 goals: (1) understanding the needs and context of the primary target group—parents—and (2) understanding what HCPs think of an app for parents with which parents can track their baby's development. After the formative phase, the insights were created during the development phase. Subsequently, in the summative phase, these insights were validated against parents' experience. As mentioned in the introduction of this paper, this study took place in the context of the overall development process of the Philips Avent uGrow app.

Formative Phase

In the formative phase, 3 studies were executed in series to understand and identify parents' and HCPs' needs for insights: a Web-based community study, a study with HCPs and professionals, and an in-home user test. Each of these studies is described below.

Web-Based Community

The Web-based community study was executed to understand the role apps have for parents (to be) who want to track their baby's development. Parents (or parents-to-be) eligible for participation in the Web-based community either had a baby between 0 and 12 months old or were in the third trimester of their pregnancy, were interested in the Philips My Baby and Me app—the predecessor of the uGrow app—and were frequent app users. The parents (to be) received compensation for the time they spent on study participation. The Web-based community comprised a private website environment that was custom made for the purpose of this study. Participants of the study were invited to this website environment, in which they could access both shared and private pages. On the shared pages, the community moderator could, for example, ask open-ended questions or poll questions. The participants could answer these while interacting with each other and while engaging in group discussions. For example, participants were asked what the *baby's healthy development* means for them, and they were asked to upload photos of how they were tracking their baby's development at the time. On the private pages, the community moderator could ask participants individual questions or give them creative tasks. For example, the moderator could ask participants to rate the importance of tracking their baby's sleeping behavior on a 5-point Likert scale or rank questions (eg, *How much milk does my baby drink from his/her bottle every day?*) they have regarding parenting from most to least important. Thus, the Web-based community used a mixed-methods design, encompassing a qualitative and quantitative approach by combining Web-based focus group discussions, in-depth interviewing, and individual and group surveys. Through a screening process, parents were selected for participation in the Web-based community. After screening, all participants went through several steps, starting with the creation of an individual user profile, followed by warm-up discussions, polls, and individual tasks, and ending with follow-up discussions. Participants were able to communicate through text and visuals (eg, pictures, interactive visual tasks, and drawings). The data collected in the Web-based community comprised qualitative data, such as written text and pictures, and quantitative data, such as rating scale data. The qualitative data were analyzed using an inductive, qualitative analysis method [27], where the researchers coded and categorized the data to discover and define overarching themes and patterns. From the quantitative data, averages and percentages were derived. Subsequently, the analysis of the qualitative and quantitative data was combined to redefine the strongest overarching themes and patterns. In addition, the qualitative data were used to provide an explanation for the outcomes of the quantitative analysis.

Health Care Providers and Professionals

After conducting the Web-based community study, in-depth interviews with HCPs were performed to understand their ideas and needs regarding an app, such as uGrow, and its insights. Independent HCPs were recruited for the study on the basis of their professional experience with parents of newborns and their interest in digital innovations and apps. The HCPs were compensated for the time they spent on study participation. Before the interview, a recruitment agency shared background information of the HCPs and sent all HCPs a high-level list of questions to prepare for the interview. The interviews were semistructured, including an intake and introduction, followed by a discussion about the meaning of a baby's healthy development, the way in which HCPs support and advise parents in daily practice, and finally a discussion on the uGrow proposition, its features, and insights. The data gathered in the interviews were analyzed using a deductive, qualitative analysis method [27], where researchers analyzed the interview answers and defined overarching patterns.

Textbox 1. List of preliminary insights included in the in-home test.

- Longest nap so far!
- This was the biggest bottle yet!
- You've tracked 3 hours of breastfeeding!
- You've tracked 10 hours of breastfeeding!
- First full night's sleep (eight hours consecutively)!
- You expressed a new record today!
- Wow, slept three nights in a row!

In-Home User Test

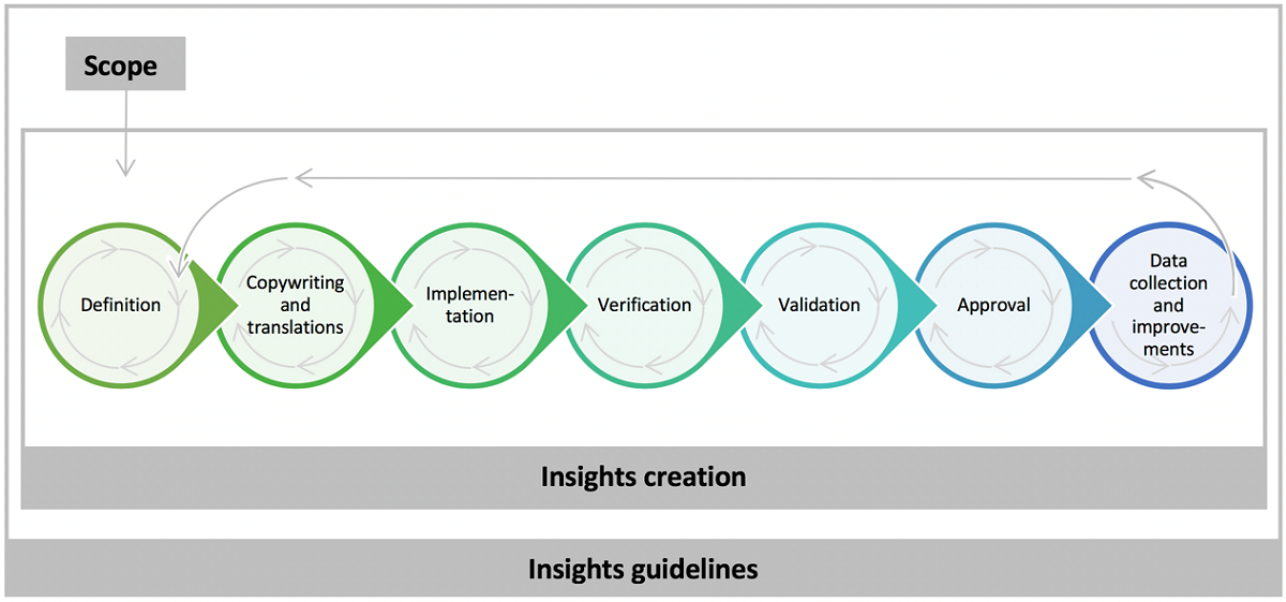
For the next study, a first version of the app, including a small set of preliminary insights (Textbox 1), was tested in an in-home user test. The aim of this test was to evaluate what parents think of the insights in the uGrow app and find out how insights might help parents in supporting their baby's healthy development. The parents taking part in this study received compensation for the time they spent on study participation. The participants were asked to use the app at home for a period of 3 weeks. During the first 2 weeks, participants used the app in their own desired way (free usage). During the third and final week of the test, participants received a series of 5 tasks, for example, *In the next 24 hours, please track all of your baby's feeds/naps*. After each of the 3 weeks, participants were asked to fill out a Web-based questionnaire containing both closed and open-ended questions.

The data collected in the in-home user test were analyzed using a deductive, qualitative analysis method [27], in combination with a quantitative analysis to derive averages and percentages.

Development Phase

The outcomes of the studies executed in the formative phase were used as input for the development of the insights. Before starting the actual development of the insights, we defined a process to ensure their controlled and systematic development. Through this process, we were able to guarantee the insights would be of high quality. Throughout the formative phase, we discovered that *quality* in the context of the insights is primarily rooted in 3 aspects. First, quality in terms of relevance, which addresses whether parents experience the topics addressed in the insights as being relevant. Second, quality in terms of appropriateness, which is about whether the insights fulfill a set of fundamental guidelines (eg, with respect to tone of voice, see section *Insights Guidelines*) to ensure success of the insights. Third, quality in terms of insights being evidence based, which means they are backed up by generally accepted guidelines or scientific evidence. To ensure this, we based insights on the general rule of thumb [8] that only information from scientific peer-reviewed literature, universities, volunteer organizations, and governmental organizations was used (eg, from United Nations Children's Fund, the World Health Organization, La Leche League, AAP, and the National Health Service). Throughout each step in the insights creation process, we iteratively monitored whether the insight text and rules were still in line with scientific evidence or national/international guidelines. To address the 3 different aspects of quality, the development phase of the first batch of insights comprised the following 3 steps (Figure 1): (1) insights scoping, addressing the relevance of the insights by defining relevant topics and types of insights, (2) insights guidelines, addressing the appropriateness of insights through a set of fundamental and generic guidelines, and (3) insights creation, encompassing the criterion that insights are backed up with guidelines or scientific evidence and developed in a controlled manner. Each of these steps is elaborated below.

Figure 1. Insights development process.



Insights: Scope

Scoping of the insights started with the selection of relevant topics. For the first version of uGrow, a limited number of topics were chosen for implementation. On the basis of the interviews with HCPs during the formative phase, feeding and sleep were concluded to be the most relevant topics for parents in the first months after the birth of their infant. Therefore, the first scope included the creation of insights on the topics of breastfeeding, bottle feeding, milk expression, and sleep. In addition, a small number of insights were added, which were related to other topics of the baby's development: crying, weight, and temperature.

Insights: Guidelines

On the basis of the results from the formative phase, several aspects were identified, which may influence whether parents experience insights in a negative or positive manner. These results were used to define and develop insights guidelines that were followed during the insights creation process. They encompass a set of rules to ensure that the insights will be successful. An insight is considered successful when parents interpret the insight correctly (eg, parents understand the message in the insights as it was intended) and when parents think it is useful and reassuring for their personal situation with their baby. Some examples of the guidelines are not to judge parents and to respect the choices they make, provide multiple angles to a problem or issue, as every child is unique, and keep in mind that although insights are backed up by professional expertise and scientific research, they do not replace an HCP.

Insights: Creation

The topics selected in the insights scoping process were the starting point for the insights creation process. It comprised the steps defined below (though not always in the fixed order as described), and was adhered to always with the insights guidelines in mind (Figure 1).

Definition

First, literature searches were conducted into the topics defined within the insights scoping process. Subsequently, on the basis of the information found in the literature, ideation sessions were conducted for developing draft ideas for the insights. Each insight draft comprised a piece of text to be shown to the user, as well as a technical rule defining when the insight should be presented. In addition, for internal use and quality control, the (scientific) references for each insight were documented. In a second ideation session, the insights text and rule definitions (or specifications) were finalized by reviewing them against the insights guidelines. Then, all insights went through a preliminary check by a legal, regulatory, clinical, and marketing board to further ensure their quality. Once the insights passed this check, they were moved to the next step in the creation process: copywriting and translation.

Copywriting and Translation

This second step took place in tandem with implementation and verification. After defining them, the insights texts were rewritten by a professional copywriter and translated into the local languages of the markets in which the uGrow app would be available.

Implementation

The insights were implemented in the uGrow app by the development team.

Verification

In this step, the insights were verified to ensure they were implemented according to their specifications (eg, to check whether an insight text was shown correctly in the app).

Validation

A set of prototypical insights was validated against user experience to understand whether parents were satisfied with the defined insights. We validated whether parents experienced the insights as adding enjoyment, as being useful and reassuring, and as being motivational. Validation of the insights either took

place after the definition phase, after copywriting and translation, or after the verification phase (see Figure 1 for these steps). When conducted after the definition phase or after copywriting and translation, validation comprised showing simple app prototypes (eg, simple screen versions) in a face-to-face user test and asking questions about the insights in these prototypes. When it took place after the verification phase, it comprised showing advanced, working app prototypes that included the insights, either in a face-to-face user test or in an in-home user test.

Approval

Insights were then formally documented, reviewed, and approved by the legal, regulatory, clinical, and marketing board before they could be released to the uGrow app in the field. For each insight, the documentation contained the final text of the insight, the technical rule specification, legal risk analysis, user risk analysis, validation results, and clinical substantiation.

Data Collection and Improvement of Insights

Once insights were live in the uGrow app in the field, they were monitored by collecting data mainly through but not limited to app analytics data and ratings and reviews. On the basis of the collected data, improvements for insights were defined and carried out.

Summative Phase

In the summative phase, the first full set of insights was validated against parents' experience through a postmarket survey in Germany. The uGrow app was launched in the Google Play Store and App Store in September 2016 in Germany and the United Kingdom. In this app release, 89 insights were included. After launch, a Web-based survey was conducted among German uGrow app users to validate parents' experience with insights in general, with respect to enjoyment, reassurance, and usefulness, and whether insights increased parents' motivation to use the app's trackers for a longer period of time. In addition, a selected group of individual insights was validated to investigate whether parents experienced insights as adding enjoyment, as being useful and reassuring, and as being motivational. The German users were targeted during this test, as Germany is a primary market for Philips Avent. Through email, users were invited to fill out a survey about their experience with the uGrow app. The emails of the users were collected via the Philips Avent customer relationship management system (CRM). The data of the survey were then analyzed in a quantitative manner.

Results

Formative Phase

Web-Based Community

The Web-based community study took place in the United States and China, and it was executed in January 2015. The study was conducted in these countries because of the business interest of Philips Avent in these territories. Furthermore, previous internal Philips studies indicated American and Chinese parents being open to digital innovations for parenting.

Study Population

A total of 60 participants took part in the Web-based community, of which 30 American participants were living in the United States and 30 Chinese participants were living in China. A total of 7 American participants were in their third trimester of their pregnancy, and 23 participants were parents with a baby between 0 and 12 months old, of which 17 were first-time parents. A total of 9 Chinese participants were in their third trimester of pregnancy, and 21 participants were parents with a baby between 0 and 12 months old, of which 14 were first-time parents. All participants taking part in the study had shown an interest in the Philips Avent My Baby and Me app—the predecessor of the uGrow app. They were frequent app users, talkative, and had good writing skills.

Results

Participants from both countries highly valued the development of their child: they support their children in finding their own identity, in exploring their individuality, and in making their own choices. Overall, American parents more often emphasized their wish to provide love, safety, and trust as a safe basis for their child to start exploring life. Chinese parents often indicated they distance themselves from the authority-based parenting style of their own parents, and they emphasized independence in raising their child. In both countries, most parents took a broad and holistic perspective to the healthy development of their child. In addition to the physical health and growth of their child, parents also emphasized the importance of their child's emotional and mental development. For example, on the one hand, parents thought about physical health and growth in terms of the child's weight gain. On the other hand, parents thought about the child's mood and whether they are achieving certain social-emotional milestones (eg, smiling, making eye contact). Tracking the physical aspects of the child's development (sleep, feeding, and growth) was most important to parents in the first weeks or months after the baby's birth. Parents used a wide range of tracking methods for this, such as taking paper-and-pencil notes, using excel files, and using forms provided by their HCP. Moreover, more and more often, parents used apps to track their child's development. Parents discussed that their usage of existing apps around the topic of child development was mostly focused on tracking the psychical aspects and milestones (special moments) of their child's development. Parents from both countries thought that the ability to track the general health, feeding sessions, and sleep/naps of the baby is an essential feature for a tracking app.

Parents in this study did not use apps to search for advice or information; they did not expect they could use an app for this. However, the Chinese parents in particular did use internet sources, such as blogs and Web-based communities. Parents perceived it as logical and relevant to have the app provide advice or information, that is, they thought it logical in the sense that an app in which they can track the baby's development can also offer general advice and information about the baby's development. In addition, they thought it relevant, as they could see how tracked data in the app can be used to provide them the right advice and information about their baby. Overall, in both countries, parents indicated they had a need for smart information on the basis of analysis of the data they tracked in

an app, on the baby's age and on the baby's development phase. When Chinese parents were asked about their ideal app, they first mentioned their need for tracking their baby's feeds, sleep, and growth, and then they mentioned their need for scientifically underpinned suggestions on the basis of data analytics. When American parents were asked the same question, they first mentioned the need for an easy-to-use solution, and then they mentioned the need for a solution that can track all important details of their baby's development (feeding, sleep, and growth). In the third place, American parents indicated the need for intelligent feedback, advice, and predications on the basis of smart data analysis.

Health Care Providers and Professionals

Interviews with Dutch, German, and British HCPs were conducted in August 2015. The HCPs were recruited from these countries because of 2 reasons. The first was accessibility, as the Philips department conducting this research was located in the Netherlands. Dutch HCPs were easiest to recruit. Next to that, German and British HCPs were recruited because of a shifting interest of the Philips Avent business in the British and German markets. The interviews with Dutch HCPs were conducted in a face-to-face meeting, and the interviews with German and British HCPs were conducted via a Web-based video meeting.

Study Population

A total of 10 HCPs took part in the study, of which 7 were Dutch, 1 was German, and 2 were British HCPs. The HCPs had a variety of backgrounds (Table 1).

Table 1. Participants' background and country.

Profession of health care professional	Country	Age	Sex
Pedagogue	Netherlands	48	Male
Pediatric nurse at the maternity ward in the hospital	Netherlands	56	Female
Pediatrician at the consultation office (*jeugdarts* in Dutch)	Netherlands	35	Male
Maternity caregiver at the consultation office	Netherlands	38	Female
Developmental psychologist	Netherlands	28	Female
Pediatrician at the consultation office (*jeugdarts* in Dutch)	Netherlands	35	Female
Pedagogue	Netherlands	42	Male
Pediatrician in the hospital	United Kingdom	46	Male
Pediatric nurse at the maternity ward and emergency unit in the hospital	United Kingdom	43	Male
Pediatrician in the hospital	Germany	42	Male

Results

First, overall, HCPs thought the uGrow app was relevant and useful to parents for keeping track of their baby's development. They saw the uGrow app as a supportive tool for parents to understand, be reassured about, and support their baby's development. They thought the app to be especially relevant for first-time parents of babies between 0 and 6 months old. In saying this, HCPs emphasized that the feeding and sleep sections in the uGrow app are most relevant for parents. HCPs explained that in the first months after their baby's birth, parents will primarily ask questions about 2 topics: first and foremost, parents' questions revolve around the baby's feedings, and then the questions revolve around the baby's sleeping behavior. Most HCPs saw some risks and limitations regarding the uGrow app, for example, some HCPs thought the uGrow app focused too much on only *measuring* the different aspects of the baby's development and focused too little on the emotional and social aspects of the baby's development. However, overall, HCPs were positive about recommending apps such as uGrow to parents, for whom they considered it appropriate and helpful. For example, a professional said the following:

> *[For] first time parents and parents unsure about the baby's development,...I would recommend [it].* [United Kingdom, Pediatrician]

Most HCPs stated that they want to be sure of the quality of uGrow before recommending it:

> *If the app is scientifically underpinned, it can be interesting to recommend it to parents. When the app focuses on the fun aspect and makes e.g. predictions about the baby's development, I would definitely not recommend this app.*

Second, overall, HCPs supported the concept of insights for the uGrow app. HCPs considered specific types of insights as relevant, but they also considered some as irrelevant or risky. An insight such as "The average daily sleep time of baby is 14 hours 21 minutes" was considered relevant by most HCPs, and they did not see any risk or harm associated with insights of this type. HCPs had more mixed opinions about an insight such as "Congratulations, you have breastfed your baby for 10 hours already!" Some HCPs considered insights of this type relevant, as they are encouraging and rewarding:

> *This insight encourages and rewards mums who are breastfeeding their baby. I like this insight.*

Other HCPs were not supportive of these type of insights:

> *This encourages mums to breastfeed their baby for more hours, that's not something we want to encourage. It is better to say eg, 10 days of breastfeeding.*

Some other HCPs viewed these type of insights as too game like, which, in their view, does not fit this type of app, and which might even make the app unprofessional. Most HCPs were supportive of insights, such as "Your baby has taken 500 ml today. HCPs recommend to feed a baby of Liam's weight between 450 and 650 ml. So, Liam is eating well!" Some HCPs were critical toward the part in the insight that states "Liam is eating well," as this might be a wrong conclusion, and they thought this conclusion should be drawn by the parent and not the app:

> *I think the app shouldn't draw the conclusion "Liam is eating well," I would leave this open for the parents to decide.*

Other HCPs were more open to the app drawing a conclusion:

> *Drawing a conclusion can be good, to tell parents that everything is ok with the baby.*

Some HCPs also considered it the responsibility of the app to inform parents when their baby is receiving too little or too much milk. In addition, some HCPs mentioned that they thought not all parents would be interested in professional guidelines, but they thought that parents might only be interested in whether their baby is happy with the feeding session. HCPs thought several elements are important for the insights in the uGrow app, for example, HCPs considered it important to clearly communicate to the parents what the target group is for the insights in the app—do the insights apply to preterm babies and sick babies? HCPs also considered it the app's responsibility to provide potentially confronting information to parents, for example, when the baby's development falls outside the norm. Some HCPs mentioned that it is difficult to predict how parents will interpret and experience an insight: "What if it isn't going well with the parent or the baby?" Furthermore, they considered it important to thoroughly evaluate insights from multiple angles. HCPs considered it important that insights guide parents in interpreting the information provided and do not present a one-and-only truth. Another point mentioned by HCPs was about the importance of underpinning insights with scientific evidence and linking insights to articles with more detailed information. All HCPs indicated that insights should not replace an HCP, but insights should complement HCPs' work. HCPs thought that in that way, insights can help educate parents and answer simple questions for which they would otherwise have contacted their HCP. HCPs also indicated that it is important to inform parents to contact an HCP when they are in any doubt about the information provided in the insights.

In-Home Use Test

The in-home use test was conducted in September 2015 in the Netherlands.

Study Population

In total, 49 Dutch parents were invited to participate in the study, of which 32 parents completed all phases of the in-home use test. Of these 32 parents, 78% (25) were mothers and 22% (7) were fathers. All parents had at least one child in the age range of 0 and 3 months. The parents were between 21 and 40 years old. Furthermore, all parents were already tracking 1 or more aspect(s) of their baby's development at the start of the study.

Results

The majority of parents noticed they received insights (Textbox 1) that were based on data they had tracked in the uGrow app during the 3-week test period. The *longest nap so far* and *biggest bottle* insights were seen by two-third of the parents after 2 weeks of app usage. The other insights were seen by a smaller part of the parents. For example, a third of parents saw the *breastfeeding for 3 hours* insight after 2 weeks of usage, and a fifth of the parents saw the insight *full night's sleep* after 2 weeks of usage. The majority of parents indicated that they experienced the amount and frequency of insights as good. Overall, most parents, 88% (28 out of 32), were satisfied with the insights. Parents gave 4 types of reasons for why they were satisfied. First, some parents indicated they experienced insights as personal:

> *The app understands me. It makes it very personal.*

Second, parents indicated that they experienced insights as rewarding, supportive, and positive:

> *It feels as a kind of reward.*
>
> *Lovely to read my child did something very well. I am not always aware of it in busy daily life.*

Third, a part of the parents indicated experiencing the insights as motivating:

> *It makes you curious, what would the next insight notification be? Therefore, you keep on using the app.*

Finally, some parents indicated that they were satisfied with the insights, as they helped them to become more aware of their baby's development:

> *Some changes do not attract my attention because I'm always busy with my child. It can be difficult to see changes in feeding and sleep rhythm. That's why I like the app pointing out small, but big changes.*

Some parents, 9% (3 out of 32), were neither satisfied nor dissatisfied with the insights:

> *To me it doesn't really add something, but I like reading them*
>
> *The only reason I got the biggest bottle message was because I have difficulties entering the exact feeding amount in the tracker field*

A small part of the parents, 3% (1 out of 32), was dissatisfied with the insights:

> *I received the notification "first time slept through the night," this was the first time for the app, but since we have only started using this app after a couple of months, this happened much earlier already. The notification is not correct. Perhaps you can phrase it in a question: was this the first time sleeping through the night?*

Table 2. Participants' evaluation of individual insights (N=32).

Insight	(Very) positive[a,b], n (%)	Neutral[a], n (%)	Negative[a], n (%)
Longest nap so far!	28 (88)	2 (6)	2 (6)
This was the biggest bottle yet!	23 (72)	7 (22)	2 (6)
You've tracked 3 hours of breastfeeding!	28 (88)	4 (12)	0 (0)
You've tracked 10 hours of breastfeeding!	26 (80)	6 (20)	0 (0)
First full night's sleep (8 hours consecutively)!	26 (80)	6 (20)	0 (0)
You expressed a new record today!	16 (50)	16 (50)	0 (0)
Wow, slept 3 nights in a row!	16 (50)	0 (0)	16 (50)

[a]Absolute number.

[b]Note that for the analyses we merged the categories *very positive* and *positive*.

A majority of parents, 70% (22 out of 32), indicated that they experienced insights as being motivational. A total of 26% (8 out of 32) of parents experienced the insights as neutral: neither motivating nor not motivating. A few parents, 3% (1 out of 32), experienced insights as not motivating. When evaluating the individual insights, at least half of the parents evaluated the individual insights as (very) positive (Table 2).

Furthermore, parents mentioned some novel ideas for the insights. For example, insights about milestones related to the baby's age, insights about the time awake between naps, insights about the duration between bottles, insights about switching between breasts, and insights about how the baby is doing compared with the population average.

Development Phase

In the first launch of the uGrow app, a total of 89 insights were implemented. They focused on babies in the age range of 0 to 3 months. They were primarily about feeding and sleep as parents, as mentioned before, generally have most questions about these topics in the first period after the baby's birth. In addition, insights about crying, weight, and temperature were implemented in the uGrow app. The distribution of the number of insights over the different topics was as follows:

- 17 breastfeeding insights
- 20 bottle feeding insights
- 20 expressing insights
- 15 sleep insights
- 7 crying insights
- 2 weight insights
- 8 temperature insights

Summative Phase

Study Population

After the first version of the uGrow app was launched, the Web-based postmarket survey was executed in Germany. Participants who created a uGrow app account and signed up for the Philips CRM program received an email invitation to complete the postmarket survey. Participants completed the survey on a voluntary basis. In total, a convenience sample of 54 German uGrow app users completed the full postmarket survey.

Results

Parents first answered a number of general questions about the insights: 85% (46 out of 54) of users reported to (fully) agree with the statement that insights add enjoyment to the usage of the uGrow app. A total of 11% (6 out of 54) of users reported to neither agree nor disagree with this statement, and 4% (2 out of 54) of users reported to disagree with this statement. A total of 94% (51 out of 54) of users reported to (fully) agree with the statement that insights are reassuring and useful. A total of 6% (3 out of 54) of users reported to neither agree nor disagree with this statement. A total of 77% (42 out of 54) of users reported to (fully) agree with the statement that insights motivate to continue tracking for a longer period of time. A total of 22% (12 out of 54) of users reported to neither agree nor disagree with this statement.

Furthermore, a subset of insights was evaluated individually. At least 78% (42 out of 54) of the parents liked all insights but one. In case parents did not answer they liked an insight, they were mostly neutral about it (neither liked nor disliked it), and only in a few cases did parent answer they disliked an insight. Overall, the percentage of parents that (very much) disliked an insight was between 0% and 3% (0 to 3 out of 54). Only in 1 case, 6% (3 out of 54) of parents (very much) disliked an individual insight. Table 3 shows the evaluation of the individual insights by parents.

Table 3. Participants' evaluation of individual insights (N=54).

Insight	(Very) positive[a,b], n (%)	% Neutral[a], n (%)	% Negative[a], n (%)
Your little one is almost 4 weeks old. It's common for a growth spurt to happen around this time, so don't be surprised if you see a change in Sara's feeding pattern.	51 (94)	3 (6)	0 (0)
Your baby's temperature is on the high side for a newborn. Best to keep a close eye on his/her health, and consider checking in with your GP[c].	49 (91)	3 (6)	2 (3)
Heads up: It's actually completely normal for babies to wake up at night. This happens because their day and night rhythm is still developing. Over time, exposure to daylight and your own daily rhythm will help them to develop a sleep rhythm that's close.	49 (91)	4 (7)	1 (2)
From your tracked feeds, we've noticed that your left breast is stealing the spotlight a little. Feeding evenly from both breasts can lead to a more stable milk supply, especially in the first few weeks.	46 (85)	8 (15)	0 (0)
Over the last week, you've tracked around 670 ml of bottle feeds per day. This is the recommended amount for babies between 4.5 kg and 5 kg.	43 (80)	10 (18)	1 (2)
Good news, your baby no longer has a fever. His/her temperature has gone down by 1.2 degrees since the last reading that you took today.	43 (80)	11 (20)	0 (0)
Heads up: Your baby may take longer than others to regain her birth weight because she was born on the larger side.	42 (78)	9 (16)	3 (6)
Around a month ago, your tracked bottle feeds averaged 490 ml per day. Now, you track on average 670 ml per day.	42 (78)	11 (20)	1 (2)
Did you know that three quarters of all mums express more milk from one breast? Based on your tracked sessions, you've expressed around 60 ml of milk from your left breast, and 40 ml from your right breast.	42 (78)	11 (20)	1 (2)
Nice work! You've recorded 3 hours of breastfeeding!	31 (57)	22 (41)	1 (2)

[a]Absolute number.

[b]Note that for analyses we merged the categories *very positive* and *positive*.

[c]GP: general practitioner.

Discussion

Principal Findings

The aim of this study was twofold. First, this study described the development process of high-quality insights for the uGrow app in the context of supporting parents with their baby's healthy development. Second, this paper presented results of a user study about parents' experiences with the insights and their opinions on whether these are supportive, insightful, and help reassure that their baby is developing in a healthy way.

Development of Insights

Before the actual development process of the insights, user studies with parents and HCPs took place to understand their needs within their contexts. Throughout the formative phase, we discovered that quality of the insights is primarily rooted in 3 aspects: relevance of the insights, appropriateness of the insights, and insights being evidence based. In this study, we described how these 3 aspects of quality can be embedded in a systematic and controlled development process, comprising scoping, guidelines, and a creation process. The insights scoping addressed whether parents experience topics covered in the insights as being relevant. The insights guidelines were about ensuring the appropriateness of the insights through a set of fundamental guidelines, which were kept in mind throughout the creation process. Subsequently, the insights creation process defined an iterative and step-wise approach to creating and implementing them. The insights creation process ensured that the texts and rules of the insights were evidence based. Throughout the insights creation process, from initial definition up to final approval, insights were iteratively reviewed and eventually approved of from multiple angles: user experience, clinical, regulatory, legal, and marketing.

Parents' Experience

In the formative phase, a series of user studies were conducted. The results of the Web-based community showed that, first, when thinking about their ideal baby tracking app, American and Chinese parents have a need for smart advice and information on the basis of data analytics. Parents could see how data tracked in the app can be used to give them the right information about their baby. Subsequently, the results of the interviews with HCPs showed that they support the concept of insights; they can see insights as a supportive tool for parents for understanding and being reassured about their baby's development. In the in-home user test, a preliminary set of insights were evaluated by Dutch parents. The results of this test showed that most parents, 88% (28 out of 32), were satisfied with the insights. Parents indicated 4 reasons for this: they experienced insights as personal, as rewarding, supportive and positive, as motivating, and as helpful in better understanding their baby's development. After development and implementation of the first batch of insights, the postmarket

survey was conducted as part of the summative phase. The results of this survey showed that German and British parents experienced the insights as adding enjoyment to the usage of the app (85%: 46 out of 54), as being useful and reassuring (94%: 51 out of 54), and as motivational (77%: 42 out of 54). When parents did not agree with a statement, they indicated they neither agreed nor disagreed with it. Overall, this shows that insights have the potential to support parents in their parenting role and positively impact app experience.

Discussion of Findings

Quality and Quantity of Insights

As stated in the introduction, the quality of health information offered in apps is an issue, and this is increasingly brought forward by both medical professionals and users [28-32]. The development process for the insights we described in this paper presents a way in which the 3 essential aspects of quality—relevance, appropriateness, evidence-based—can be embedded in a systematic and controlled development process. The process presented here covers standard phases, such as definition, design, implementation, verification, validation, and maintenance, as well as phases described in known and industry-standard software development process models (eg, waterfall model, incremental model, V-model, and agile model). Furthermore, standard user-centered design principles have been applied while developing the insights. Both the parents' and professionals' perspectives were addressed by iteratively involving both user groups in the process. In this way, we could ensure quality of the content provided in the insights on all of the 3 quality aspects. With respect to quantity, the overload of health information on the Web has been identified as a serious problem [33]. Insights address this problem in 2 ways. First, the information in the insights is targeted, and it is thus more personal, as it is based on actual data of the baby that their parents have tracked in the app. Second, the information is more dosed, as insights only encompass a few lines of text and only link to an article with more in-depth information if necessary. Thus, in summary, insights in the uGrow app have been created in close collaboration with the target group, and they are relevant, appropriate and evidence-based, and tailored for the user. In this way, insights provide a solution to common issues with respect to quantity and quality found on the Web and in apps.

Follow-Up Questions

As summarized above, in our user studies, we found that parents think insights help them in better understanding their baby's development. An interesting and relevant follow-up question is whether that understanding could contribute to parent-child bonding and attachment. From the literature, we know that (psycho-)education may improve bonding and attachment and reduce parental stress [34-36], and that that may improve parenting skills [37-39] and maternal sensitivity [38,40-42]. In addition, a positive association has been found between parental sensitivity and secure infant attachment [43-45], which in turn has been found to have positive physical, psychological, social, and cognitive long-term effects [46-49]. Taken together, one could argue that as insights contribute to parents' improved understanding of their infant's development, they may positively affect the development of bonding and attachment. However, as we did not collect information on these topics, follow-up research is required to investigate this hypothesis further. Another interesting question pertains to the personal nature of our insights. As it has become clear from the abovementioned, insights are intended to support parents in understanding their baby's development and providing them with relevant information and education about that. To be able to do this, effective relay of the information provided in the insights is essential. Available literature shows that, in comparison with general communication, personalized communication stimulates active processing of information significantly more, and it thereby facilitates information adaptation [50-52]. From our postmarket survey, we learned that parents experience the insights as being personal. Given this, it can be argued that insights could present a more effective way than larger-scale communications to promote and support parents regarding the healthy development of their baby. Follow-up research by means of questionnaires and interviews could help answer the question whether information from the insights is indeed adapted more easily than that from mass communications.

Strengths and Limitations

This study knows a number of limitations. First, the findings from the validation studies described in this paper are based on Dutch and German parents, and they are thus not generalizable to other countries, especially not to nonwestern countries in, for example, Africa and Asia. Furthermore, the current insights have been based on globally accepted evidence, and they thus present a global solution. This means that the insights might not be tuned to local conceptions; therefore, insights might not be culturally sensitive. In addition, the sample size was relatively small, and the studies encompassed relatively short evaluation periods. A strong element of the findings in this paper is that they are based on multiple iterations and interactions with both parents and professionals. Furthermore, the insights are highly evidence-based and cover a wide variety of topics related to the infant's development. In addition, as parents experienced insights as highly positive, the professional and parent perspective come together nicely in the insights.

Conclusions

The uGrow app is one of the first apps that shows how insights based on tracked app data can be useful and reassuring for parents in supporting their baby's healthy development and how they can add enjoyment to app usage. The insights development process that was followed shows how quality of the insights can be guaranteed in terms of insights being relevant, appropriate, and evidence-based, by following a systematic and controlled development process. Furthermore, the insights in uGrow provide an example of DDI by turning the tracked data of the baby into meaningful advice for parents, which may potentially support parent-infant bonding and attachment.

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Conflicts of Interest

The authors of this paper were employed by Philips Consumer Lifestyle BV and Philips Electronics Nederland BV.

Multimedia Appendix 1

From left to right the uGrow tracker menu, the timeline including an insight, and a graph of tracked sleep data.

[PDF File (Adobe PDF File), 169KB - mhealth_v7i7e12666_app1.pdf]

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Abbreviations

AAP: American Academy of Pediatrics
CRM: customer relationship management
DDI: data-driven innovation
HCP: health care professional

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Original Paper

A Mobile Phone–Based Intervention to Improve Mental Health Among Homeless Young Adults: Pilot Feasibility Trial

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Abstract

Background: Youth homelessness is a substantial issue, and many youths experiencing homelessness have mental health issues as both a cause and consequence of homelessness. These youths face many barriers to receiving traditional mental health services, and as a result, only a few youths experiencing homelessness receive any form of mental health care.

Objective: This project aimed to develop and determine the feasibility and acceptability of engaging young adults (ie, individuals aged 18-24 years) experiencing homelessness in a remotely delivered mental health intervention. This intervention provided brief emotional support and coping skills, drawing from cognitive behavioral principles as an introduction into psychosocial support. The intervention was piloted in a homeless shelter network.

Methods: A total of 35 young adults experiencing homelessness participated in a single-arm feasibility pilot trial. Participants received a mobile phone, a service and data plan, and 1 month of support from a coach consisting of up to 3 brief phone sessions, text messaging, and mobile mental health apps. We evaluated feasibility by looking at completion of sessions as well as the overall program and acceptability with satisfaction ratings. We also collected clinical symptoms at baseline and the end of the 1-month support period. We used validity items to identify participants who might be responding inappropriately and thus only report satisfaction ratings and clinical outcomes from valid responses.

Results: Most participants (20/35, 57%) completed all 3 of their phone sessions, with an average of 2.09 sessions (SD 1.22) completed by each participant. Participants sent an average of 15.06 text messages (SD 12.62) and received an average of 19.34 messages (SD 12.70). We found higher rates of satisfaction among the participants with valid responses, with 100% (23/23) of such participants indicating that they would recommend participation to someone else and 52% (12/23) reporting that they were *very* or *extremely* satisfied with their participation. We found very little change from pre- to posttreatment on measures of depression (d=0.27), post-traumatic stress disorder (d=0.17), and emotion regulation (d=0.10).

Conclusions: This study demonstrated that it was feasible to engage homeless young adults in mental health services in this technology-based intervention with high rates of satisfaction. We did not find changes in clinical outcomes; however, we had a small sample size and a brief intervention. Technology might be an important avenue to reach young adults experiencing homelessness, but additional work could explore proper interventions to deliver with such a platform.

Trial Registration: ClinicalTrials.gov NCT03620682; https://clinicaltrials.gov/ct2/show/NCT03620682

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KEYWORDS

mental health; homelessness; telemedicine; treatment

Introduction

Youth homelessness is a substantial issue. In 2018, 36,361 youths, that is, those younger than 25 years, experienced homelessness on a single night [1], and this number is higher when individuals experiencing housing instability or insufficient housing are included. Youth homelessness is a complex phenomenon that spans a continuum of experiences from street-based youth to shelters to unstable accommodations. In a previous literature review, we found that the stresses of homelessness have adverse consequences on physical and mental health among youth [2]. Individuals experiencing homelessness have high rates of mental illness and substance misuse, nearly twice as high as those among their housed peers [3]. Youth experiencing homelessness have disproportionate rates of emotional and behavioral problems [4-6]. Estimates suggest that nearly two-thirds of homeless youth meet criteria for a psychiatric disorder [7], with particularly high rates of depression and anxiety [8,9]. Unfortunately, the vast majority of homeless individuals have little or no access to comprehensive health care and virtually no access to mental health services. Many of the realities of homelessness make receiving mental health care, especially traditional face-to-face services, more challenging. For example, it is often difficult for individuals experiencing homelessness to make and keep scheduled appointment times given the frequency of other time-urgent demands that supersede scheduled activities.

As such, traditional mental health services may be ineffective at reaching and addressing the needs of this population. One complement to traditional mental health services that could help overcome some of these barriers would be technology-based treatment options [10]. Such options include resources such as teletherapy, text messaging, and mobile apps. Technology may be an especially promising strategy to engage hard-to-reach populations. For example, Fortney and colleagues [11] showed that a telemedicine outreach program for rural veterans increased engagement in post-traumatic stress disorder (PTSD) treatment. Moreover, technology may be especially suited for engaging youth given that they have mobile phones, and many report being online *almost constantly* [12]. Indeed, access to health care services is insufficient and much lower than the general population, but individuals experiencing homelessness, including youth and adults, have a level of access to mobile technologies comparable with similar aged peers. One-fourth of homeless young adults report using the internet for more than an hour a day (most often accessed via mobile devices) [13,14], and rates of mobile phone ownership are also high (eg, ranging from 44% to 62%) [15,16], with those aged between 18 to 29 years accounting for the top end of that range [17]. Mobile technology may be even more important for people who lack a fixed place of residence. Mobile phones allow for social connections, searching for resources, and entertainment (to pass time) that are important parts of survival when faced with homelessness or unstable housing.

Thus, technology-based resources have the potential to be useful for homeless youth. A first question is what types of resources might yield themselves to technology-based interventions in this population. A few studies have suggested that cognitive behavioral therapy (CBT) delivered in shelters can lead to significant decreases in depression and other mental health problems and improvements in self-efficacy [18,19]. However, these studies have demonstrated considerable barriers to engagement. In 1 study, only treatment completers displayed significant benefits, and over half of the young adults who began treatment discontinued after the first session [19]. Thus, evidence-based practices must be provided in ways that are appropriate and acceptable for the setting and population.

Notably, CBT principles are amenable to delivery both in very brief formats [20] and also via technology [21]. For example, Schleider and Weisz [22] showed that in a group of high-risk adolescents, a single-session computer-guided growth mindset intervention led to greater improvements in depression and anxiety than a supportive-therapy control with lasting effects. To our knowledge, there are no published studies providing mental health interventions to homeless youth via technology. Our previous work exploring the interest of homeless youth in the use of mobile technology for mental health purposes indicated that youth would be most eager to receive help in the form of emotional support, help with life decisions, managing day-to-day stressors, problem solving, advice, and dealing with difficulties related to homelessness [23]. Thus, we were interested in building a very brief intervention, leveraging CBT principles that could serve as an initial step to engage youth in mental health services and alleviate distress with support and coping skills. Given these goals, we deemed this intervention the Stepping Stone project.

In this study, we evaluated the feasibility, acceptability, and preliminary benefits of a multicomponent mobile phone–based intervention for homeless young adults. Although youth refers to those younger than 25 years, we only engaged those in the age group of 18 to 24 years who were receiving services from a homeless shelter network focused on this age group. Feasibility was determined based on the young adults' engagement with various components of the program. Acceptability was determined based on satisfaction ratings of the program as a whole as well as its different components. Finally, preliminary benefits were explored by examining changes in symptoms of depression, PTSD, and emotion regulation. To do so, we conducted a single-arm pilot trial of our multicomponent intervention recruiting participants from an urban homeless shelter network.

Methods

Participants

Participants were recruited from January 2016 to November 2017 from a homeless shelter network located in Chicago, IL, United States. Young adults responded to flyers distributed throughout the shelters or were referred to the study by their

case manager. Potential participants were screened at the shelter by a member of the study staff. If eligible and interested, the participant went through the informed consent process and then filled out a series of baseline assessments on an iPad. These assessments collected information about demographics, trauma history, experience with technology and with the mental health care system, and current psychological symptoms. After completion of the surveys, they were provided with a mobile phone with an activated data plan, phone case, and headphones. Participants were then shown how to use the 3 study apps and were given tips on conserving data usage and using the phone responsibly and safely in an urban space including how best to secure their phones both physically (eg, keeping it safely concealed in certain spaces) and digitally (eg, setting up a password).

The eligibility criteria included (1) aged between 18 and 24 years, (2) English-speaking, and (3) homeless as defined by lacking "a fixed, regular, and adequate nighttime residence," and sleeping in a Chicago-based shelter for at least 4 nights of the past week. In the initial phase of the study, we had the additional inclusion criterion that participants must have had a self-reported history of physical or sexual abuse before the age of 17 years. This criterion of childhood abuse was removed a year and a half into the study (corresponding to 24 participants) to allow us to reach more young adults who could benefit from the program. The exclusion criteria included (1) cognitive impairment that would prevent them from understanding or fully engaging in study procedures, (2) involvement in any psychotherapy or legal proceedings that would impact participation, and (3) significant suicidal ideation or behaviors or alcohol or substance dependence in the past 6 months. The substance dependence exclusion criterion was removed a year and a half into the study (corresponding to 28 participants) as long as participants were able to engage in the study procedures.

Procedures

This pilot trial was approved by the Rush University Medical Center institutional review board. People interested in participating completed an initial intake interview and, if eligible to continue, were offered participation in the pilot trial. We referred to the developed intervention program as the Stepping Stone Project, which was a name collaboratively developed with young adults in focus groups. More information about the other substantive findings of these focus groups are reported elsewhere [23]. The name Stepping Stone highlighted that this intervention was viewed as an introduction into mental health services that could hopefully serve as a bridge to other services once individuals were engaged. All Stepping Stone participants received a mobile phone (Nexus 5, LG Electronics) preloaded with 3 mental health apps developed at the Center for Behavioral Intervention Technologies (Pocket Helper, Purple Chill, Slumber Time described below), a service and data plan, and 1 month of support from a coach in the form of three 30-min phone sessions, as well as opportunities to contact the coach outside of these sessions by phone and text. Coaches were trained therapists experienced in providing treatment in homeless settings. The apps transmitted data to a secure and encrypted University server, and the phone used for text messaging the participants was a University-owned mobile phone that was password protected and encrypted. Participants were provided with training around best practices for maintaining security of their phones including adding a password. Participants completed assessments at baseline and at 1 month. Participants were compensated for completing assessments in the form of the service and data plan. All participants received 1 month of a service and data plan at first. If they completed the endpoint assessment, they received an additional 5 months of service and data for a total of 6 months. Compensation was not tied to engagement in phone sessions or app use.

Mobile Phones and Phone Apps

Three apps were preinstalled on all mobile phones before distribution to study participants. All participants were asked to use the phones provided by the study and were provided help transferring over their contacts and other phone data if necessary. The service plans were linked to the phones provided to the participants to reduce the likelihood that participants would use multiple phones during the study period. The preinstalled apps included Pocket Helper, which is a daily survey app developed specifically for this study based on focus group input from homeless young adults from the same shelter network [23] and 2 apps (Purple Chill and Slumber Time) from the IntelliCare suite [24,25]. IntelliCare is a collection of mini-apps focused on specific behavior change strategies. We describe these apps in more detail below.

Pocket Helper

Pocket Helper is an app that consists of a daily survey and a daily coping skills–focused tip. Data entered into the app were displayed as feedback to the participant and sent to a coach dashboard. Figure 1 displays screenshots from the app highlighting these main features. The daily survey was intended to take no more than 5 min to complete and asked questions about a participant's stress level, sleep duration and quality, and the biggest challenge they faced that day. Each daily tip drew randomly from a set of 30 tips that focused on various coping strategies or motivational messages. Tips were sent to participants as push notifications and were also viewable from the home screen when the app was launched. Most tips were associated with either a picture or video that were displayed when the push notification was triggered or could be viewed within the app by expanding the view of the tip from the home screen.

Pocket Helper was also accompanied by a coach dashboard (Figure 2) that provided the coach with real-time updates regarding information entered into the app. Coaches could view results from a participant's daily surveys as well as their ratings of coping skill tips. The intention of the dashboard was to allow the coach to incorporate this information into their phone sessions, to use this information as context for the text messages, and to identify the types of skills that might be helpful for each participant based on their needs (stress level and challenges) and interests (responses to daily tips).

Figure 1. Screenshots of the Pocket Helper app.

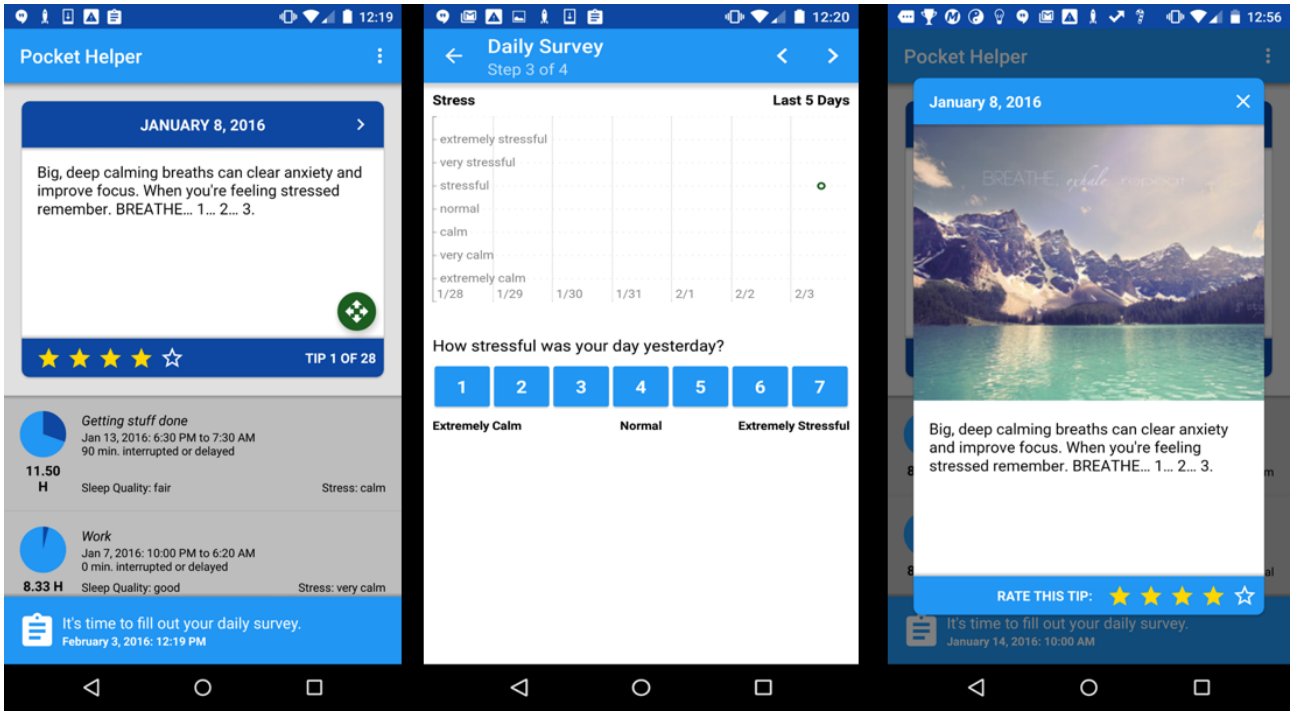
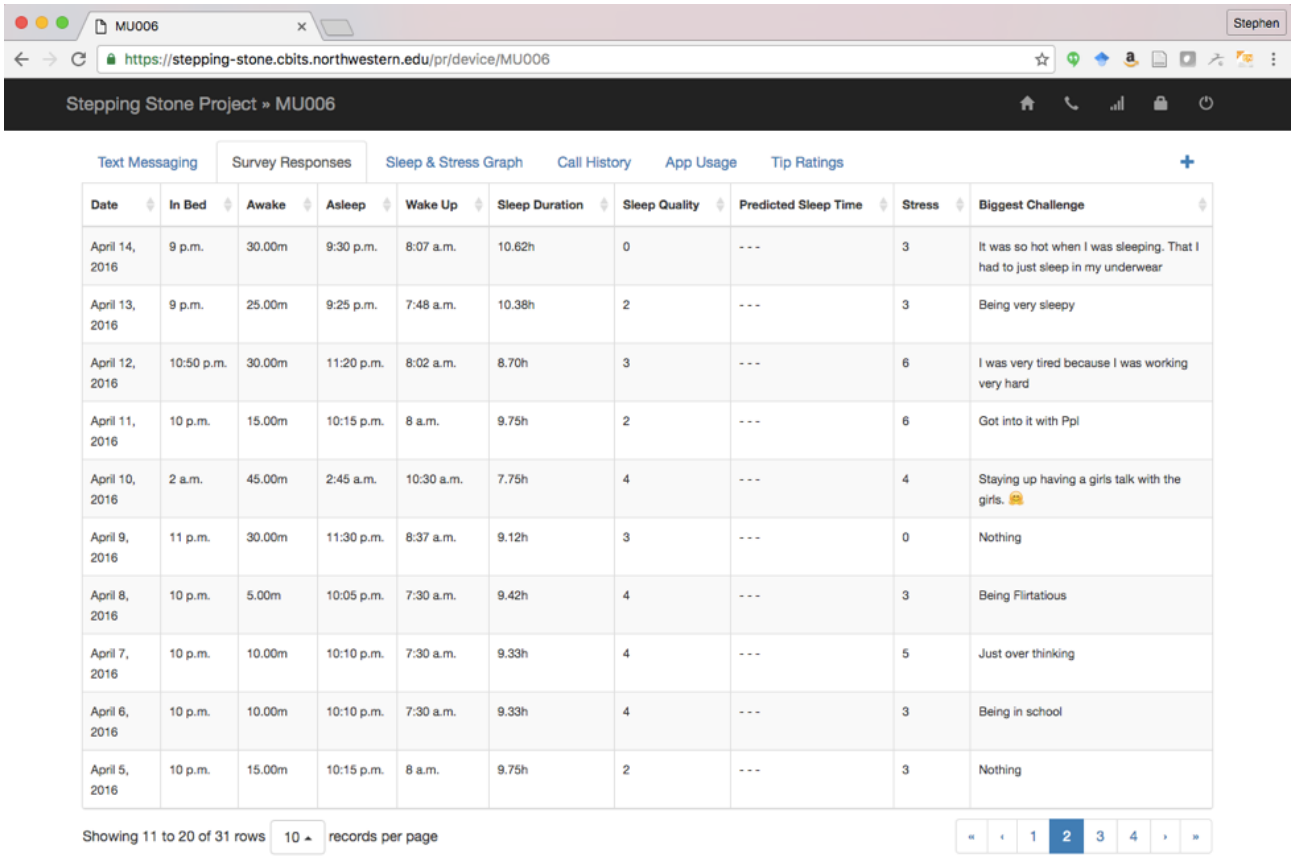


Figure 2. Coach dashboard for the Pocket Helper app.



Date	In Bed	Awake	Asleep	Wake Up	Sleep Duration	Sleep Quality	Predicted Sleep Time	Stress	Biggest Challenge
April 14, 2016	9 p.m.	30.00m	9:30 p.m.	8:07 a.m.	10.62h	0	---	3	It was so hot when I was sleeping. That I had to just sleep in my underwear
April 13, 2016	9 p.m.	25.00m	9:25 p.m.	7:48 a.m.	10.38h	2	---	3	Being very sleepy
April 12, 2016	10:50 p.m.	30.00m	11:20 p.m.	8:02 a.m.	8.70h	3	---	6	I was very tired because I was working very hard
April 11, 2016	10 p.m.	15.00m	10:15 p.m.	8 a.m.	9.75h	2	---	6	Got into it with Ppl
April 10, 2016	2 a.m.	45.00m	2:45 a.m.	10:30 a.m.	7.75h	4	---	4	Staying up having a girls talk with the girls.
April 9, 2016	11 p.m.	30.00m	11:30 p.m.	8:37 a.m.	9.12h	3	---	0	Nothing
April 8, 2016	10 p.m.	5.00m	10:05 p.m.	7:30 a.m.	9.42h	4	---	3	Being Flirtatious
April 7, 2016	10 p.m.	10.00m	10:10 p.m.	7:30 a.m.	9.33h	4	---	5	Just over thinking
April 6, 2016	10 p.m.	10.00m	10:10 p.m.	7:30 a.m.	9.33h	4	---	3	Being in school
April 5, 2016	10 p.m.	15.00m	10:15 p.m.	8 a.m.	9.75h	2	---	3	Nothing

IntelliCare Apps

IntelliCare is a modular treatment suite consisting of 13 mini-apps, each focused on a singular behavior change technique drawn from CBT and positive psychology [24,25]. IntelliCare has been shown to be effective at reducing depression and anxiety in an 8-week single-armed field trial where participants received the IntelliCare app suite along with brief coaching to support engagement [25]. We selected a subset of the IntelliCare apps that were consistent with content included in the Pocket Helper app as well as that reinforced through the manual for the phone sessions. The 2 IntelliCare apps selected for inclusion

in this study were Purple Chill and Slumber Time. Purple Chill provides users with a library of audio recordings that draw from mindfulness, progressive muscle relaxation, deep breathing, and imagery exercises. The goal of Purple Chill is to help promote relaxation and mindfulness practices to reduce stress and worry. Slumber Time prompts the user to complete sleep diaries to track sleep. It provides users with a bedtime checklist based on evidence-based sleep hygiene strategies. It also includes audio recordings to facilitate rest and relaxation and an alarm clock feature to facilitate sleep tracking.

Phone Sessions and Coaches

All participants were eligible to receive up to three 30-min sessions with the coach over the course of 1 month; these sessions were conducted over the phone. The first session was either scheduled during the onboarding procedure conducted in the shelter, or the coach contacted the participant within 24 hours of onboarding to provide a brief introduction into the schedule and protocol for sessions. Subsequent sessions were scheduled either during the first session or via call, text, or email. These sessions were designed to help provide coping skills to participants in line with CBT principles. We used a modular manualized format in which we outlined the general structure of the 3-session format and identified specific skills and strategies that could be provided based on a participant's needs and preferences.

The session format was as follows: session 1 consisted of orientation and identification of goals, problems, and resources; session 2 consisted of a check-in on progress and a dedicated focus on a specific topic or skill; and session 3 consisted of reviewing progress and discussing steps for moving forward. The skills and strategies outlined in the manual included the following: psychoeducation, problem solving, mindfulness, relaxation, emotion regulation, imagery rehearsal, sleep hygiene, distress tolerance, interpersonal effectiveness, and safety planning. Session content drew from principles of cognitive behavioral approaches; the session structure was not based on any particular treatment but drew from our experience in designing and delivering mobile-based mental health treatments. Participants were also instructed that they could text message the coach at times outside of these scheduled sessions or set up a brief check-in call of approximately 10 to 15 min. For our initial participants, these consisted of *Virtual Office Hours* in which the coach set aside 1 hour each weekday during which participants could call or text with the coach and receive either 15 min of time over the phone or up to 5 text messages per office hour. After 5 participants, however, we found that few participants were making use of these *Virtual Office Hours*, and we received feedback that this was because the times set each day were not convenient for the participants. As such we moved to a model where participants could text message coaches or set up a brief check-in at times outside of their scheduled sessions and would receive an answer within working hours within no less than 24 hours (except on the weekends).

Sessions, phone, and text messaging support were provided by clinical psychology postdoctoral fellows (AKR and CLD). These fellows underwent weekly supervision where they provided updates on their current participants, the activities in the phone sessions, and any outreach made via text messages. The content of all text messages was transcribed and stored, and coaches completed a form outlining their activities during the phone sessions to indicate the skills and strategies that were covered.

Assessment and Measurement

Participants completed a series of self-report assessments during enrollment and again at the conclusion of the 1-month intervention.

Demographics

Demographic information was collected using a 20-item questionnaire developed by the study team. This was administered only at the baseline session. Variables assessed included age, race and ethnicity, gender, sexual orientation, educational, employment, homelessness status, and history of head injuries.

Experience With Technology

Current technology usage habits were assessed using a 10-item Technology Questionnaire. This was administered only at the baseline session. This questionnaire was created by the study team and asked individuals to respond to items indicating the types of devices used (ie, desktop computer, laptop computer, tablet, and mobile phone), and how often they have access to a mobile phone, phone reception, and Wi-Fi. Items also asked how often they used texting, email, and mobile apps, and what incentives and barriers there were to using telemental health resources.

Depression

Current depressive symptoms were assessed using the 9-item Patient Health Questionnaire (PHQ-9) [26]. The PHQ-9 asks participants to rate how 9 symptoms have affected them in the past 2 weeks. Response options range from 0 (*Not at all*) to 3 (*Nearly every day*). Higher scores indicate greater symptom severity.

Emotion Regulation

Adeptness in identifying and regulating emotions was assessed using the 36-item Difficulties in Emotion Regulation Scale (DERS) [27]. The DERS asked participants to respond to items indicating their level of introspection regarding their emotions and their thoughts and behaviors when they feel upset. Response options range from 1 (*Almost never*) to 5 (*Almost always*). There are 6 subscales including nonacceptance of emotional response, difficulty engaging in goal-directed behavior, impulse control difficulties, lack of emotional awareness, limited access to emotion regulation strategies, and lack of emotional clarity. Eleven items are reversed scored, and higher scores indicate greater problems with emotion regulation.

Post-Traumatic Stress Disorder

Current symptoms of PTSD were assessed using the 20-item PTSD Checklist for Diagnostic and Statistical Manual of Mental Disorders-5 (PCL-5) [28]. The PCL-5 is a self-report measure that asks individuals to rate symptoms in the past month based on 1 event that causes them the most distress. Items are rated on a scale of 0 (*Not at all*) to 4 (*Extremely*). Higher scores indicate greater symptom severity.

Experience With Mental Health Treatment

Lifetime experience with mental health and psychiatric treatment were assessed using a 19-item Treatment Questionnaire, developed by the study team. Individuals responded to questions asking if they had ever, or if they currently, received one-on-one therapy, attended support groups, used self-help resources (books, websites, and mobile phone apps), or taken medication for psychological problems.

Trauma Exposure While Enrolled in Study

Participants were asked to report whether or not they had been exposed to 12 different types of traumatic events during the 1-month study period using a modified version of the Traumatic Events Questionnaire [29]. Specifically, participants were asked about their exposure to the following events *since beginning the study*: a serious transportation accident; serious fire or explosion; serious accident at work, home, or during recreational activity; a natural disaster; physical assault; sexual assault; an unwanted or uncomfortable sexual experience; combat; danger of losing their life or being seriously injured; witnessing someone who was mutilated, seriously injured, or violently killed; or receiving the news of the mutilation, serious injury, or violent or unexpected death of someone close. Item 13 allowed participants to describe any other very traumatic events that occurred during the study period that were not accounted for by the events listed. Participants were considered to have been exposed to trauma during the study period if they said yes to any of the 12 items or said yes to item 13 and provided a sufficient description of a potentially traumatic event.

Program Feedback

Feedback on and satisfaction with various aspects of the study (ie, coaching sessions, daily tips, daily surveys, and IntelliCare apps) were assessed using a 20-item Feedback Questionnaire created by the study team. This was administered only at the endpoint session. Satisfaction with the different aspects of the study was indicated on a 5-point Likert scale. Open-text responses were also provided for participants to describe what they liked most and what they liked least about the coaching sessions, office hours (or contact with the coach outside of scheduled sessions), and the Pocket Helper app. Participants were also asked to give suggestions to improve the study.

Data Analysis

Due to the challenges associated with remote data collection, we instituted several procedures to ensure data quality including attempts to reduce missing data by having research staff follow up with participants, incentivizing completion of questionnaires, and offering to set up in-person meetings to promote survey completion. We also attempted to evaluate the validity of the completed self-report measures. Included in both the baseline and follow-up survey were 4 validity questions. These validity question items were placed at the end of a survey and asked the participant to respond with a certain answer. For example, a validity question embedded in the PCL-5 stated “For this question, please select the answer ‘A little bit’.” If an individual completed more than 1 of these incorrectly, their data were considered to be invalid. For clinical outcomes, which were based on self-report questionnaires, we analyzed data from the 22 participants who completed the study and provided valid responses to both the pre- and postassessment. For satisfaction data, which were completed only at the postassessment, we reported on data from all 26 participants with a valid postsurvey. Because participants received the mobile phones, apps, and phone sessions regardless of providing self-report data, we included all participants’ reports of their use of the apps, sessions, and text messaging to demonstrate feasibility of working in this population.

Results

Sample

A total of 35 participants consented and were enrolled in the field trial. Figure 3 outlines the recruitment flow as well as engagement with the intervention. These participants had an average age of 19.06 years (SD 0.85). Most of the participants were women (23/35, 65%), with 31% (11/35) men and 1 transgender (1/35, 3%). Participants were predominantly African American (23/35, 66%), 9% were white (3/35), 17% mixed race (6/35), 3% other (1/35), and 6% either refused or did not know (2/35). In addition, 20% of the sample reported being Hispanic (7/35). The demographics of these homeless youth are reflective of national trends, which show disproportionate ethnic minorities and lesbian, gay, bisexual, transgender, queer, or questioning youth experiencing homelessness [1]. We also asked participants several questions related to educational and occupational attainment and past experiences with homelessness. A total of 21 (21/35, 60%) participants were either in school or employed. Although many of our participants had completed high school (14/35, 40%) quite a few reported less than a high school education (11/35, 31%). Half of the sample reported experiencing homelessness before the age of 18 years (17/34, 50%) with 1 participant noting that their earliest experience with homelessness was at the age of 3 years. Although for many participants this was their first experience with homelessness (13/35, 37%), the rest of participants reported they were homeless between 2 (7/35, 20%) to 10 (2/35, 6%) separate times. We compared those participants who provided valid responses at pre and post as determined by our validity items with those who did not provide valid responses and found no significant differences on any of these characteristics. The clinical characteristics of valid responders at baseline and endpoint are displayed in Table 1.

Figure 3. Participant flow through recruitment and intervention.

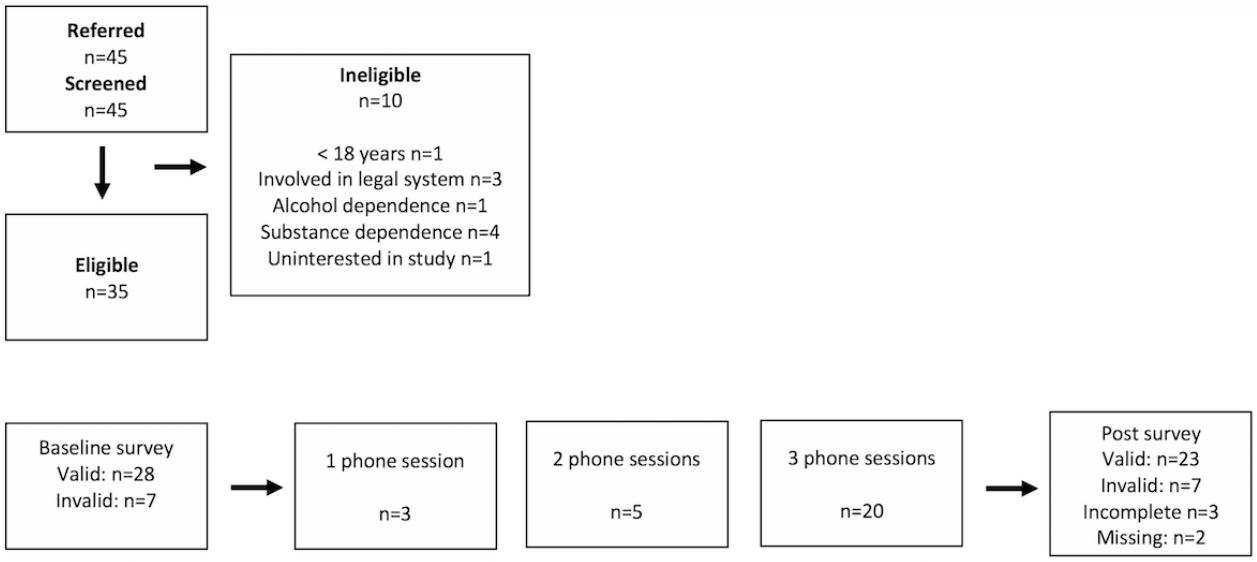


Table 1. Clinical characteristics of sample at baseline and endpoint (1 month).

Outcome	Baseline, mean (SD)	Endpoint, mean (SD)	Probable disorder at baseline, n (%)	Probable disorder at endpoint, n (%)
Depression[a]	11.2 (8.0)	10.1 (8.2)	10 (46)	10 (50)
Post-traumatic stress disorder[b]	32.4 (23.8)	28.2 (23.1)	11 (50)	9 (42)
Emotion regulation	88.9 (30.6)	87.0 (34.6)	No clinical cutoff exists	No clinical cutoff exists

[a]Clinical cutoff for probable depression ≥ 10.

[b]Clinical cutoff for probable post-traumatic stress disorder ≥ 33.

We also assessed participants' access to and use of various technologies at baseline including computers, mobile devices, and the internet. Most of our participants had mobile phones (25/35, 71%) before receiving one as part of participation in this study, although the type of mobile phone varied considerably. Participants also had access to a variety of other devices including desktops (24/35, 69%), laptops (21/35, 60%), and tablets (19/35, 54%). Similarly, most participants reported having cellular access (20/35, 57%) and access to Wi-Fi for at least half of the waking day (21/35, 60%) although it is worth noting that 20% of our participants (7/35) noted they did not have Wi-Fi access for any part of the day. Use of text messaging and email appeared to be similarly high with 63% (22/35) endorsing texting at least a few times per day and 60% (21/35) endorsing checking email at least a few times per day. Thus, although internet access and use is not ubiquitous, it is quite high.

Few of our participants reported either current or past experience with mental health treatments, with only 17% (6/35) engaged in current and 37% (13/35) engaged in past individual therapy, 3% (1/35) engaged in current and 31% (11/35) engaged in past group therapy, and 6% (2/35) receiving current and 23% (8/35) receiving past medication. Thus, according to self-report, this is a fairly treatment-naïve population.

Session Attendance and App Use

Most participants (20/35, 57%) completed all 3 of their phone sessions with an average of 2.09 sessions (SD 1.22) completed by each participant. The complete breakdown of the number of sessions completed by participants is provided in Figure 3. It is worth noting that the distribution of sessions was not normally distributed, as the second most frequent number of sessions completed was zero (7/35, 20%). Participants sent an average of 15.06 text messages (SD 12.62) to the coach during the 1-month period or just fewer than 4 text messages per week. Coaches sent slightly more with an average of 19.34 text messages (SD 12.70) or just under 5 text messages per week. There was a correlation between the number of sessions attended and the number of text messages a participant sent (r=.35, P=.04) but not the number of text messages the coach sent (r=.28, P=.11). We also examined whether valid responding on the validity items corresponded to increased engagement either in the number of phone sessions attended or the number of text messages sent. Participants who answered the validity items incorrectly attended significantly fewer sessions (mean 1.23) than participants who answered the validity items correctly (mean 2.59, t_{33}=−3.74, P=.001). This was not the case for text messages sent by participants, t_{33}=−0.62, P=.54.

As mentioned previously, we also had our coaches track session content using a reporting form with codes drawing from the topics included in our manual. A total of 73 sessions were provided, and 66 had codes. Of the sessions with codes, 17 had multiple codes with 16 including 2 codes and 1 including 3 codes resulting in 84 total codes across all sessions. The sessions most commonly addressed interpersonal issues (16/84, 19%)

or stress management (15/84, 18%). Other common topics included goal setting (9/84, 11%), emotion regulation (8/84, 10%), and family conflict (6/84, 7%). Consistent with our skills-focused approach, very few sessions covered exclusively psychoeducation (1/84, 1%).

Satisfaction

Satisfaction with the intervention was high, with 100% (23/23) of participants indicating that they would recommend the study to someone else and 52% (12/23) reporting that they were *very* or *extremely* satisfied with the study and the Stepping Stone project. However, less than half indicated they thought it was helpful (10/23, 43%), so it is unclear what their rationale for satisfaction and the recommendation were based on. The most popular component of the intervention was the daily tips, with 64% (14/22) indicating they liked them *quite a bit* or *a lot*. Participants were less enthusiastic about the IntelliCare apps (6/23 or 26% indicating liking them *quite a bit* or *a lot*). The coach support (11/23, 48%), and the office hours (10/23, 43%) were also less popular than the daily tips but received higher satisfaction rating than the IntelliCare apps.

Almost half of participants found the skills they learned in session to be beneficial (11/23, 48%), and almost as many report that they regularly used the skills (10/23, 43%). The intervention length was deemed appropriate by most participants with 56% (12/23) indicating that the 1-month intervention was *just right*. Use of skills learned during coaching sessions was significantly positively related to satisfaction with Pocket Helper (r=.78, P<.001) and other skills apps (r=.46, P=.03).

Feasibility and Safety

We logged all issues that occurred with regard to mobile phones provided to participants. Mobile phone loss (through damage, theft, or other loss) was an anticipated event in this study, and we budgeted mobile phones such that we would be able to replace phones of participants if problems occurred. Overall, we replaced 4 mobile phones during the study period. Two of these phones were replaced because of theft, and 2 phones were replaced because of issues with the device. Issues with the device were a result of our mobile service provider switching carriers, which resulted in complications with access to service. This represents a phone replacement rate of 11% (4/35) and a theft rate of 6% (2/35). The cause of phone loss was obtained through self-report, with the exception of replacements because of issues with mobile service, which was validated independently by our research team through communication with the mobile service provider.

In addition to mobile phone loss, we also closely monitored the use of mobile phone data. All participants received a service plan consisting of unlimited calls and text messages and a data plan consisting of 5 GB of data per month. Although we encountered some issues with participants exceeding this data limit, most participants were able to adopt strategies to allow them to remain within this data cap including monitoring data use on their device and switching to Wi-Fi when secure networks were available. During a period where data caps were temporarily suspended, we did have 1 participant use over 100 GB of data mostly because of streaming videos and music, which demonstrates the tendency to use devices as entertainment devices, which can result in large data demands.

Clinical Outcomes

Participants experienced very little change on clinical outcomes with small effect sizes for symptoms of depression, d=0.27, and effect sizes of d=0.17 for symptoms of PTSD and d=0.10 for emotion regulation. Given the small sample size, none of these changes were significant (all P s>.50). Notably, 45.5% (10/22) of the participants reported exposure to trauma during the 1-month intervention period. Exposures to traumatic events included the following: 18.2% (4/22) serious transportation accident; 18.2% (4/22) physical assault; 13.6% (3/22) serious danger of death or serious injury; 13.6% (3/22) witnessed someone who was mutilated, seriously injured, or violently killed; 9.1% (2/22) serious accident at work, home, or during recreational activity; 9.1% (2/22) received news of the mutilation, serious injury, or violent or unexpected death of someone close; and 4.5% (1/22) natural disaster (note, some individuals had exposure to multiple events). We conducted a post hoc analysis to determine if trauma during the intervention period affected clinical outcomes. Using a multivariate repeated measures analysis of covariance, there were no significant differences in clinical change between those who did and did not have trauma exposure ($F_{3,16}$=2.44, P=.10); however, there did appear to be a different pattern in changes. Given the small sample size of this study and the resultant statistical power, we will still comment on these changes as exploratory analyses. In this regard, we noted that on average, those who had not experienced a traumatic event during the intervention period had a reduction in PTSD symptoms (mean decrease 6.42, SD 22.01), almost no change in depressive symptoms (mean increase 0.33, SD 3.89), and slightly poorer emotion regulation from pre- to posttreatment (mean increase 1.00, SD 22.41). Those who experienced a traumatic event had an increase in PTSD symptoms (mean increase 3.78, SD 26.67), t_{19}=0.96, P=.35, d=0.42, a very small decrease in depressive symptoms (mean decrease 2.25, SD 6.96), t_{18}=−1.07, P=.30, d=−0.49, and slight improvements in emotion regulation (mean decrease 3.89, SD 22.48), t_{19}=−0.49, P=.63, d=−0.22.

Discussion

Principal Findings

This study is the first attempt to deploy and evaluate a mobile phone–based intervention to address the mental health needs of young adults experiencing homelessness. Our findings demonstrated promising results regarding the feasibility and acceptability of such an intervention. Most participants engaged with the program and reported they were satisfied with their participation, although less than half reported that they found the program helpful. Our goal in this study was to establish whether it would be possible to consider digital interventions as a means to bridge individuals until they are ready for care or act as adjunctive elements to more traditional treatment.

Although this pilot feasibility trial was neither designed nor powered to determine the efficacy of the intervention on clinical outcomes, our exploratory results suggest several points for

consideration in future studies. For example, most participants experienced only slight improvements in symptoms of depression, PTSD, and emotion regulation as indicated by small effect sizes quantifying the change. We found larger benefits in PTSD symptoms for those who did not experience traumatic events during the course of our 1-month intervention, but those participants also had slight increases in symptoms of depression and emotion dysregulation. Overall, it seems that our intervention was an attractive way to engage young adults experiencing homelessness, but further work might need to consider proximal outcomes that correspond to long-term outcomes of interest and the most effective interventions to deploy within this style of engagement.

In terms of feasibility, we found that engagement with the program tended to be bimodal with most participants completing either 0 or 3 of the offered phone sessions, although nearly 3 times as many participants completed 3 sessions than 0 sessions. This tends to be quite a different pattern from engagement in technology-based interventions more generally where most people who start do not continue with the intervention after an initial use [30]. Moreover, there were no incentives to participate in the intervention, only to complete the study assessments. This seems to suggest that the young adults found something valuable in these calls to continue to engage and that barriers for dropping out were low (as indicated by those who dropped out without completing any sessions). We also found that participants who did not answer our validity questions correctly were also less likely to engage in the phone sessions. As such, it might be possible to determine who is likely to engage long term through early indicators, potentially even as early as patterns of responding to baseline questionnaires. In our other work with technology-based interventions, we have similarly found that the way people use programs can indicate who is likely to persist over time [31].

In terms of acceptability, we found high levels of satisfaction with the program as a whole as well as many of the individual components. Specifically, the daily tips and Pocket Helper app was viewed positively by the young adults. Interestingly, this was the part of the program that was developed specifically for this population, based on our formative work with residents of the same shelter network [23]. Participants also commented positively on the frequency and length of intervention, although some did request additional flexibility with scheduling the coach support components of our program. This desired flexibility prompted us to change the text messaging support from scheduled *office hours* to text messages as needed because participants indicated that the scheduled times were often not convenient for them. We had initially used this scheduled format as we were concerned that participants might overuse the opportunity to text and thus overwhelm our study coach, but that was not the case and the load of around 4 text messages each week was very much manageable.

Findings for satisfaction and acceptability, however, did not correspond to statistically or clinically significant changes on clinical outcomes. Although these findings might be due to our small sample size, it is also worth considering if other factors were at play. For example, perhaps the participants appreciated the attention and support but did not have enough opportunities or structure in their day-to-day lives to implement the skills learned. Another possibility is that the clinical outcomes overlooked other improvements in well-being, such as sense of connection or validation, that might have been worth exploring. Future work might consider more flexibility in the intervention both in terms of content and dosing as well as exploring alternative means of understanding impact. It is worth considering if the dose of the intervention negatively affected the potential to find benefits as three 30-min sessions over a 1-month period is a relatively light intervention, especially in the context of the stressors and challenges faced by homeless young adults. It might be the case that a longer intervention or an intervention of similar length but targeted at times of high need might be more beneficial for homeless young adults. For example, young adults could be monitored through daily surveys as used in our program, and phone support could be initiated when users face significant challenges such as traumatic events or interpersonal stressors or have needs related to work or school placement. Identifying a treatment strategy that will lead to clinical benefits while remaining feasible for youth is an important direction for future research.

Limitations and Future Work

Our findings are worth contextualizing with regard to the limitations of our design and methods and the formative stage of this work to inform the delivery of technology-based interventions to meet the needs of individuals experiencing homelessness. First, we focused on quantitative data to assess satisfaction and feasibility, and qualitative data could have helped elaborate some of the satisfaction and feasibility issues, particularly the potentially conflicting results on high satisfaction and low helpfulness. Second, although we had fairly broad eligibility criteria, we did allow for some iteration in these criteria during the study. As noted, we removed the criterion related to substance or alcohol dependence but only after 5 potential participants had already been screened out because of those criteria. Of those 5 participants, however, 3 were also receiving concurrent counseling that would also have made them ineligible for this study. Third, it is impossible to disentangle the impact of the clinical intervention (eg, the apps, phone sessions, and text messaging) from receiving a mobile phone with data service. Access to a mobile device with internet connectivity may be an intervention in and of itself. Some research shows that mobile devices may be used by individuals to help cope with stressful situations and when used appropriately can improve psychological and physiological functioning [32]. Games, music, and communication features can all be used to distract or deal with negative emotions, and young adults talked about using mobile devices in this way in our formative work [23]. Finally, although the mobile apps from the IntelliCare suite received the lowest satisfaction ratings of any aspect of the program, it is worth noting that those apps were not deeply integrated into our intervention. We only used 2 of the 13 available IntelliCare apps and did not have specific coach support focused on engagement with those apps as has been tested elsewhere [25]. It would be worth exploring if a full deployment of IntelliCare could be useful for homeless young adults.

Although our satisfaction ratings might be viewed as somewhat mixed given the positive reviews of the program as a whole, the lower ratings of the coach support and office hours, and the lowest ratings of the IntelliCare apps, it is also worth comparing these ratings with satisfaction with other mental health services, especially among young adults experiencing homelessness. Indeed, past work has demonstrated that homeless young adults have low rates of satisfaction with mental health services and that issues of mistrust must be overcome in engaging these young adults successfully in treatment. Our overall rate of 57% of participants completing all of their sessions compares favorably with outpatient psychotherapy generally [33], which is noteworthy given that individuals experiencing homelessness are likely harder to engage and retain than other populations of those with mental health needs. Future work might consider ways to provided *blended* forms of treatment that combine technology and face-to-face treatments or leverage technology to improve the ability of young adults experiencing homelessness to flexibly and successfully engage with treatment. We also note that we developed a multicomponent intervention with support for some but not all elements. Future work might consider this study as a starting point to contribute to the screening phase for Multiphase Optimization Strategy designs, which aim to combine intervention elements into a package for refinement, optimization, and testing [34].

We again note that the impact on clinical symptoms was small and somewhat disappointing in light of the high levels of engagement and positive evaluation of the program we received from the participants. Future work should also assess more proximal outcomes that might mediate subsequent symptom change. Judging from the topics covered in our sessions, outcomes worth assessing would be interpersonal functioning and social support, emotion regulation and coping, and goal setting and problem solving. It must be noted that many of our participants reported using the skills they learned in the sessions and through the apps, but it would be worth evaluating this. Unfortunately, the impact of our intervention on clinical symptoms was small to moderate, with the exception of symptoms of PTSD for individuals who did not experience traumatic events or depression symptoms for those individuals who did experience traumatic events during the intervention period. As noted previously, it is possible that our intervention did not provide a proper dose of treatment. Another possibility is that the intervention itself, but not the delivery platform, may have been a poor fit for our population. Although we used CBT-based coping strategies based on past work that indicated benefits of cognitive behavioral treatments for individuals experiencing homelessness [18,19], we did not engage in a process of specific population–focused tailoring or adaptation. Our coaches did have experience of more generally providing psychotherapy to homeless populations; however, the modularized, brief support provided through our intervention differed from their other clinical experiences. It might be worthwhile to engage in a process of tailoring modularized or common treatment approaches, similar to that we used, to homeless young adult populations. Such approaches have been used in various low-resource settings such as low- and middle-income countries and have demonstrated promising results [35,36].

Conclusions

This pilot trial of a mobile phone–based mental health intervention for homeless young adults provides mixed support for the promises of such an intervention moving forward. On one hand, we found high rates of engagement and satisfaction, which is noteworthy especially among a population that typically has low rates of trust and satisfaction with mental health services. On the other hand, we found only small benefits in symptoms of mental health issues such as depression, PTSD, and emotion regulation. Given this was a pilot study focused on feasibility and acceptability, we caution against over interpretation of these findings. Nevertheless, we would remiss if we did not note that the extent of changes in clinical symptoms were smaller than we had hoped. We think future work could consider more proximal outcomes to clinical symptom change, as well as other outcomes linked to intervention engagement such as interest in mental health resources, mental health literacy, or mental health stigma. In addition, future research should consider whether intervention content or dose could be modified to be more appropriate for the platform we developed. As such, we believe the major contribution of this study is that it reveals important lessons about engaging homeless young adults using mobile technology. These lessons include the benefits of consistent outreaches (ie, tips and text messaging) as well as the success of providing mobile phones and remote interventions without significant safety issues or loss of devices. We hope further studies continue to explore best ways to create engaging and impactful mental health interventions for homeless young adults and believe this study demonstrated potential ways that technology could play an important role in improving mental health care access for this population.

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Conflicts of Interest

None declared.

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Abbreviations

CBT: cognitive behavioral therapy
DERS: Difficulties in Emotion Regulation Scale
PCL-5: PTSD Checklist for Diagnostic and Statistical Manual of Mental Disorders-5
PHQ-9: 9-item Patient Health Questionnaire
PTSD: post-traumatic stress disorder

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Original Paper

Leveraging Positive Psychology to Support Smoking Cessation in Nondaily Smokers Using a Smartphone App: Feasibility and Acceptability Study

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Abstract

Background: Nondaily smoking is an increasingly prevalent smoking pattern that poses substantial health risks.

Objective: We tested the feasibility of using a smartphone app with positive psychology exercises to support smoking cessation in nondaily smokers.

Methods: In this prospective, single-group pilot study, nondaily smokers (n=30) used version 1 of the *Smiling Instead of Smoking* (SiS) app for 3 weeks while undergoing a quit attempt. The app assigned daily happiness exercises, provided smoking cessation tools, and made smoking cessation information available. Participants answered surveys at baseline and 2, 6, 12, and 24 weeks after their chosen quit day and participated in structured user feedback sessions 2 weeks after their chosen quit day.

Results: App usage during the prescribed 3 weeks of use was high, with an average 84% (25.2/30) of participants using the app on any given day. App use was largely driven by completing happiness exercises (73%, 22/30) of participants per day), which participants continued to complete even after the end of the prescribed period. At the end of prescribed use, 90% (27/30) of participants reported that the app had helped them during their quit attempt, primarily by reminding them to stay on track (83%, 25/30) and boosting their confidence to quit (80%, 24/30) and belief that quitting was worthwhile (80%, 24/30). Happiness exercises were rated more favorably than user-initiated smoking cessation tools, and 80% (24/30) of participants proactively expressed in interviews that they liked them. App functionality to engage social support was not well received. Functionality to deal with risky times was rated useful but was rarely used. Within-person changes from baseline to the end of prescribed use were observed for several theorized mechanisms of behavior change, all in the expected direction: confidence increased (on a 0-100 scale, internal cues: b=16.7, 95% CI 7.2 to 26.3, P=.001; external cues: b=15.8, 95% CI 5.4 to 26.1, P=.004), urge to smoke decreased (on a 1-7 scale, b=−0.8, 95% CI −1.3 to −0.3, P=.002), and perceptions of smoking became less positive (on a 1-5 scale, psychoactive benefits: b=−0.5, 95% CI −0.9 to −0.2, P=.006; pleasure: b=−0.4, 95% CI −0.7 to −0.01, P=.03; on a 0-100 scale, importance of pros of smoking: b=−11.3, 95% CI −18.9 to −3.8, P=.004). Self-reported abstinence rates were 40% (12/30) and 53% (16/30) of participants 2 and 24 weeks post quit, respectively, with 30% (9/30) biochemically validated as abstinent 2 weeks post quit.

Conclusions: A smartphone app using happiness exercises to aid smoking cessation was well received by nondaily smokers. Given the high nonadherence and dropout rates for technology-delivered interventions reported in the literature, the high engagement with positive psychology exercises is noteworthy. Observed within-person changes and abstinence rates are promising and warrant further development of this app.

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KEYWORDS

smartphone; mHealth; smoking cessation; happiness; cigarettes

Introduction

Background

Cigarette smoking continues to be the leading cause of preventable disease and death in the United States, accounting for more than 480,000 deaths every year [1]. Although the prevalence of smoking has steadily declined over a number of years [2], an increasingly prevalent pattern of smoking is nondaily smoking. Currently, 24.3% of all adult smokers are nondaily smokers, which constitutes a 27% increase in prevalence in the last decade [3]. Nondaily smoking poses substantial health risks [4,5]. It is disproportionally represented in ethnic minority groups [6-10] and increasingly prevalent in adults with a mental health or substance use problem [11]. For smoking in general, substantial disparities continue to exist. In the general population, the prevalence of smoking is 15.5% [2]. This rate is substantially higher among American Indians and Alaska Natives (31.8%), persons with no more than a high school diploma/General Education Diploma (40.6%), persons living below the poverty level (25.3%), lesbian, gay, or bisexual adults (20.5%), and adults with serious psychological distress (35.8%) [2]. New patterns of smoking coupled with persisting disparities call for renewed efforts to provide easily accessible and engaging tobacco cessation support.

One promising emerging treatment option for providing such support is the use of smartphone apps. Smokers are motivated to quit smoking. Recent estimates suggest that 69% of all smokers want to quit; 52% made a quit attempt in the past year, but only 6% successfully quit [12]. Proven treatment strategies exist to support smoking cessation [13], increasing quit success rates from 5% in persons trying to quit smoking without support, to 16% with behavioral support, and 24% with combined behavioral and pharmacological support [14]. Existing treatments, however, are currently underutilized by smokers, with only 32% of current smokers having used counseling and/or medication when they tried to quit smoking [12]. Smartphone apps offer a way of providing behavioral counseling without the need to access the health care system or overcome logistical barriers to present for in-person counseling. They are particularly promising given the demonstrated effectiveness of text-messaging interventions to support smoking cessation [15]. Smartphone apps offer greater functionality than text-messaging interventions and thus potentially may be able to provide more engaging and effective means of providing smoking cessation support. Indeed, consumer interest in smoking cessation smartphone apps is high, with well over 200 apps in the Android store alone generating more than half a million downloads in 2014 [16]. The reach of smartphone apps is also excellent and increasingly equitable. Currently, 77% of US adults own a smartphone, with sharp upticks in lower income Americans and those aged 50 years and older [17]. In smokers motivated to quit smoking, smartphone ownership is particularly high (83%) [18], thereby making smartphone apps an increasingly equitable and viable option to aid smoking cessation.

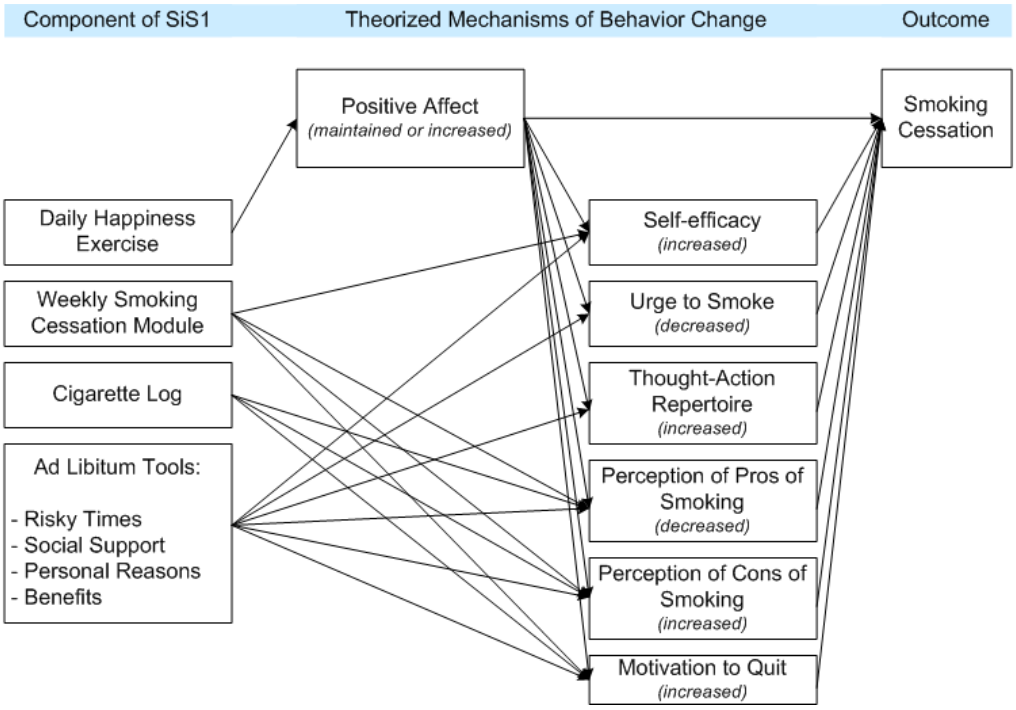
Despite considerable interest in smoking cessation smartphone apps, evidence-based apps remain few and far between. Existing apps in the iPhone and Android stores generally fall short of adhering to clinical practice guidelines for smoking cessation [16,19,20] and underutilize functionality that would allow active engagement with smokers trying to quit [16]. Meanwhile, apps developed through research are rare and inaccessible. A recent systematic review identified only 6 smoking cessation apps with some level of scientific support, only 3 (50%) of which were available in an app store [21]. Thus, there continues to be a need for empirically grounded smoking cessation apps.

Objectives

To address this need, we developed a smoking cessation app for nondaily smokers. Nondaily smokers are even less likely than daily smokers to seek or receive treatment [16]. To engage nondaily smokers in smoking cessation support, we chose a positive psychology approach, as detailed elsewhere [22], as the pursuit of happiness is generally appealing and nonstigmatizing and thus might overcome treatment resistance. Moreover, positive emotion during smoking cessation has been shown to increase an individual's likelihood of successfully quitting smoking [23], and previous work has demonstrated the potential of positive psychotherapy to support smoking cessation [24,25].

This paper presents the findings of the first in a series of 3 studies designed to pilot-test and further develop the *Smiling Instead of Smoking* (SiS) app. In this study, 30 nondaily smokers interested in quitting smoking were asked to use the app (SiS1) for 3 weeks. We evaluated the feasibility and acceptability of the app on 3 dimensions: actual app usage patterns, direct feedback via survey and structured user feedback, and by testing if theorized within-person changes were taking place.

Figure 1. Conceptual model of how SiS1 was theorized to support smoking cessation.



On the basis of previous research, and as detailed in our previous paper detailing the design of this app [22], we hypothesized that engaging in positive psychology exercises would offset expected decreases in positive affect in the days leading up to the quit day [26], where lowered positive affect on the quit day has been linked to relapse [27,28]. We also hypothesized that engaging in positive psychology exercises would increase self-efficacy (ie, confidence to quit smoking and to stay quit) [29], reduce the desire to smoke [30,31], broaden the thought-action repertoire (ie, the number of alternative options for actions a person can come up with in a specific situation) to deal with challenging times [32], and decrease defensive processing of self-relevant health information (eg, the tendency to discount the importance of information that appears threatening or worrisome) [33], all of which should enable nondaily smokers to remain smoke-free after their chosen quit day. We operationalized processing of self-relevant health information by assessing 3 measurable aspects: the degree to which participants believed that smoking cigarettes would result in specific positive or negative effects, the importance they place on these effects, and their motivation to quit. The other components of SiS1 were designed to support these mechanisms, as summarized in Figure 1.

Methods

Participants

Participants were adult nondaily smokers, who were interested in using a smartphone app to help them quit smoking (recruited August 8, 2017-January 24, 2018). Study recruitment information was displayed on Craigslist, Smokefree.gov, a study recruitment website at Massachusetts General Hospital, websites of local universities, and an ad placed in a public transportation newspaper. Potential participants were included in the study if they were older than 18 years; smoked at least weekly, but no more than 25 out of the past 30 days; had a current quit intention; owned an Android smartphone (version 1 of the app was only created for the Android); spoke English; and were willing to come in for 2 in-person study visits. The study was approved by the Partners Healthcare Institutional Review Board. All participants provided informed consent.

Procedure

Participants were phone-screened and asked to complete a screening test. To pass, participants had to (1) complete an Web-based baseline survey, and correctly (100%) respond to 5 randomly placed check-questions to verify that respondents were truly reading survey items; participants received US $10 versus US $35 for surveys with incorrectly versus correctly answered check-items, respectively, (2) provide contact information for 2 collaterals who would be able to assist research staff in locating participants for follow-ups, if necessary, and (3) provide their social security number to enable remuneration by check. Participants were notified by phone if they passed the screening test, and during this phone call, they were asked to set a quit day. An enrollment visit was then scheduled to occur 1 week before the chosen quit day at the research lab. During visit 1 (enrollment), participants were guided through downloading, installing, and using the app. After 3 weeks, participants returned for visit 2 (2 weeks after their chosen quit day, end of prescribed app support) for a structured user feedback session and the 2-week follow-up survey. Participants who reported abstinence provided a saliva sample for biochemical verification. Thereafter, participants completed follow-up surveys online 6, 12, and 24 weeks after their initially chosen quit day. All surveys were administered via the research electronic data capture system, REDCap, a secure, Web-based application designed to support data capture for research studies [34].

In total, we phone-screened 157 individuals, 58% (91/157) of whom signed online consent and took the baseline survey; 15% (24/157) decided against the study during the phone screen, and 27% (42/157) were ineligible, largely because of being daily smokers (n=25) or not owning an Android smartphone (n=12). After signing online consent, 33 individuals failed the check-items in the survey, and 27 changed their mind about participating in the study. A total of 31 individuals came in for visit 1; 1 person was unable to install the app because of too little phone storage space and decided against the study at that point. The remaining 30 comprise the sample reported in this paper. Remuneration was US $40 per survey and US $75 per in-person visit. Participants who missed a survey were contacted for subsequent surveys, unless participants actively withdrew from the study.

Treatment

Participants received version 1 of the SiS app, as described elsewhere [22]. In brief, SiS version 1 is an Android smartphone app that engages participants in daily positive psychology exercises over the course of 3 weeks and provides behavioral support via 3 app-delivered sessions and ad libitum user-initiated tools. To engage participants in positive psychology exercises, each day the app selected 1 of 3 exercises at random, all of which have been previously shown to be effective in enhancing positive affect [35-37], and reminded participants to complete it, if they had not done so by 7 pm. The exercises were *3 Good Things* (participants enter text describing 3 good things that happened to them that day), *Savoring* (participants enter text describing 2 experiences they savored), and *Experiencing Kindness* (participants describe an act of kindness they performed and one they witnessed). The app logged all entries and allowed participants to browse through their log of happy moments.

Participants were also prompted to complete 3 app-delivered behavioral support sessions, scheduled to be completed 1 week before the chosen quit day, on the quit day, and 1 week after the quit day. Session content was based on recommended clinical guidelines [13], in that it asked about current smoking and smoking triggers, advised participants to quit smoking, assessed participants' readiness to quit, addressed barriers they may perceive, assisted participants in setting a quit day, provided support during the quit attempt, and checked in with participants after their quit day. Tools were available to self-monitor cigarette use, specify personal reasons for quitting smoking, set personalized reminders to remain smoke-free during times of anticipated challenging times, enlist social support, display information on benefits of quitting smoking, and address commonly expressed concerns about quitting smoking. Participants were asked to use the app for 3 weeks, 1 week before and 2 weeks following their chosen quit day. Participants were free to continue using the app thereafter or to discontinue its use, as they deemed fit.

Measures

App Usage

The app passively time stamped interactions with the app, from which we calculated the percentage of participants who used each function on a given day.

User Feedback

Via Survey

In the 2-week survey, participants were asked to rate the ease-of-use and usefulness of each component of the app (10 items each) on a 4-point Likert scale (ease-of-use: 0=*not easy at all*, 1=*somewhat easy to use*, 2=*easy to use*, and 3=*very easy to use*; useful: 0=*not at all useful*, 1=*somewhat useful*, 2=*usef* ul, and 3=*very useful*). Participants also indicated if the app helped them in their quit attempt (*yes/no*) and in which ways the app helped them (10 items, rated on a 5-point Likert scale, 1=*strongly disagree*, 2=*disagree*, 3=*neither agree nor disagree*, 4=*agree*, and 5=*strongly agree*).

Via Structured User Feedback Session

During visit 2, participants were presented with a summary of their interactions with the app. Staff asked 22 specifics on phenomenology of nondaily smoking, specific suggestions for adding to drop-down menus, feedback about specific tools in the app, and participants' bottom-line take-home recommendation for adding or removing features from the app.

Indices of Putative Mechanisms of Behavior Change

Surveys assessed constructs theorized to underlie the process of smoking cessation. For ease of interpretation, we calculated scale scores by averaging across items (ie, rather than sum scoring), so that scores can be interpreted directly on the scale participants used to rate them. Baseline Cronbach alphas observed in this study are reported below.

Positive Affect

The Positive and Negative Affect Schedule (PANAS, 10 items, 1=*very slightly or not at all*, 5=*extremely*) [38] uses mood adjectives to assess to what extent participants felt specific emotions during the past week. Participants also used a single-item slider (0=*not at all happy,* 100=*extremely happy*) to indicate how happy they were feeling right before completing the survey. Overall satisfaction with life and happiness were assessed with the Satisfaction with Life Scale (5 items, 1=*strongly disagree*, 7=*strongly agree*) [39] and the Subjective Happiness Scale (4 items, item-specific anchor points, eg, *In general, I consider myself…*,1=*not a very happy person*, 7=*a very happy person*) [40].

Self-Efficacy

The Smoking Self-Efficacy Questionnaire (24 items; 0=*not at all confident*, 100=*extremely confident*) [41] assessed confidence in the ability to abstain from smoking when facing internal (eg, feeling depressed) and external stimuli (eg, being with smokers).

Urge to Smoke

The brief Questionnaire of Smoking Urges (10 items, 1=*strongly disagree* and 7=*strongly agree*) [42] assessed craving (eg, *I have an urge for a cigarette*).

Breadth of Thought-Action Repertoire

To measure the breadth of participant's thought-action repertoire, we used the Twenty Statements Test [43]. In this test, participants are asked to describe a strong emotion they have just experienced, take a moment to feel it deeply, and are then instructed: *Given this feeling, please list all the things you would like to do right now*. This instruction is followed by 20 blank lines that began with the following: *I would like to…* To score, the number of items completed is counted, resulting in a score from 0 to 20, with larger scores indicating a larger thought-action repertoire. In this study, participants were asked to *name the strongest emotion you feel when thinking about your quit attempt.*

Perception of Pros and Cons of Smoking

The Attitudes Towards Smoking Scale-18 items (1=*strongly disagree*, 5=*strongly agree*) [44] assessed the degree to which participants perceive adverse effects of smoking (eg, *smoking is ruining my health*), psychoactive benefits of smoking (eg, *smoking calms me down when I am upset*), and pleasure of smoking (eg, *it feels so good to smoke*). The Decisional Balance Inventory for Smoking (6 items, 0=*not at all important* and 100=*extremely important*) [45] assessed perceived importance of commonly expressed pros (eg, *Smoking cigarettes relieves tension*) and cons (eg, *My cigarette smoking bothers other people*). Participants also used single-item sliders (0=*not at all important*, 100=*extremely important)* to rate their own defined pros and cons (eg, *Think about all the things you LIKE/LOVE about quitting/being smoke-free. Taken together, how important are those things to you RIGHT NOW*?).

Motivation to Quit Smoking

The Commitment to Quitting Smoking Scale (8 items, 1=*strongly disagree*, 5=*strongly agree*) [46] captures the extent to which persons feel personally bound or obligated to persist in quitting smoking despite potential difficulties, craving, and discomfort. Participants also used a single-item measure (0=*not motivated at all*, 100=*extremely motivated*) to rate their motivation (ie, *How MOTIVATED are you to quit smoking/stay quit?*).

Outcome of the Smiling Instead of Smoking–Supported Quit Attempt

Abstinence

In each survey, participants were asked: *What is your smoking status?* The response options were *I smoke daily*, *I smoke nondaily*, and *I do not smoke at all*. If participants reported not smoking, they were asked *Have you been abstinent for 7 days?* (*yes/no*). If yes, they were asked *Have you been abstinent for 30 days?* (*yes/no*). For the primary endpoint (ie, 2 weeks post quit), abstinence self-reports were biochemically verified using saliva cotinine (<15 ng/mL) [47,48].

Analytic Strategy

To describe feasibility, acceptability, and outcome, we calculated descriptive statistics. For user feedback sessions, content analyses were performed on the responses to the 22 questions by 2 independent coders. Major themes were identified. Coding differences were reviewed with the study team to resolve discrepancies.

To test if nondaily smokers using SiS experienced changes over time on constructs theorized to underlie smoking cessation, we used the online survey data (n=30) and fit one repeated measures mixed effects model per construct of interest, where the construct was the dependent variable and time (baseline, 2, 6, 12, and 24 weeks) was the predictor. Per protocol, the primary endpoint of interest was treatment end (ie, 2 weeks after the chosen quit date). Correlations over time were modeled with an unstructured covariance matrix. Given the explorative nature of this study, we did not correct for multiple testing.

Results

Participant Characteristics

The participants' age ranged from 23 to 63 years, and the mean age was 45 years (SD 14.1). Most participants were male (22/30, 73%; Table 1). Our sample matched published rates of nondaily smoking [49] and quit intentions [7] but had greater racial-ethnic diversity than is nationally representative: 40% (12/30) of our participants were non-Hispanic white; 55% of nondaily smokers were non-Hispanic white in the National Health Interview Survey 2015 [50]. Nearly all participants completed all surveys; completion rates were 100% (30/30), 93% (28/30), 97% (29/30), and 97% (29/30) at follow-ups occurring 2, 6, 12, and 24 weeks after the quit day, respectively.

App Usage

App usage during the prescribed 21 days of use was high (Figure 2). On average, and excluding the first day on which participants were guided through the app, 84% (25.2/30) of participants used the app on any given day. App use was primarily driven by the completion of the daily happiness exercises (73%, 22/30) of participants on any given day). Viewing the happiness log occurred relatively rarely, with only 6% (2/30) of participants doing so on a given day. This usage pattern, however, was in line with viewing the graph generated by logging one's cigarettes (7%, 2/30) and using other ad libitum functions, such as *Risky Times* (7%, 2/30), *Social Support* (7%, 2/30), *Personal Reasons* (10%, 3/30), and *Benefits* (3%, 1/30).

In addition, frequently used were the behavioral sessions, which were intended to be accessed once per week but could be accessed multiple times, and making cigarette reports in the cigarette log. Within a weekly context (Figure 3), on average, 86% (25.8/30) of participants completed behavioral sessions during the prescribed 3 weeks, and 34% (10.2/30) made smoking reports, where it was expected that nondaily smokers would stop making smoking reports as they quit smoking; 97% (29/30) of participants completed happiness exercises in any given week during the prescribed 3 weeks.

Table 1. Sample characteristics (n=30).

Characteristics	Values
Demographics	
Age (years), mean (SD)	44.7 (14.1)
Gender (female), n (%)	8 (27)
Race, n (%)	
White	12 (40)
Black	13 (43)
Other or unknown	5 (17)
Hispanic, n (%)	2 (7)
Education, n (%)	
High school or less	8 (27)
Some college	11 (37)
Bachelor's or higher	11 (37)
Smoking characteristics	
Days smoked in past 30 days, mean (SD)	15.6 (6.0)
Cigarettes smoked per smoking day, mean (SD)	4.5 (2.9)
Ever smoked daily? Yes, n (%)	18 (60)
Ever quit before? Yes, n (%)	21 (70)

Figure 2. App usage during the prescribed 21-day period. SiS: Smiling Instead of Smoking.

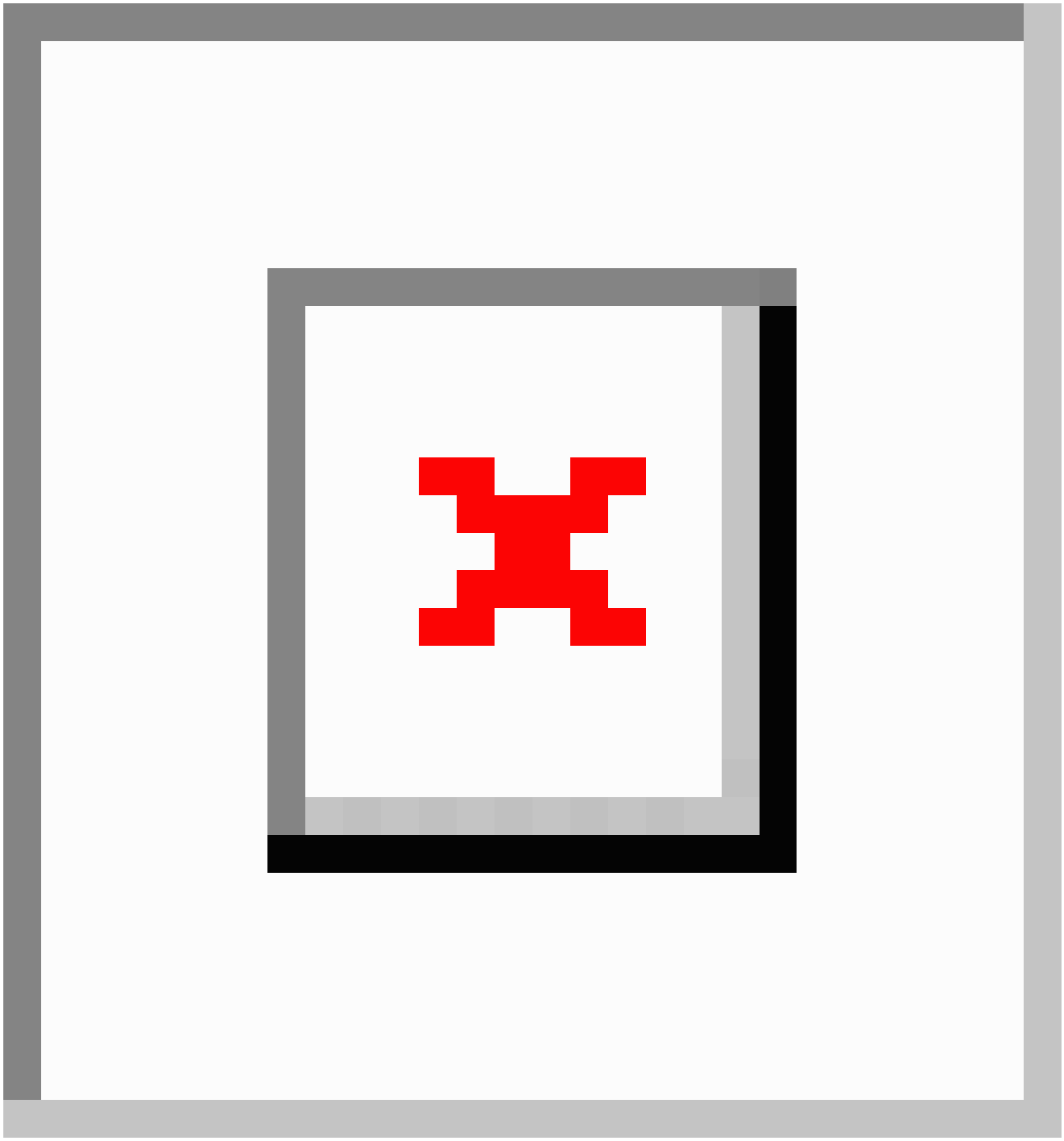
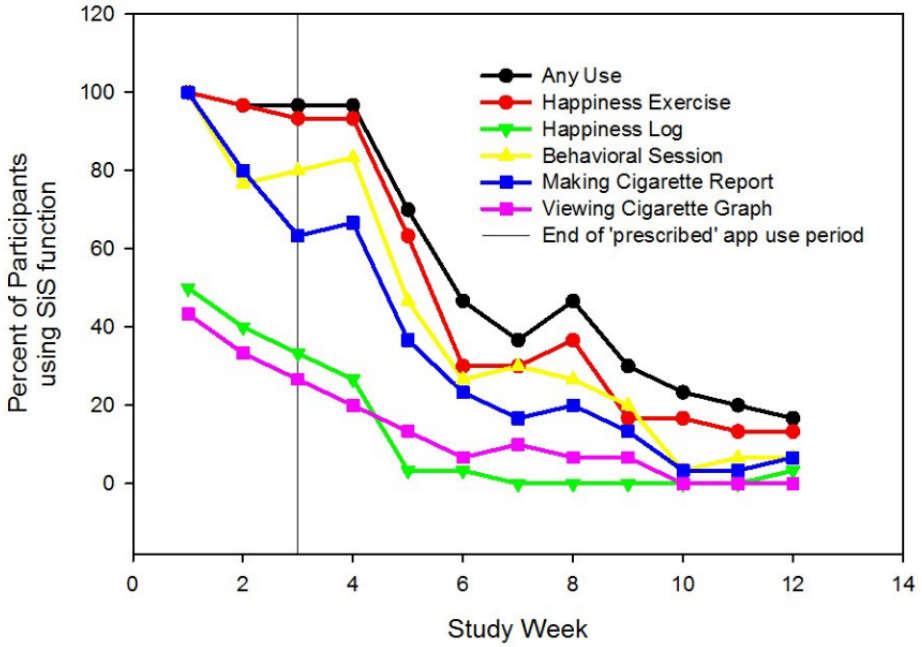


Figure 3. App usage per study week. SiS: Smiling Instead of Smoking.



After the end of treatment, some participants continued to use the app. Excluding week 4, during which participants may still have been completing visit 2, 40% (12/30) of participants completed happiness exercises during any given week from week 5 to 8.

User Feedback

Survey responses indicated that the best-rated features, both in terms of ease-of-use and usefulness, were *Scheduling Your Quit Day* and *Your Reasons for Quitting* (Table 2). Nearly all participants (90%, 27/30) felt that the app had helped them in their quit attempt (Table 3). In particular, the app appeared to reinforce the value of quitting, with ratings of 4.1 (on a 1-5 scale) for *reminded me why I wanted to quit* and 4.0 for *made me think it was worthwhile for me to quit*. The app's role in reminding participants to *stay on track* (83%, 25/30 indicated agreement) and in giving confidence (80%, 24/30 indicated agreement) were also important aspects. The app was less successful in helping participants seek social support (57%, 17/30 endorsement) and dealing with risky situations (57%, 17/30 endorsement; Table 3).

Table 2. Ratings of the Smiling Instead of Smoking functions.

Function	Ease of use[a], mean (SD)	Useful[b], mean (SD)
Completing the positive psychology exercises every day	2.0 (0.9)	1.8 (0.9)
Specifically, completing *3 Good Things*	2.1 (0.9)	1.9 (0.8)
Specifically, completing *Savoring*	2.1 (0.8)	1.9 (0.9)
Specifically, completing *Experiencing Kindness*	2.1 (0.9)	1.9 (0.9)
Completing the smoking sessions	2.0 (0.8)	1.8 (0.9)
Accessing and updating your smoking cessation tools	1.8 (0.9)	1.7 (1.0)
Specifically, Scheduling Your Quit Day	2.3 (0.9)	2.1 (0.9)
Specifically, Your Reasons for Quitting	2.4 (0.7)	2.3 (0.7)
Specifically, Managing Your Challenging Times	1.9 (0.8)	1.6 (0.9)
Specifically, Enlisting Your Social Support	2.0 (0.8)	1.6 (1.0)

[a]Ease of use was rated on a 4-point scale: 0=*not easy at all*, 1=*somewhat easy to use*, 2=*easy to use*, and 3=*very easy to use*.

[b]Useful was rated on a 4-point scale: 0=*not at all useful*, 1=*somewhat useful*, 2=*useful*, and 3=*very useful*.

Table 3. Perceptions of how the app might have helped.

Perceptions	Mean[a] (SD)	Agree, n (%)
The app helped remind me to stay on track with quitting.	3.9 (0.9)	25 (83)
The app gave me confidence that I can quit smoking.	3.9 (1.0)	24 (80)
The app made me think that it was worthwhile for me to quit.	4.0 (1.1)	24 (80)
The app made me feel that someone cared if I quit.	3.9 (1.1)	23 (77)
The app reminded me why I wanted to quit.	4.1 (0.8)	23 (77)
The app helped me stay positive while quitting.	3.8 (1.1)	21 (70)
The app gave me the feeling I could get trusted advice at any time.	3.7 (1.1)	21 (70)
The app made me feel that I knew the right steps to take to quit.	3.5 (1.1)	18 (60)
The app motivated me to reach out to the people in my life about quitting.	3.4 (1.2)	17 (57)
The app helped me deal with risky smoking times.	3.5 (1.2)	17 (57)
Taken altogether, do you think that the app helped you in your quit attempt?	—[b]	27 (90)

[a]Rated on a 5-point Likert scale: 1=*strongly disagree*, 2=*disagree*, 3=*neither agree nor disagree*, 4=*agree*, 5=*strongly agree.*

[b]Not applicable.

During structured user feedback sessions, 80% (24/30) of participants expressed that they liked the happiness exercises (Figure 4) and felt it was good for them to complete them. Participants (23%, 7/30) wanted more happiness exercises to provide greater variety. Regarding behavioral counseling, participants (47%, 14/30) liked the content but expressed a desire for shorter, more frequent, proactive (ie, initiated by the app) interactions that are less wordy and use more graphics. Participants highlighted problems with the *Risky Times* and *Social Support* functions (Figure 5), with many (33%, 10/30) expressing that they found the *Risky Times* tool useful but too cumbersome, and most (43%, 13/30) disliking the functionality for enlisting the help of social support. Several participants (13%, 4/30) reacted negatively to the suggestion that supportive people in their lives could *reward them for reaching smoking cessation milestones*. Rather than involving people in their lives in their smoking cessation process, participants suggested adding links to or information about support groups. If involving people in their lives, participants suggested that it would be better to do so without a focus on smoking cessation (eg, meeting up to go running).

When asked about their personal bottomline recommendation for the app, more than half of the participants (67%, 20/30) did not want to cut anything from it. At the same time, most participants (83%, 25/30) felt that things could be added to the app, where the most frequent recommendations were to add functionality to encourage more frequent interaction with the app (37%, 11/30), reinforce the pros of quitting (20%, 6/30), add a component to interact with other app users (17%, 5/30), add gamification to the app (10%, 3/30), and/or a relational agent (10%, 3/30).

Indices of Putative Mechanisms of Behavior Change

Within-person changes from baseline (ie, as measured in the survey administered as part of the screening procedure before study enrollment) to treatment end (ie, 2 weeks after the chosen quit day) were observed for several theorized mechanisms of behavior change, all in the expected direction (Table 4). Namely, on average, participants indicated greater confidence in their ability to quit smoking and stay quit, both in response to internal and external cues, and less desire to smoke, including reduced positive outcome expectancies of smoking, as measured by multiple scales (ie, pleasure of smoking, psychoactive benefits of smoking, personal importance of pros of smoking).

After the end of treatment, these effects were sustained through study end (ie, 6 months after the chosen quit day), with the exception of decreases in *pleasure of smoking*, as measured via the ATS, which did not reach statistical significance at the 6- or 12-week assessment (P=.06 for both tests, comparing 6-week/12-week to baseline), but were statistically significant 24 weeks after the quit day (b=−0.54, P=.009). At the same time, however, other trends emerged that were less supportive of smoking cessation. Namely, the importance of the pros of quitting, as measured via a single item, was significantly lower 6, 12, and 24 weeks after the quit day by 10 to 14 points on a 0 to 100 scale (P=.02, .02, and .01, respectively) than that at baseline. Similarly, motivation decreased and was significantly lower than baseline 6 months after the quit day, by about 14 points (P=.03). The thought-action repertoire, as measured by the TST, also decreased after treatment end (P=.008, .006, and .01, respectively, at 6, 12, and 24 post quit, compared with baseline). Similarly, positive affect was lowered, with a significantly lower past week PANAS score 12 weeks post quit (b=−0.4, P=.004) and a significantly lower momentary happiness score 6 weeks post quit (b=−10.3, P=.04).

Figure 4. Screenshots of completing the daily happiness exercises in SiS1. SiS: Smiling Instead of Smoking.

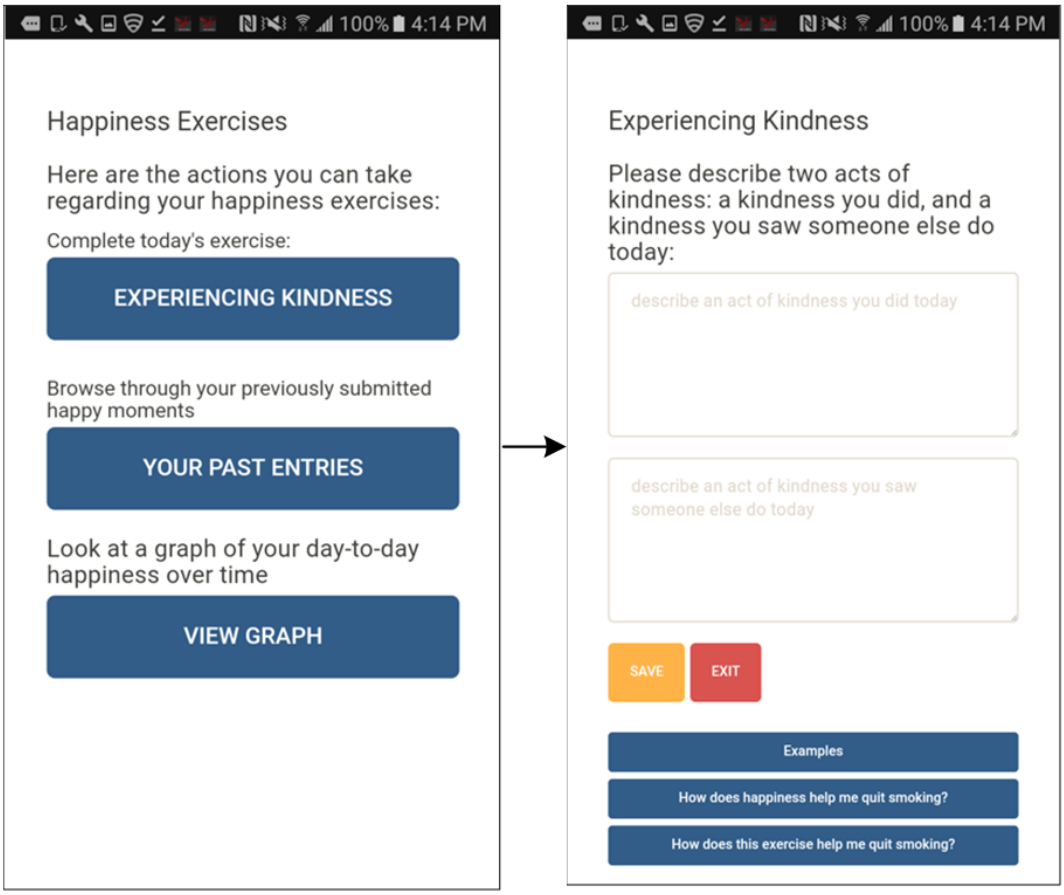
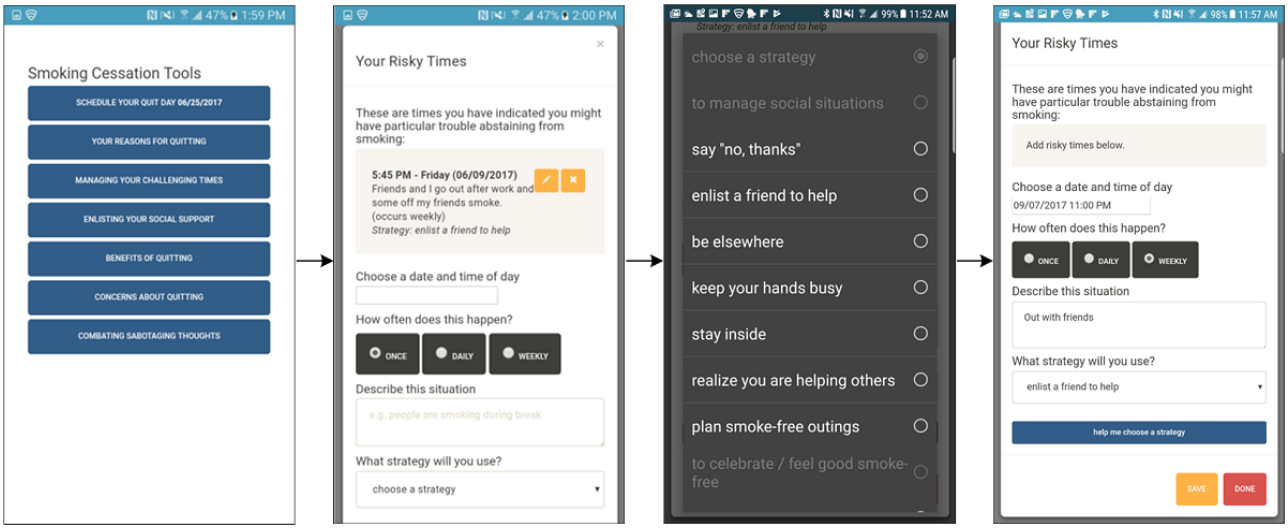


Figure 5. Screenshots of completing the ad libitum tool Risky Times in SiS1. SiS: Smiling Instead of Smoking.



Outcome of the Smiling Instead of Smoking–Supported Quit Attempt

At the end of prescribed app use, 40% (12/30) of participants reported having been abstinent for the past 7 days. Salivary cotinine values for 3 participants, however, were greater than 15 ng/mL without having reported current use of other nicotine products (ie, e-cigarette use and nicotine replacement therapy). Thus, the biochemically verified point-prevalence abstinence rate was 30% (9/30). Following the end of prescribed app use, and assuming that survey nonresponders were not abstinent, 7-day point-prevalence abstinence was self-reported by 53% (16/29), 48% (14/29), and 55% (14/29) of participants 6, 12, and 24 weeks after the quit day, respectively; 30-day point-prevalence abstinence was self-reported by 41% (12/29), 45% (13/29), and 48% (14/29) of participants 6, 12, and 24 weeks after the quit day, respectively.

Table 4. Within-person changes on theorized mechanisms of change from baseline to the end of treatment.

Construct, scale	Cronbach alpha at baseline	Baseline[a], mean (SD)	Scale range	2-week versus baseline	
				b[b] (CI)	*P* value
Happiness					
PANAS[c] (past week positive affect)	.88	3.6 (0.6)	1-5	−0.2 (−0.4 to 0.1)	.17
PANAS (past week negative affect)	.83	1.7 (0.5)	1-5	0.1 (−0.1 to 0.4)	.27
Single item—how happy right now	—[d]	69.9 (17.8)	0-100	−6.0 (−13.9 to 1.9)	.13
Satisfaction with Life	.81	4.0 (1.2)	1-7	0.2 (−0.2 to 0.6)	.36
Subjective Happiness	.88	5.4 (1.3)	1-7	−0.1 (−0.5 to 0.3)	.52
Self-efficacy					
SEQ-12[e] (internal cues)	.92	44.9 (24.3)	0-100	16.7 (7.2 to 26.3)	.001[f]
SEQ-12 (external cues)	.88	47.3 (25.3)	0-100	15.8 (5.4 to 26.1)	.004[f]
Desire					
Questionnaire of Smoking Urges (smoking urges)	.86	3.1 (1.1)	1-7	−0.8 (−1.3 to −0.3)	.002[f]
Breadth of thought-action repertoire					
Twenty Statement Test	—	9.5 (6.8)	0-20	−2.5 (−5.2 to 0.3)	.08
Processing self-relevant health information					
ATS[g] (adverse effects)	.94	4.2 (0.9)	1-5	0.0 (−0.3 to 0.4)	.86
ATS (psychoactive benefits)	.81	3.6 (0.8)	1-5	−0.5 (−0.9 to −0.2)	.006[f]
ATS (pleasure)	.88	3.0 (1.0)	1-5	−0.4 (−0.7 to −0.0)	.03[h]
DCB[i] (importance of pros of smoking)	.64	48.6 (21.8)	0-100	−11.3 (−18.9 to −3.8)	.004[f]
DCB (importance of cons of smoking)	.64	60.6 (25.6)	0-100	−4.3 (−13.8 to 5.2)	.37
Single item—pros of quitting	—	92.3 (11.0)	0-100	−6.6 (−14.7 to 1.5)	.11
Single item—cons of quitting	—	50.4 (39.9)	0-100	2.0 (−16.8 to 20.7)	.83
Commitment to Quitting Smoking Scale (commitment to quitting)	.91	3.8 (0.7)	1-5	−0.2 (−0.5 to 0.2)	.35
Single item—how motivated	—	88.0 (13.7)	0-100	−5.1 (−12.6 to 2.4)	.18

[a]Baseline occurred before SiS download, and 2-week follow-up occurred at the end of the prescribed 21 days of app use (ie, 2 weeks post quit day).

[b]Repeated measures mixed effects model parameter estimate.

[c]PANAS: Positive and Negative Affect Schedule.

[d]Not applicable.

[e]SEQ: Self-Efficacy Questionnaire.

[f]Flags differences with $P<.01$.

[g]ATS: Attitudes Towards Smoking.

[h]Flags differences with $P<.05$.

[i]DCB: Decisional Balance Inventory for Smoking.

Discussion

Principal Findings

In this first pilot test of version 1 of our smoking cessation app *SiS*, we evaluated the feasibility and acceptability of the app. To provide a comprehensive test, we used 3 types of data sources: passively recorded app usage, standardized survey self-reports, and face-to-face feedback sessions with participants after they had used the app.

On the whole, the gathered data support the notion that leveraging positive psychology tools, or more precisely, happiness exercises, may be well received by nondaily smokers and feasible, at least over the short term. A very high percentage of participants completed the daily exercises throughout the prescribed period of app use, and after completing them for 3

weeks, participants rated the exercises as easy to use and useful. Moreover, in structured user feedback sessions, participants pointed out that they enjoyed doing the happiness exercises, and many continued to complete them long after the formal treatment period was over. As was our goal, by the end of prescribed app use, positive affect appears to have been maintained at precessation levels; at least, we did not observe any statistically significant declines by treatment end, where, of course, our ability to detect such differences was limited because of our small sample size. Once prescribed app use had ended, there was some evidence of a decline in the positive affect.

In designing the app, we had hypothesized that maintained positive affect would favorably affect known mechanisms of smoking cessation [22]. In line with these expectations (though certainly not a direct test thereof), we observed within-person changes such as increased confidence in ability to quit smoking, decreased smoking urges, and a shift to a less positive view of smoking. All of these changes are changes that are hoped for in successful smoking cessation. In particular, an increase in confidence is an important mechanism by which benefit is conferred in text-messaging approaches to smoking cessation [51], making the observed increases in users of the SiS app a promising sign of its potential effectiveness.

Also promising were self-reported quit rates. To date, mobile health (mHealth) approaches to smoking cessation have only been tested in daily smokers. Here, abstinence rates have ranged from 26% to 36%, with 26% of daily smokers using the app *Clickotine* (n=416) reporting being 30 days abstinent at 2-month follow-up [52]; 36% of daily smokers using an mHealth program combining real-time tailored advice with asynchronous secure messaging with a cessation counselor reporting abstinence 5-month follow-up [53]; and an average of 28% (treatment) versus 13% (control) of daily smokers across 4 randomized controlled trials testing text-messaging smoking cessation interventions reporting abstinence 4 to 6 weeks post quit [54-57]. Abstinence rates in our study were consistently higher (ie, ≥40% [≥12/30] at 6, 12, and 24 weeks post quit).

Areas for Further Development

These promising abstinence rates notwithstanding, our data also suggested that it may be useful to consider implementing more app-initiated, varied, and frequent interactions with the app, and to do so over a longer period. This theme emerged from several types of data. First, participants directly told us that they desired more app-initiated, frequent, varied interactions with the app. Second, once app support was withdrawn, some less-than-favorable within-person changes emerged, where there was evidence of sporadically lowered positive affect, decreased motivation, and diminished thought-action repertoire. Although these decreases did not seem to impact smoking cessation in this small pilot sample of engaged and motivated study participants, they may translate to poorer outcomes in smokers who use the app on their own without research staff interactions. This is especially of concern given that participants indicated in surveys that a key reason the app helped them was because it reminded them to stay on track. As an app can only serve as a reminder when users are actively engaging with it, we think it may be important to continuously engage users with the app. This feedback is in line with emerging findings on adherence to technology-delivered interventions. Dropout and nonadherence are often high in technologically delivered interventions [58], which may be problematic, because higher adherence is associated with better mental health outcomes [59,60]. Moreover, recent findings suggest that adherence to technology-delivered interventions can be improved through frequent intended usage [61]. Identifying the optimal level of app engagement to promote smoking cessation and other health behaviors is an important topic for future research.

The happiness exercises seemed to engage persons well on a day-to-day basis and indeed, were the primary driver of interactions with the app (Figure 2). Nevertheless, doing the same 3 exercises can become tiresome over a longer period, and participants indicated their desire for additional types of exercises to be included in the rotation. Participants also indicated that they liked the content provided in the behavioral counseling sessions, and, even though only offered on a weekly basis, this content was an important contributor to overall app use. To support more frequent app interaction, it may be useful to present this content in shorter, more frequent installments.

Another theme for improvement that emerged was an increased focus on the pros of quitting smoking. Participants recommended that we add more content on the pros of quitting smoking to future versions of the app. This recommendation was supported by the quantitative data on within-person changes, where the importance of the pros of quitting diminished after treatment end, when app support was withdrawn. SiS version 1 included functionality that asked participants to list their personal reasons for quitting smoking during the first behavioral counseling session, a list that could be updated by users subsequently. This function was, surprisingly, the highest user-rated function of the app (Table 3). Users of the SiS app used the *Personal Reasons* functionality only sporadically, possibly because this functionality did not offer novelty over time. Future studies should address how to improve user engagement with more varied content about the pros of quitting smoking over a longer period.

Furthermore, a noteworthy aspect was the negative appraisal of the social support functionality in the SiS app. We had included app functionality that encouraged app users to reach out to important people in their lives to support them in their quit attempts because enlisting social support has been recommended for smoking cessation support [13]. In retrospect, however, this functionality was ill chosen because nondaily smokers oftentimes keep their smoking hidden from important people in their lives and frequently will deny their smoking habit when asked by family, friends, and health care providers [62]. Other ways to encourage the attainment of social support, such as, for example, anonymous online chat groups and other social media technologies [63,64], may be more suitable for nondaily smokers.

Limitations

First, as a first pilot study of an evidence-based smoking cessation app that leverages positive psychology exercises to engage and support nondaily smokers in their quit attempts, this

study is subject to several important limitations, with the chief limitation among them being the small sample size and the lack of a randomized control group, which preclude conclusions about the potential efficacy of the app. Observed effects are likely influenced by a self-selection process, where participants particularly interested in using a smoking cessation app, and thus potentially particularly likely to benefit from such an app, enrolled in the study. Second, a surprisingly small percentage of women participated in the study. In a similar study with identical eligibility and screening procedures, with the exception of no requirement to attend in-person visits [65], we recruited 66% women, suggesting that perhaps the in-person component was a deterrent. The requirement to provide the social security number information to allow us to provide remuneration was generally not seen as a deterrent, with only 1 of 157 screened potential participants deciding against the study because of it. Finally, it must be noted that biochemical verification of smoking status was only conducted once, at the primary endpoint and not at subsequent follow-ups, and only used salivary cotinine and not carbon monoxide in exhaled breath. Smoking status was also not reassessed at enrollment, and participants may have changed their smoking in between screening and enrollment, which were on average 15±13 days apart.

Conclusions

This first feasibility test of a smoking cessation app for nondaily smokers shows that an app that leverages positive psychology exercises to engage and support users is well received by nondaily smokers, who used the app on a near daily basis for the prescribed 3 weeks. Users of the app appeared to make important smoking cessation progress, showed within-person changes on several theorized mechanisms of change, and proactively expressed liking the positive psychology approach of the app. Further development of this line of work is warranted.

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Conflicts of Interest

None declared.

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Abbreviations

ATS: Attitudes Towards Smoking
DCB: Decisional Balance Inventory for Smoking
PANAS: Positive and Negative Affect Schedule
SEQ: Self-Efficacy Questionnaire
SiS: Smiling Instead of Smoking

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Original Paper

Using Health and Well-Being Apps for Behavior Change: A Systematic Search and Rating of Apps

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Abstract

Background: Smartphones have allowed for the development and use of apps. There is now a proliferation of mobile health interventions for physical activity, healthy eating, smoking and alcohol cessation or reduction, and improved mental well-being. However, the strength or potential of these apps to lead to behavior change remains uncertain.

Objective: The aim of this study was to review a large sample of healthy lifestyle apps at a single point in time (June to July 2018) to determine their potential for promoting health-related behavior change with a view to sharing this information with the public. In addition, the study sought to test a wide range of apps using a new scale, the App Behavior Change Scale (ABACUS).

Methods: Apps focusing on 5 major modifiable lifestyle behaviors were identified using a priori key search terms across the Australian Apple iTunes and Google Play stores. Lifestyle behavior categories were selected for their impact on health and included smoking, alcohol use, physical activity, nutrition, and mental well-being. Apps were included if they had an average user rating between 3 and 5, if they were updated in the last 18 months, if the description of the app included 2 of 4 behavior change features, and if they were in English. The selected behavior change apps were rated in 2 ways using previously developed rating scales: the Mobile App Rating Scale (MARS) for functionality and the ABACUS for potential to encourage behavior change.

Results: The initial search identified 212,352 apps. After applying the filtering criteria, 5018 apps remained. Of these, 344 were classified as behavior change apps and were reviewed and rated. Apps were given an average MARS score of 2.93 out of 5 (SD 0.58, range 1.42-4.16), indicating low-to-moderate functionality. Scores for the ABACUS ranged from 1 to 17, out of 21, with an average score of 7.8 (SD 2.8), indicating a low-to-moderate number of behavior change techniques included in apps. The ability of an app to encourage practice or rehearsal, in addition to daily activities, was the most commonly identified feature across all apps (310/344, 90.1%), whereas the second most common feature was the ability of the user to easily self-monitor behavior (289/344, 84.0%).

Conclusions: The wide variety of apps included in this 2018 study and the limited number of behavior change techniques found in many apps suggest an opportunity for improvement in app design that will promote sustained and significant lifestyle behavior change and, therefore, better health. The use of the 2 scales for the review and rating of the apps was successful and provided a method that could be replicated and tested in other behavior change areas.

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KEYWORDS

smartphone; mobile apps; health promotion; health behavior; rating

Introduction

Modifiable Risk Factors for Chronic Disease

Life expectancies across many developed countries have steadily increased over the past century. Newborns in developed countries can expect to live for 80 years or more, with an average increase of 3 years per decade [1]. At the same time, death rates in developed countries continue to fall, with the leading underlying causes of death being age-related diseases, including coronary heart and Alzheimer disease and cancers [1]. Although these overall patterns are encouraging and suggest that activities to improve health are working, areas of concern remain. An analysis of data reporting on the global burden of disease suggests that although overall life expectancy has increased, much of the burden of disease could be prevented through a reduction in exposure to modifiable risk factors, including tobacco use, high body mass, high alcohol use, physical inactivity, and high blood pressure [2]. Rates of overweight and obesity have increased, with the vast majority of adults and children not consuming the recommended quantities of fruits and vegetables or engaging in the recommended amount of daily physical activity [2]. Although rates of smoking, daily alcohol use, and overall alcohol consumption have decreased somewhat in the adult population in recent years, they remain significant contributors to disease burden [2]. In addition to the focus on physical health, global data related to mental health indicate that approximately 1 in 4 people worldwide will experience a diagnosable mental illness over their lifetime [2].

Interventions to Address Modifiable Risk Factors

A large amount of research has investigated the variety of responses to the most common modifiable risk factors: obesity, physical inactivity, poor nutrition, tobacco use, risky alcohol use, and poor mental health. In the quest for solutions for poor health, this research has explored the clinical as well as community setting, proposing solutions that exist at the societal, environmental, household, and individual level. Much of the research investigating ways to increase physical activity is focused on children and adolescents, as most adolescents are physically inactive, with this inactivity continuing into adulthood [3].

A recent review found that, similar to many high-income countries, chronic disease is Australia's biggest health challenge, responsible for 83% of premature deaths [4]. This review found that interventions targeting the workplace, facilitated group-based exercise programs, the promotion of activities that encourage or provide the ability to self-monitor behavior, tobacco cessation programs that embed coaching or counselling, and practical support for weight loss are most likely to be effective [4]. Although interventions that have little effectiveness include those focused on education or awareness raising, particularly around healthy food and beverage options, modifications to workplace and community environments have been identified as a way to encourage physical activity as have interventions that include financial rewards or penalties [4].

Smartphone Apps for Health

Although this evidence points to some success in supporting positive health by modifying risk factors, the intensive nature and expense often associated with these programs, can prohibit the large-scale rollout of such interventions. Smartphone apps represent a potential supplement to these efforts that could lead to substantial population-level impact and long-term health behavior change. Approximately 70% of the populations of developed countries own a smartphone [5]. The versatility of smartphones has led to the creation of millions of apps beyond those originally supplied to consumers, such as mail, map, and messaging apps, and now include gaming, banking, recipe finders, and health apps. Apps are created by developers and can be downloaded from a variety of digital marketplaces depending on the operating system of the device. Such technologies make available interventions that are low cost and can be accessed by much of the population.

In recent years, there has been a proliferation of apps designed to improve health. This has included apps that promote physical fitness through attendance at gyms or via counting steps, apps that track calorie intake and suggest modifications, apps that aim to assist users with smoking cessation or reducing alcohol consumption, and apps that promote mindfulness and positive mental health. However, it is unclear if these apps follow best practices in app design or health behavior change, or indeed what is the best practice for designing health behavior change apps. Although some studies have reported on the behavior change content of apps, for example, smoking cessation [6], alcohol reduction [7,8], physical activity [9], or for specific medical conditions [10], there is also research suggesting that many apps fail to include techniques or features that have been shown to be effective in behavior change, such as the ability to be customizable to users' needs or personal characteristics or to be responsive to change [7,10,11]. There is also a risk that improper or unsupervised use of apps or the use of apps that do not align with current recommendations may result in harmful outcomes for users [12,13].

Evaluation of Mobile Health Apps

Part of the problem in evaluating the effectiveness or accuracy of information in apps is related to limitations in the methods available and inconsistencies in the approach to research in this area. Using smartphone apps for healthy behavior change is an emerging area of investigation, and as a result, much of the current research is focused on the evaluation of single apps [14] and apps that have been purposely designed for a research project [6], or a small number of *top-rated apps* [15,16], rather than focusing on a thorough large-scale investigation of the potential of apps that already exist on the market to promote behavior change [17].

A recent systematic review investigated approaches to the evaluation of health apps with the aim of identifying current best practice approaches [18]. The review of 38 papers found no single best practice method of evaluating mobile health and well-being apps. Most approaches did not include sufficient information or evaluation, potentially meaning consumers are provided with incomplete and inaccurate information about the apps. The review suggested that the evaluation of apps should

include a review of the functionality and usability of the app, as well as an assessment of the apps' potential to promote behavior change. It found that although not specific for smartphone apps, the Coventry, Aberdeen, and London—Refined taxonomy, developed by Michie et al [19], was the most commonly used instrument for assessing behavior change techniques in interventions and the Mobile Apps Rating Scale (MARS), developed by Stoyanov et al [20] was the most commonly used tool for assessing the quality and functionality of mobile health apps.

On the basis of this review, McKay et al [21] developed a scale specifically designed to determine the behavior change potential of smartphone apps. This tool, the App Behavior Change Scale (ABACUS), based off the health behavior change intervention literature, is a 21-item instrument that reports high percentage agreement, Krippendorff alpha, interrater reliability, and high internal consistency.

This study aims to rate the potential effectiveness of the apps using a scale that assesses the inclusion of features that are known to assist individuals with behavior change, designed to reduce alcohol consumption or smoking, improve nutrition or mental well-being, or increase physical activity to provide potential app users information on the content of apps and their likely effectiveness in supporting the user's lifestyle behavior change goals.

The ratings are housed on a website developed by the Victorian Health Promotion Foundation (VicHealth) to assist the public in making informed choices about effective healthy lifestyle apps. VicHealth is a public health agency based in the Australian state of Victoria that is focused on promoting good health and preventing chronic disease. The previously mentioned 5 healthy lifestyle areas were selected as these were the focus of VicHealth's programs and reflected major lifestyle risk factors that contributed to the burden of disease in Australia [22].

In addition, this study also sought to describe the method used in the rating of apps for health-related behavior change with a view to enabling application of the method to regular review and public update about the effectiveness of health apps. This approach has a broad application in other health areas where the assessment of an app's potential to support effective adoption of healthy behaviors is required and where health agencies or government health departments have a mandate to support the public in making effective choices for health. This is particularly critical for app consumers as there is a proliferation of health apps on the market with claims regarding their effectiveness in supporting health behaviors, including behaviors related to a healthy lifestyle and illness self-management. Application of a consistent app review method can simplify the process of regularly reviewing apps on the market to keep the public informed of their potential effectiveness.

Methods

This study employed 2 scales to rate smartphone apps. The first was MARS [20] for functionality, and the second was ABACUS [21] to determine the potential for behavior change. Independent raters applied these scales to the apps identified from the Apple iTunes and Google Play stores.

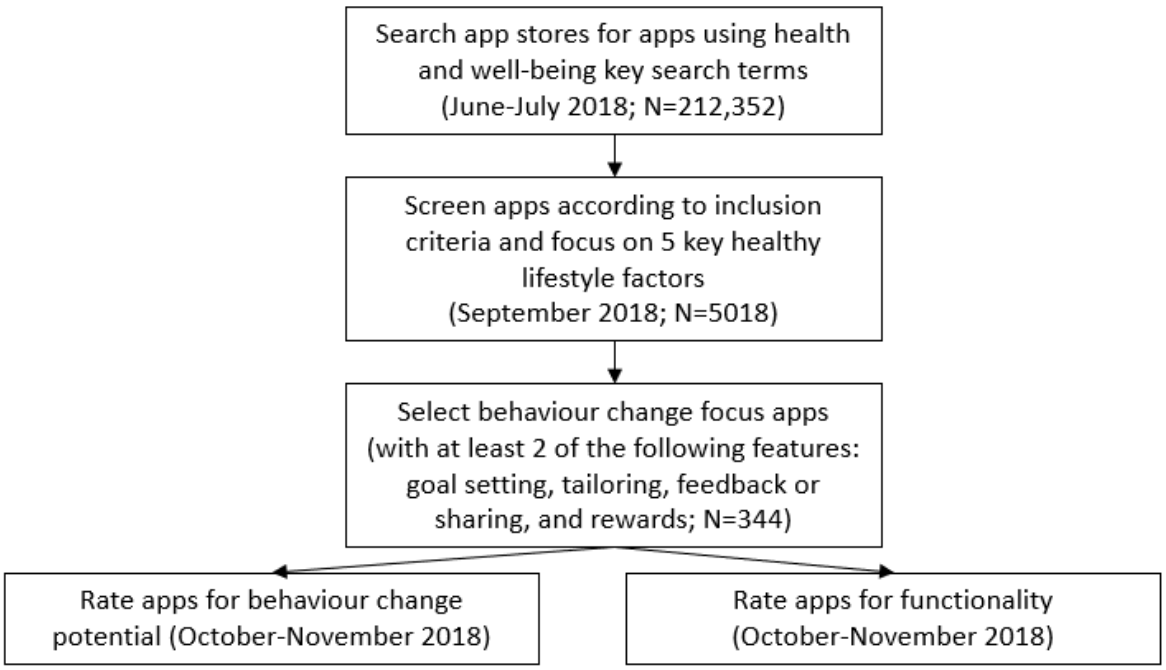
Sample Selection

The Australian Apple iTunes and Google Play stores were searched to identify health and well-being apps using a priori key search terms outlined below from June to July 2018. Identified apps underwent a 4-step screening, review, and rating process (see Figure 1).

All apps available for download in Australia containing a predefined keyword in either the title or description were collected from the Google Play and Apple iTunes stores from June to July 2018. Search terms were developed by health promotion experts in the fields of alcohol and tobacco cessation, healthy eating, physical activity, and mental well-being. This study sought to investigate apps that would encourage health behavior change, rather than those that would simply enable health promotion; therefore, search terms that would identify a specific condition were not included. The search terms used were as follows: health, lifestyle, alcohol, alcoholic, drinks, drinking, booze, sober, blood alcohol, BAC, smoking, smoke, cigarette, tobacco, fitness, exercise, running, exercising, physical activity, active, steps, walking, training plan, nutrition, social isolation, healthy eating, diet, healthy eating, healthy food, health food, healthy drink, health drink, water, hydration, junk food, salt, sodium, social connection, anxiety, well-being, relaxation, mindfulness, stress, mood, meditate, meditation, emotional intelligence, empathy, gratitude, loneliness, friendship, resilience, and resilient. Apps were filtered according to the following inclusion criteria: average user rating of greater than or equal to 3 and at least 10 user reviews (all versions), updated in the last 18 months, and in the English language. Apps were then categorized into 5 key healthy living categories: promoting healthy eating, encouraging regular physical activity, preventing tobacco use, reducing alcohol consumption, and improving mental well-being.

Apps were further filtered and excluded if conflicts of interest were identified, for example, apps promoting negative behavior such as prosmoking in tobacco apps; the app targeted a specific clinical population such as people living with diabetes, or the treatment of psychological disorders, as this review sought to evaluate apps that encourage health behavior change through health promotion and not clinical management of a disease or condition; or the app was not relevant to Australia, including those where a currency other than Australian dollars was only used, nonmetric measures, or a gym franchise in countries other than Australia.

Figure 1. Process for identifying and rating apps.



Following this, app descriptions were reviewed independently by 2 reviewers to determine if they could be classified as promoting behavior change. Behavior change, in this instance, refers to the new activities or actions one needs to do regularly to achieve a healthier lifestyle, for example, exercising, eating healthier food, or managing stress. To investigate the potential for behavior change, app descriptions were reviewed against 4 criteria: (1) the ability to set goals for the actions the user would like to achieve, (2) the ability to tailor the app, (3) the ability to share progress with others (for example, through connections on social media), and (4) the ability to receive rewards or acknowledgments when activities are completed or progress toward a goal is made. These criteria are based on previous health promotion and behavior change research [23]. As this review was interested in apps that had the potential to change behavior, apps that only provided information or connected users to a service or facility and did not meet at least 2 of the 4 behavior change elements listed above were excluded.

All behavior change apps were downloaded for use on an iPhone. If an app was not available for one of those platforms (or was incompatible with the device used), reviewers identified and used a compatible device. Where an app was available on both Google Play and Apple iTunes, for ease, the apps were downloaded for review on an Apple device. When data were collected, the description for apps on Google Play and Apple iTunes were compared. Similarities and differences in app description were noted at this point; however, if the app was described the same way (excluding differences in terms of the user experience, design, or layout as these are expected across the different platforms), the app was considered identical across both Android and Apple platforms. However, this review did not validate every feature of every app across both platforms, as such, there is a possibility that some apps may have differences when used on an Android versus iOS device.

Functionality Review and Rating

The functionality rating uses the MARS [20]. This rating scale was used to examine app elements, such as engagement, functionality, utility, aesthetics, and information. This scale includes 23 items across 5 categories with each item scored using a series of questions on a 5-point ordinal scale response. An overall functionality score out of 5 was derived using this scale.

All apps were scored by at least 2 people with expertise in reviewing apps. To standardize the approach between reviewers, a pilot of a small group of apps was initially conducted and results were compared. Each app was downloaded and, consistent with other studies [15,20], used for approximately 10 min to allow the rater to familiarize themselves with the functionality of the app and user experience. Reviewers attempted to use all parts of each app, noting if the app crashed or its functions were not accessible. Where functionality scores differed, the reviewers considered the app together, sought consensus, and determined a final score.

Technical features of apps were also recorded but did not form part of the functionality rating. These features included the following: whether the app had a privacy policy, required login, allowed password protection, allowed for social media integration, allowed data export, had an app community, sent reminders, needed Web access to function, required add-ons such as a fitness band to use the app (and whether this was a one-off purchase, such as a fitness tracker or an ongoing purchase), the presence of in-app-advertising or payments

(product purchases made within the app, such as unlocking extra features including videos or removing advertisements), and whether the app asked permissions to send push notifications.

Behavior Change Potential Review and Rating

The ABACUS [21] was used to measure behavior change potential. This rating scale comprises 21 items and was used to examine the potential behavior change of the app in relation to goal setting, action planning, barrier identification, self-monitoring, and feedback.

All apps were reviewed and scored by at least 2 reviewers with expertise in public health and health promotion. Interrater reliability was examined with good reliability observed between reviewers (intraclass correlation .906 [95% CI 0.854-0.936]). Each app was first explored by the reviewer to gain familiarity with the app and the interface. The reviewers used all app functions including images, cartoons, videos, record keeping, calendars, and reminders. A total theoretical score out of 21 was calculated by summing the item scores.

Data Analysis

Basic descriptive statistics were conducted to characterize the sample. Percentages are presented for categorical variables and means, or for medians presented for continuous variables. All analyses were conducted using SPSS for Windows, version 22.0 (SPSS Inc).

Results

The initial search was conducted between June 28 and July 2, 2018 and identified 212,352 apps. After applying the filtering criteria, 5018 apps remained. Of these, 356 were classified as behavior change apps, of which 12 were unavailable at the time of review and eventually removed (11 physical activity apps and 1 mental well-being app), leaving 344 for review. These apps were categorized as either physical activity (n=275), healthy eating (n=23), mental well-being (n=27), tobacco (n=14), or alcohol (n=5). All apps were reviewed by 2 reviewers.

Most apps were free (279/344, 81.1%), and all were available on the iTunes platform (344/344, 100.0%), with over two-thirds (236/344, 68.6%) also available on the Google Play store. Around half of the apps required some form of purchase, for example, 171 apps (171/344, 49.7%) required an ongoing purchase including membership or subscription, whereas 141 apps (141/344, 40.9%) required a one-off purchase. Physical activity apps were most likely to require some form of in-app payment (191/344, 55.5%) or one-off purchase (113/344, 32.8%). Two-thirds of all apps (233/344, 67.7%) required some form of in-app payment, typically allowing the user to unlock a feature or to remove advertisements. Advertisements were identified in 93 apps (93/344, 27.1%), mostly in those that were categorized as physical activity apps (75/344, 21.8%); see Table 1 for more app features.

All apps were assessed against both the MARS [20] and ABACUS [21] (see Multimedia Appendix 1 for an overview of scores). Using the MARS, apps were assigned a score out of 5. Apps in this review were given an average score of 2.93 (SD 0.58, range 1.42-4.16), indicating moderate functionality across all apps. Table 2 shows the average scores for the whole sample from the highest average score to the lowest on the MARS. Overall, accuracy of description (3.88), performance (3.30), and layout (3.42) were the highest rating features, whereas the credibility of the app (2.11) was the lowest scoring feature.

The apps that were categorized as mental well-being received the highest MARS scores (average of 3.26), and apps categorized as promoting healthy eating received the lowest MARS scores (average of 2.71). Apps that were categorized as improving mental well-being also scored the highest on many of the individual elements. For example, mental well-being apps scored highest in the elements of accuracy of design (4.17), performance (3.78), target group (3.75), gestural design (3.64), layout (3.6), graphics (3.53), quality (3.43) and quantity (3.05) of information, visual appeal (3.35), interest (2.67), credibility (2.64), visual information (2.5), and entertainment (2.28).

The ABACUS was applied to all apps, resulting in a score for each app from 0 to 21. Scores in this review ranged from 1 to 17, with an average score of 7.8 (SD 2.8), indicating a low-to-moderate number of behavior change techniques included in apps. The apps categorized as tobacco cessation scored the highest on the ABACUS indicating the highest number of behavior change features, with an average of 10.2 in each of the 14 apps rated; this was followed closely by apps categorized as improving mental well-being and promoting healthy eating, which were identified as having on average 8.7 and 8.6 items, respectively. The ability of an app to encourage practice or rehearsal in addition to daily activities was the most commonly identified feature of all apps in total (310/344, 90.1%), and specifically the apps categorized as increasing physical activity (263/275, 95.6%), healthy eating (20/23, 86%), and improving mental well-being (23/27, 85.2%). The second most common feature across all apps was the ability of the app to allow the user to easily self-monitor behavior. This feature was identified in 84.0% (289/344) of apps across all categories and in 100% (14/14) of smoking cessation apps. Apps aiming to reduce alcohol consumption were identified as having the fewest features that could promote behavior change; however, this finding needs to be interpreted with caution as there were only a small number of apps (n=5) in this category (see Table 3 for more details on the frequency of each behavior change technique).

Table 1. App features.

Features	Total sample (n=344)	Increasing physical activity (n=275)	Promoting healthy eating (n=23)	Improving mental well-being (n=27)	Preventing tobacco use (n=14)	Reducing alcohol consumption (n=5)
Price (Aus $), mean (SD)	1.19 (3.73)	1.27 (3.8)	0.78 (1.74)	0.89 (3.00)	0.89 (2.9)	0.89 (2.01)
User rating, mean (SD)	4.43 (0.41)	4.44 (0.39)	4.32 (0.36)	4.5 (0.54)	4.28 (0.47)	4.6 (0.42)
Platform availability—Apple iTunes, n (%)	344 (100)	275 (100)	23 (100)	27 (100)	14 (100)	5 (100)
Can be used without add-ons, n (%)	194 (56.4)	182 (66.2)	22 (95)	27 (88)	14 (100)	5 (100)
Requires in-app payments, n (%)	233 (67.7)	191 (69.5)	15 (65)	17 (62)	8 (57)	2 (40)
One-off purchase required, n (%)	141 (40.1)	113 (41.1)	10 (43)	10 (37)	6 (42)	2 (40)
Had in-app advertisements, n (%)	93 (27.1)	75 (27.2)	8 (34)	3 (11)	6 (42)	1 (20)
Had a privacy statement, n (%)	344 (100)	275 (100)	23 (100)	27 (100)	14 (100)	5 (100)
Allowed password protections, n (%)	32 (9.3)	25 (9.0)	3 (13)	4 (14)	0 (0)	0 (0)
Allowed data to be exported, n (%)	36 (13.4)	35 (12.7)	6 (26)	5 (18)	0 (0)	0 (0)
Allowed sharing, n (%)	219 (63.7)	191 (69.5)	8 (34)	11 (40)	10 (71)	0 (0)
Had an app community, n (%)	106 (30.8)	88 (32.0)	3 (13)	6 (22)	9 (46)	1 (20)
Required login, n (%)	134 (38.9)	110 (40.0)	8 (34)	14 (51)	2 (14)	1 (20)
Sent reminders, n (%)	215 (62.5)	168 (61.1)	14 (60)	20 (74)	12 (85)	2 (40)
Needed Web access to function, n (%)	118 (34.3)	94 (34.2)	6 (26)	12 (44)	5 (35)	1 (20)
Asked permission for push notifications, n (%)	225 (65.4)	182 (66.2)	14 (60)	17 (62)	11 (78)	1 (20)

Table 2. Performance on individual Mobile App Rating Scale elements (highest to lowest).

Item	Mean score	Increasing physical activity (score)	Promoting healthy eating (score)	Improving mental well-being (score)	Preventing tobacco use (score)	Reducing alcohol consumption (score)
Accuracy of description (in app store)	3.88	3.82	3.77	4.17	4.06	4.09
Gestural design	3.30	3.28	3.18	3.64	3.2	3.45
Performance	3.49	3.45	3.32	3.78	3.46	4.0
Target groups	3.33	3.33	3.09	3.75	3.06	3.36
Ease of use	3.29	3.29	3.00	3.60	3.00	3.63
Navigation	3.20	3.19	3.14	3.32	3.13	3.45
Layout	3.42	3.46	3.05	3.60	3.13	3.18
Graphics	3.20	3.20	3.0	3.53	2.8	3.27
Visual appeal	2.94	2.96	2.68	3.35	2.6	2.36
Customization	2.88	2.92	3.05	2.82	2.8	1.81
Interactivity	3.23	3.23	3.36	3.28	3.53	2.54
Interest	2.30	2.29	2.0	2.67	2.06	2.63
Entertainment	2.16	2.19	2.09	2.28	1.93	1.54
Visual information	2.31	2.39	1.59	2.5	2.0	1.81
Goals	2.97	2.88	3.18	3.25	3.6	3.0
Credibility	2.11	2.03	1.91	2.64	2.46	2.63
Quality of information	2.49	2.38	1.77	3.43	2.73	3.9
Quantity of information	2.18	2.11	1.64	3.05	2.2	2.9
Overall rating	2.93	2.93	2.71	3.26	2.75	2.82

Table 3. Performance on App Behavior Change Scale (ABACUS) criteria (most to least frequently used).

Behavior change technique	Frequency	Increasing physical activity	Promoting healthy eating	Improving mental well-being	Preventing tobacco use	Reducing alcohol consumption
Allow or encourage practice or rehearsal in addition to daily activities, n (%)	310 (90.1)	263 (95.6)	20 (86.5)	23 (85.2)	2 (14.2)	2 (40)
Allow the user to easily self-monitor behavior, n (%)	289 (84.0)	238 (86.5)	19 (82.5)	17 (63.0)	14 (100)	1 (20)
Provide instruction on how to perform the behavior, n (%)	233 (67.7)	197 (71.6)	7 (30.5)	23 (85.2)	3 (21.4)	3 (60)
Customize and personalize some features, n (%)	227 (60.0)	186 (67.6)	10 (43.5)	18 (66.7)	10 (71.4)	3 (60)
Reminders and/or prompts or cues for activity, n (%)	225 (65.4)	184 (66.9)	14 (60.5)	18 (66.7)	8 (57.1)	1 (20)
Baseline information, n (%)	192 (55.8)	154 (56.0)	15 (65.5)	6 (22.2)	14 (100)	3 (60)
Give user feedback (person or automatic), n (%)	191 (55.5)	164 (59.6)	4 (17.5)	20 (74.1)	2 (14.2)	1 (20)
Encourage positive habit formation, n (%)	186 (54.1)	151 (54.9)	12 (52.5)	19 (70.4)	2 (14.2)	2 (40)
Share behaviors with others and/or allow for social comparison, n (%)	155 (45.1)	129 (46.9)	4 (17.5)	10 (37.0)	11 (78.5)	1 (20)
Provide general encouragement, n (%)	138 (40.1)	105 (38.1)	8 (34.5)	15 (55.6)	9 (64.2)	1 (20)
Goal setting, n (%)	102 (29.7)	69 (25.0)	20 (86.5)	4 (14.8)	6 (42.8)	3 (60)
Review goals, update, and change, n (%)	98 (28.5)	65 (23.6)	20 (86.5)	3 (11.1)	7 (50)	3 (60)
Understand the difference between current action and future goals, n (%)	83 (24.1)	51 (18.5)	15 (65.5)	2 (7.4)	13 (92.8)	2 (40)
Material or social reward or incentive, n (%)	69 (20.1)	53 (19.2)	7 (30.5)	3 (11.1)	5 (35.7)	1 (20)
App created with expertise and/or information consistent with national guidelines, n (%)	60 (17.4)	27 (9.81)	12 (52.5)	10 (37.0)	9 (64.2)	2 (40)
Information provided about the consequences of continuing and/or discontinuing behavior, n (%)	34 (9.9)	11 (4.0)	1 (4.5)	6 (22.2)	13 (92.8)	3 (60)
Restructure the physical or social environment, n (%)	30 (8.7)	5 (1.81)	3 (13.5)	17 (63.0)	3 (21.4)	2 (40)
Distraction or avoidance	23 (6.7)	3 (1.09)	2 (8.5)	12 (44.4)	4 (28.5)	2 (40)
Provide the opportunity to plan for barriers, n (%)	22 (6.4)	4 (1.45)	4 (17.5)	9 (33.3)	3 (21.4)	2 (40)
Data export, n (%)	18 (5.2)	15 (5.45)	0 (0)	1 (3.7)	2 (14.2)	0 (0)
Willingness for behavior change, n (%)	12 (3.5)	7 (2.54)	0 (0)	0 (0.0)	3 (21.4)	2 (40)
ABACUS average score	7.8	7.56	8.6	8.7	10.2	8.0

Discussion

Principal Findings

This study shows the extent to which smartphone apps incorporate behavior change techniques and basic functionality by using 2 validated scales, the MARS [20] and ABACUS [21]. This study extends on previous app review work by examining a greater number of apps across 5 separate categories and testing the ABACUS for the first time, on a large number of apps [21]. Despite the increase in sample, the results for this Australian study are consistent with past research investigating the inclusion of behavior change techniques in apps for alcohol [24] and smoking cessation [25], weight loss [26,27], and improved physical activity [28], showing that smartphone apps include a limited number of behavior change techniques.

The most common behavior change techniques included in apps in this study were those related to practice and rehearsal, instruction, self-monitoring behavior, customizing features, and the inclusion of reminders or prompts of activity. Given the large amount of research identifying goal setting as important in achieving behavior change [29,30] and with goal setting shown to increase success in changing behaviors around nutrition [31] and physical activity [32], it is disappointing to note that only around one-third of apps included an option for users to set and change goals, with many of the apps only allowing for the review of automatic goals. It is also interesting to note that the ability to plan for barriers, export data from the app (for example, to a health care professional), or gather background on willingness for behavior change were not prominent in the apps reviewed, despite the technology being readily available for these features and other research highlighting such features as important in encouraging positive behavior change [33].

Although we identified a very large number of physical activity apps (almost 80% of the sample) leading to a high level of consumer choice, we found that most included a limited number of techniques known to promote sustained behavior change.

The apps that were categorized as promoting physical activity had on average 7 to 9 behavior change techniques. In over 90% of physical activity apps, the app allowed repeat practice or rehearsal. This feature allows users of the apps to engage in the behavior more than once each day, for example, in a yoga app, the user would be permitted to undertake more than 1 yoga session in a defined period. This is particularly important as behavior change intervention research suggests that repetition is an important component of a successful intervention [34].

Around one-quarter of the physical activity apps contained features allowing users to set their own goals or update these goals. Given the large number of physical activity apps on the market, this is a clear gap in app design, particularly given the large amount of research that has already been conducted on the importance of these features [23,35,36]. However, this is consistent with previous research which indicates that many of the physical activity apps on the market have limited behavior change features [37], and their features consist mainly of step-by-step instructions for particular exercises [35]. It is also disappointing to note that goal setting was missing from alcohol and tobacco cessation apps, given the importance of goal setting in decreasing negative health behaviors [38,39].

Apps that were categorized as improving mental well-being, promoting healthy eating, or reducing alcohol consumption were identified as having around 8 behavior change techniques. Although the small number of alcohol reduction apps received ratings across a large range (range 2-17), the mental well-being and healthy eating apps had ratings across a smaller range (4-16 and 1-12, respectively). Unlike physical activity apps, the healthy eating apps were more likely to include a function to set and revise goals, whereas the mental well-being apps were more likely to encourage positive habit formation, with many of the apps encouraging and enabling daily practice. Mental well-being apps were also identified as allowing users to monitor their behavior against a set goal. This is positive, as there is some emerging research on mental well-being apps showing that those apps with some self-monitoring features are more likely to have positive impacts [28,40].

Limitations

Although there are some interesting findings presented here, there are limitations to this study. First, this study features apps that were available in the Australian Apple iTunes and Google Play stores, and we found no apps that were present in the Google Play store only. Apps that did not allow Australian currency and that did not service an Australian audience were excluded. This could mean that we have missed apps that promote behavior change but are specific to another market. As such, caution needs to be taken when extrapolating these findings to other countries.

It may also be possible that by downloading apps from the Apple iTunes store that were also available in the Google Play store, we have missed an app that has an identical name and description in both stores but different features. Although the listings for apps were compared as part of the identification process to ensure that they were similar, we did not review or rate duplicate apps, and as such, there is a chance that some apps may have differences when used on an Android versus iOS device.

It is important to note that this study only presents an analysis of apps available at a single point in time: 2018. Although this research provides a reference point for further research into the quality of apps and a review of a large number of apps, given the fast-moving nature of this field, some of these apps may no longer be available or may have had their features updated.

A further limitation is the absence of content assessment of health information included within the apps. Although there has been some content investigation of single apps, or a small set of apps, this study is still in its infancy and represents an area for future investigation. Within this review, we also did not seek to measure the quality of the advice given or the relationship between the information provided with that of national and international guidelines.

Finally, with these data, we are unable to draw any conclusion relating to long-term behavior change. Given that we know that sustaining long-term behavior change is difficult, that even those programs that are effective have been shown to result in small changes [41], and that apps are typically used only on a few occasions before they are deleted [24,42], this is an area that needs more research attention as we strive to create apps that will be able to assist in improving the health of a large number of people at a low cost.

Conclusions

The wide variety in apps and the low number of behavior change techniques found in most apps included in this 2018 study suggests an opportunity for growth in apps that can promote sustained and significant behavior change. Furthermore, the small number of apps on the market for reducing alcohol and tobacco consumption may also represent an opportunity for developers to create high quality apps that can assist with behavior change in these areas. Given that app development outpaces research and knowledge translation, it is difficult to see a time where apps will be based on best practice or most up-to-date behavior change techniques. However, with the increasing body of research identifying limitations in current apps, there is a potential for the creation of apps to more likely encourage behavior change. To this end, this research is complemented by a set of guidelines for app developers to assist them in developing apps that can effectively support lifestyle behavior change [43].

Overall, the use of the ABACUS [21] taxonomy for behavior change and the MARS [20] was successful. The reviewers reported having clear guidelines for the review, the time taken for each app was not prohibitive, and interrater reliability was good. Therefore, it provides a method that could be replicated and tested in other behavior change areas or used on a periodic basis to review apps available on the health app market to enable consumers to make optimal app selections.

Acknowledgments

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Authors' Contributions

HS and MU identified health and well-being apps in the Australian Apple iTunes and Google Play stores and collected data relating to app features and functionality using the MARS. FM led the research team that collected data relating to potential behavior change effectiveness using the ABACUS. FM analyzed the data. FM and AW drafted the manuscript. All authors read and contributed to the finalization of the manuscript. All authors approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Process for identifying and rating apps.

[XLSX File (Microsoft Excel File), 21KB - mhealth_v7i7e11926_app1.xlsx]

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Abbreviations

ABACUS: App Behavior Change Scale
MARS: Mobile App Rating Scale
VicHealth: Victorian Health Promotion Foundation

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Original Paper

Applying a User-Centered Approach to Building a Mobile Personal Health Record App: Development and Usability Study

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Abstract

Background: A personal health record (PHR) system encourages patients to engage with their own health care by giving them the ability to manage and keep track of their own health data. Of the numerous PHR systems available in the market, many are Web-based patient portals and a few are mobile apps. They have mainly been created by hospitals and electronic health record (EHR) vendors. One major limitation of these hospital-created PHR systems is that patients can only view specific health data extracted from their EHR. Patients do not have the freedom to add important personal health data they collect in their daily lives into their PHR. Therefore, there is an information gap between clinical visits.

Objective: The aim of this study was to develop and evaluate a new mobile PHR app that can be easily used to manage various types of personal health data to fill the information gap.

Methods: A user-centered approach was used to guide the development and evaluation of the new mobile PHR app. There were three steps in this study: needs assessment, app design and development, and conducting a usability study. First, a large-scale questionnaire study was conducted with the general population to gain an understanding of their needs and expectations with regard to a mobile PHR app. A mobile PHR app for personal medical data tracking and management was then created based on the results of the questionnaire study. End users were actively involved in all stages of the app development. Finally, a usability study was performed with participants to evaluate the usability of the mobile PHR app, which involved asking participants to finish a set of tasks and to respond to a usability questionnaire.

Results: In the questionnaire study for needs assessment, there were 609 participants in total. The answers from these participants revealed that they wanted to manage various types of personal health data in a mobile PHR app. Participants also reported some features they desired to have in the app. On the basis of the needs assessment findings, a new mobile PHR app (PittPHR) was created with 6 major modules: health records, history, trackers, contacts, appointments, and resources. This app allows users to customize the trackers according to their needs. In the usability study, there were 15 participants. The usability study participants expressed satisfaction with the app and provided comments and suggestions for further development.

Conclusions: This new mobile PHR app provides options for users to manage a wide range of personal health data conveniently in one place. The app fills the information gap between clinical visits. The study results indicated that this new mobile PHR app meets the need of users and that users welcome this app.

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KEYWORDS

mobile app; personal health record; needs assessment

Introduction

Background

To improve the quality of health care and reduce costs, the Institute of Medicine has recommended the creation of high-quality health data collection systems [1]. This recommendation and the Health Information Technology for Economic and Clinical Health (HITECH) act have led to a dramatic increase in the adoption of electronic health record (EHR) systems in the United States in recent years (from 20.8% in 2004 to 85.9% in 2017), which makes it possible for physicians to easily access detailed patient data [2].

However, the current EHR systems only store data collected during patients' clinic and hospital visits. Anything happening in between those visits is not included in EHR systems, for instance, did the patient take prescribed medication on time? Did the patient become more active after the doctor suggested increasing physical activity? To what extent did the mood of the patient stabilize in the period of time after a mental health intervention was delivered? This type of information can be critically important for health care providers to determine the effectiveness of their treatment strategy and to identify the reason behind disappointing treatment outcomes. In most cases, health care providers can only obtain this type of information by asking their patients when they visit a clinic or hospital, and the information obtained at that moment is typically not highly reliable because the accuracy of the data mainly depends on the memory of the patient.

To fill this *information gap* and to empower patients so that they can be more active in their own health care, one approach is to provide personal health record (PHR) systems to patients and allow patients to access and manage their own health data [3-6]. According to the Office of the National Coordinator for Health Information Technology (ONC), PHR is "an electronic application through which patients can maintain and manage their health information (and that of others for whom they are authorized) in a private, secure, and confidential environment" [7]. The International Organization for Standardization (ISO) also provided a definition for PHR and emphasized the health records in PHR should be "primarily managed and controlled by the individuals who is the subject of the record, or his/her authorized representative" [8].

Previous Work

There are many PHR systems on the market; many are Web portals created by hospitals or EHR vendors to provide patients *preselected* data items from corresponding EHR systems, such as laboratory test results, medications, immunization records, visit notes, and appointment schedules [9]. This type of PHR is called by many different names, such as EHR-tethered PHR portal, tethered PHR portal, PHR portal, or simply, patient portal. One example of a PHR portal is My HealtheVet from the Veterans Health Administration [10,11]. Another example is MyChart, created by Epic Systems Corporation and used by many hospitals. Both MyChart and My HealtheVet provide patient data access, prescription refills, and *a few* patient-reported health data items, such as blood pressure and blood sugar. Several other Web-based PHR portals offer similar major features, with variations in terms of the patient information tracking tools, specific data items provided, and patient populations targeted [12-17].

These PHR portals provide useful health-related data access to patients and empower patient self-management. Some earlier studies reported improved quality of care and clinical outcomes as a result of using PHR portals [17-19]. The common limitation of these PHR portals is that they do not provide much flexibility to patients in terms of what health data generated between clinical visits can be entered. In other words, the *information gap* mentioned earlier is still there, even with the availability and use of these PHR portals.

In recent years, PHR technology has moved forward, and a number of mobile PHR apps have been created, such as the mobile app version of MyChart, an EHR-tethered PHR app named MyHealthKeeper, and several mobile PHR apps without unique app names [20-22]. These mobile apps make access to PHRs easy, given the rapid growth of mobile device ownership in recent years and the high portability of mobile devices.

However, most of these mobile PHR apps are also limited, as they only offer features similar to those in Web-based PHR portals. Moreover, many of them were also created by hospitals and EHR vendors, meaning the major data source for these mobile PHRs was still the corresponding EHR systems. Hence, although these mobile PHR apps can provide a certain level of convenience and empowerment to patients, they still cannot fill the *information gap* between the typical clinical visits because patients can only enter very limited types of personal health data items in these PHR mobile apps [6,23]. In other words, as with those PHR portals, the patient data are still fully controlled by hospitals and health care providers; therefore, patients can only use these PHR systems to *access and manage data items selected by health care providers*.

This could be one major reason for high interest in but low adoption of PHR portals and mobile PHR apps [24,25]. In several previous research studies and systematic reviews, study participants expressed the belief that PHRs could be useful for better quality of health care; however, before they actually use any PHR portals or apps, they expect PHRs to offer a wide range of secure, user-friendly, and patient-centered functionalities so that they can perform self-management of their conditions [6,19,26-30]. Examples of desired features are personalization for patients and their health issues and patient-generated health data (PGHD) reporting [31]. This study will mainly focus on the PGHD reporting as the availability of this feature will allow the information gap between patients' clinical visits to be filled.

According to the definition from the ONC, PGHD is "health-related data created and recorded by or from patients outside of the clinical setting to help address a health concern" [32]. One type of PGHD is readings from various wearable sensors. In recent years, many types of wearable sensors and their corresponding mobile apps have been released to the market. A number of research studies have evaluated the reliability of these wearable sensors. The study results have indicated that some wearable sensors are highly reliable in terms of some health data tracking such as steps, heart rate, and sleep

[33-39]. Hence, the data items from these wearable sensors are sufficiently accurate to make them valuable for patients' health management and monitoring. Many people have started to use these wearable sensors to track their health data [40-42]. However, the data collected from these wearable sensors are currently stored in different places such as the memory of devices or the corresponding mobile apps, which makes it difficult for patients to manage these data items.

Then, a desirable feature of PHR portals or apps would be the ability for patients to store readings from these wearable sensors in *one single place* so that they can manage *all* of their health data conveniently [6,23]. It is believed that if all patient-needed health data are stored in a PHR portal or mobile app, the PHR adoption rate might improve because the PHR could satisfy patients' health information needs and further improve the convenience of using it. Their health data would become easier to manage. Moreover, reliability of the health data could also be improved because patients only need to manage one copy of their health records. This single place storage for all health data also would make it easy for patients to share their health data with their health care providers, which in turn might encourage health care providers to utilize patient-generated data in their clinical decision making [6,23]. Unfortunately, many existing PHR portals and mobile apps do not provide this desired feature.

Objectives

In this study, a user-centered approach was used to develop and evaluate a new mobile PHR app. This mobile app can be used to manage various types of personal health data, including the data types usually offered in the current PHR systems (Web portal or mobile app), as well as the data items generated by multiple types of trackers and personal health monitoring devices such as pedometers, smart watches, digital blood pressure monitors, and digital weight scales. It is expected that this new mobile PHR app is lightweight, highly portable, and convenient to use and will serve the target users better in terms of personal health data management. Here, the target users are anyone who want to manage all their health data in a single place. The app is expected to fill the information gap between clinical visits.

In the remaining of this article, we describe the methods, results, discussion, and conclusions of the study. The Methods section presents the study design and procedure for a needs assessment, the mobile app architecture, and the usability study. The Results section provides the results obtained in the needs assessment, the features implemented in the mobile PHR app according to the assessment, and the outcomes of the usability study. The Discussion section explains the principal findings, comparison with other studies, and the limitations of this study. The last part is the conclusions of the study.

Methods

User-Centered Approach for App Development and Evaluation

In a user-centered approach, target users of a system are actively involved in all the stages of system development, including requirement analysis, system design and implementation, and system evaluation. With regard to this project, it includes (1) specifying users' requirements, (2) designing the app according to users' requirements, (3) having users evaluate the mobile app (usability study), and (4) making all necessary adjustments to the app design and implementation according to users' feedback [43,44]. These are the steps we took in this study. The details of these steps are described in the following sections.

Questionnaire for Needs Assessment

To create the desired mobile PHR app, the first step was to perform requirement analysis by collecting users' expectations with respect to the specific data items they plan to manage in the app. A questionnaire with 14 questions was created to collect target users' ideas about a mobile PHR app.

In the first section of the questionnaire, respondents were asked to provide answers to a set of demographic and background questions. The demographic questions were about age, gender, race, marital status, education, and income level. In addition, two background questions were asked about the health status and experience using mobile health (mHealth) apps: (1) What is your own assessment of your health? (2) Have you used mobile health apps before?

In the second section of the questionnaire, 6 questions were used to determine users' desired health data content and format. For each question, there was a list of options, and the respondents were allowed to choose one option (Q3 and Q5) or multiple applicable options (Q1, Q2, Q4, and Q6) or add their own answers. The options for the first question were arranged in three groups. The following are the 6 questions:

- Q1. What content would you like to see in a mobile PHR app?
  - Q1.1. Medical records to manage
  - Q1.2. Information to track
  - Q1.3. Other information
- Q2. What specific health issues do you plan to manage with this proposed PHR app?
- Q3. What type of user interface works the best for you in the proposed PHR app?
- Q4. If you plan to manage your laboratory test results in this proposed PHR app, what is the desired format for showing the laboratory results?
- Q5. Do you expect to see an overview dashboard to show the summary of your health information in this proposed PHR app?
- Q6. What type of security protection do you expect to see in this proposed PHR app to protect your personal health information?

This questionnaire study was conducted via the Web-based Qualtrics system (Qualtrics). A public announcement including the purpose of the study and the link to the questionnaire was distributed to roughly 2000 recipients via a bulk email system at the University of Pittsburgh. Study participants provided their answers to these questions on the Web-based system. The obtained data were statistically analyzed using SPSS version 25 (IBM).

Mobile App Design and Development

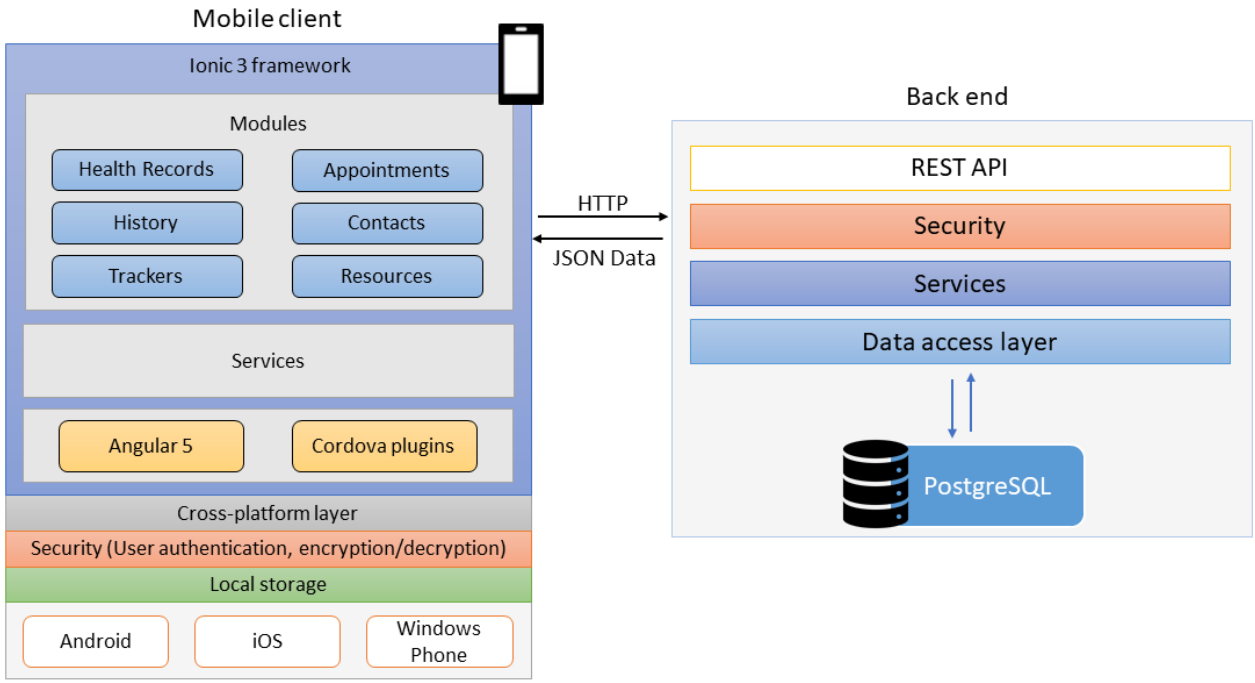
A mobile PHR app (PittPHR) was designed and developed based on the information collected in the questionnaire study. Users were involved throughout the PHR app's design and implementation process. During both the design and implementation stages, users actively contributed their ideas and provided their feedback to multiple versions of the app prototype in terms of usability and user experience. Their suggestions have been incorporated into the current version of the mobile PHR app.

The Ionic 3 (Drifty, Co.) was chosen to implement this mobile app as it is a cross-platform framework allowing the app to run on mobile devices with iOS, Android, or Windows Phone system. The app can be deployed natively on a mobile device using Apache Cordova (Apache Software Foundation). After the deployment, the app runs in the Web browser as a Progressive Web App. The app cannot be used if an internet connection is not available. PostgreSQL (PostgreSQL Global Development Group) was chosen for the back-end database because it is a powerful, highly scalable, cross-platform, and free open-source relational database system.

Figure 1 shows the architecture of the app. The left-hand side is the mobile client app running on the user's mobile device, including the modules identified in the needs assessment study, supported by Angular 5, Cordova plugins, and security services (mainly user authentication, encryption, and decryption). Local storage is available for this system but is not used for any patient data storage. On the right-hand side are the components of the back-end server, mainly the PostgreSQL database, which can be accessed by the mobile client app via the interface of the REST (REpresentational State Transfer) API (Application Programming Interface). The data exchange between the mobile client and the back-end server takes place through the HTTP protocol and the JSON (JavaScript Object Notation) data standard.

Data encryption and user authentication features are implemented in the app for patient data security protection. When a user has a specific data item to enter into this mobile app, the user needs to log into the mobile PHR app (user authentication), choose a specific category, and enter the information into the app. The entered data are encrypted with the Advanced Encryption Standard (AES) algorithm and sent to the remote secure server behind a firewall for permanent storage. The entered data are only stored on the remote server in an encrypted format. To review health records on the mobile app, the encrypted data are retrieved from the remote server and decrypted only on the mobile device to show the content. In other words, only authenticated users can enter and view their own health data on the app.

Figure 1. System architecture of the mobile personal health record app. REST: REpresentational State Transfer; HTTP: HyperText Transfer Protocol; API: application programming interface; JSON: JavaScript Object Notation.



Mobile App Evaluation

A usability study was conducted on PittPHR with 15 participants to evaluate the usability of the mobile PHR app. In a usability study, 4 to 5 participants are sufficient for identifying 80% of usability issues, whereas 15 participants are sufficient for identifying all usability problems [45-47]. The study advertisement was posted on the Pitt + Me website [48]. Potential study participants expressed their interest in participating in this usability study on the website, and a random selection was performed from this potential participant pool by considering their age (≥18 years and having representatives of different age groups) and gender (balanced male and female participants). The study protocol was approved by the institutional review board at the University of Pittsburgh.

In this usability study, after signing a consent form, the study participants were introduced to the PittPHR app by being given the purpose of the study and a brief demonstration of the features in the app. The study participants were then required to complete several tasks, including (1) logging into the app on a mobile device (iPad Mini 4, iOS 11.4, 7.9-inch); (2) entering records in various categories such as laboratory test results, immunization records, medical history, allergies, food consumed in one day, and a doctor's appointment; (3) reviewing the entered health information; and (4) updating the information on the app. Both the mobile device and the health-related records entered into the mobile app were provided by the research team.

Upon completion of all assigned tasks, the participants were asked to complete the Post-Study System Usability Questionnaire (PSSUQ) to provide their overall impression of the app [49]. The study participants were also asked to provide general comments and suggestions regarding the mobile PHR app after they filled out the usability questionnaire. Descriptive statistics of the responses to the usability questionnaire were calculated using SPSS version 25. The participants' comments were summarized.

Results

In this study, we performed the needs assessment using a questionnaire to collect ideas directly from users of the app, implemented the user-desired features in the new mobile PHR app, and evaluated the usability of the app. This mobile PHR app enabled users to manage all their health data conveniently in one place, which in turn may encourage users to be more involved in their health care and fill the information gap between typical clinical visits.

Results of the Questionnaire Study

In total, 609 people answered the Web-based questionnaire. As the email announcement about the questionnaire was distributed to approximately 2000 people, the response rate was approximately 30.45%. Considering that the email announcement was only distributed once, this response rate was good. The demographic information for these respondents and their answers to the background questions (self-assessed health status and experience of using mHealth apps) are summarized in Table 1. The numbers show that these study participants consist of people of different age groups, genders, races, education levels, marital status, income levels, mHealth app use experiences, and health status. For each question, there were a few to several subjects who chose not to provide an answer to the question. These were different people for different questions. Those numbers are not shown in the table. Please note that for the race question, *other* was one of the options; similarly, for the household income question, *decline to answer* was one of the options. Therefore, the corresponding numbers are listed in the table.

The answers to the questions about user-desired data contents, format, and other features in a mobile PHR app are summarized in Table 2. As mentioned in the Methods section, when the study participants provided their answers to Q1, Q2, Q4, and Q6, they were allowed to choose one or multiple options and add answers that were not shown in the given options. They were only allowed to choose one option or add their own answer to Q3 and Q5. Again, there were some study participants who chose not to answer some questions.

The answers to Q1 are arranged into three groups in Table 2, that is, medical records to manage, information to track, and other desired information. The data in the *medical records to manage* group are the typical medical records such as laboratory test results, doctor visit notes, medication, immunizations, medical history, and social history. More than half of the study participants indicated that they would like to use the mobile PHR app to manage the first 5 types of data items. Only 11.5% of the study participants wanted to use the app to manage social history. Some respondents suggested including additional types of records such as surgical history, family history, and allergies.

In the *information to track* group, the respondents chose many types of data that they wanted to track in the app. In Table 2, only a few major ones are listed, including nutrition, physical activity, health activity, and health diary. Other data items specifically mentioned by the study participants in their answers as items they would like to track are calorie intake, weight, pain level, period, lens prescription, and sleep duration.

In the *other information* group, the respondents indicated multiple types of other data items that they would like to see in the mobile PHR app, such as reliable resources for various diseases, family members' and doctors' contact information, and doctor's appointments.

The study participants' answers to Q2 provided the specific health issues they would like to use the mobile PHR app to manage. The top 4 were weight management, medication management, cardiovascular disease, and diabetes. Some respondents (116/609, 19.0%) mentioned several other health issues they would like to manage with the mobile PHR app, such as pain, sleep, asthma, blood pressure, anxiety, and stress.

In the answers to Q3, the study participants indicated their preferences regarding the user interface of the mobile PHR app. More than 40% of the study participants claimed that they would like to see a colorful and graphical user interface. Approximately 31% of the study participants (188/609, 30.9%) reported that they would like to have a customizable user interface, and around 21% (127/609, 20.9%) stated that they would like to have a text-based user interface.

In Q4, the study participants reported their preferred format for laboratory results: 40% (243/609, 39.9%) of the study participants preferred to have their laboratory results shown as lists, close to 40% liked tables, and around 20% liked to see them as graphs.

The study participants were asked whether they needed an overview dashboard in Q5. About 60% of them claimed that they would like to have an overview dashboard in the app to quickly check the recently updated health data on a single page. Close to 30% of them were not sure whether a dashboard was necessary, and a small number (38/609, 6.2%) felt that it was not necessary.

Table 1. Demographics and background of the study participants (N=609).

Demographics	Value
Age (years), mean (SD)	43.3 (13.28)
18-28, n (%)	106 (17.4)
29-45, n (%)	222 (36.5)
46-55, n (%)	142 (23.3)
≥56, n (%)	131 (21.5)
Gender, n (%)	
Male	134 (22.0)
Female	473 (77.7)
Race, n (%)	
African American	15 (2.5)
White	557 (91.5)
Asian	21 (3.4)
Other	13 (2.1)
Education, n (%)	
High school or lower	15 (2.5)
Some college credits, no degree	55 (9.0)
Associate degree	31 (5.1)
Bachelor’s degree	231 (37.9)
Master’s degree	176 (28.9)
Doctoral degree	89 (14.6)
Professional degree	10 (1.6)
Marital status, n (%)	
Single	157 (25.8)
Married	406 (66.7)
Divorced	37 (6.1)
Widowed	6 (1.0)
Household income, n (%)	
< US $25,000	24 (3.9)
US $25,001-US $50,000	109 (17.9)
US $50,001-US $75,000	109 (17.9)
US $75,001-US $100,000	96 (15.8)
US $100,001-US $125,000	71 (11.7)
>US $125,000	116 (19.0)
Decline to answer	70 (11.5)
Used mobile health apps before, n (%)	
Yes	359 (58.9)
No	248 (40.7)
Self-assessed health status, n (%)	
Excellent	53 (8.7)
Very Good	263 (43.2)
Good	234 (38.4)
Fair	55 (9.0)

Demographics	Value
Poor	3 (0.5)

Table 2. Summary of answers to questions about data content and format and desired features (N=609).

Contents and features	Value, n (%)
Q1.1. Medical records to manage	
Test results	398 (65.4)
Doctor visit notes	272 (44.7)
Medication	372 (61.1)
Immunizations	382 (62.7)
Medical history	389 (63.9)
Social history	70 (11.5)
Q1.2. Information to track	
Nutrition	417 (68.5)
Physical activity	413 (67.8)
Health activity	371 (60.9)
Health diary	295 (48.4)
Q1.3. Other information	
Reliable resources	268 (44.0)
Other	46 (7.6)
Q2. Health issues to manage	
Weight management	428 (70.3)
Medication management	209 (34.3)
Cardiovascular disease	89 (14.6)
Diabetes	43 (7.1)
Other	116 (19.0)
Q3. User interface	
Colorful and graphical	259 (42.5)
Customizable user interface	188 (30.9)
Clean text interface	127 (20.9)
Q4. Format for laboratory results	
List	243 (39.9)
Table	237 (38.9)
Graph	131 (21.5)
Q5. Overview dashboard	
Yes	368 (60.4)
Maybe	173 (28.4)
No	38 (6.2)
Q6. Security protection	
User authentication	503 (82.6)
Encryption	230 (37.8)
Data backup	131 (21.5)

The last question, Q6, was about user-desired security protection. The vast majority of the study participants indicated that they wanted to see user authentication in the mobile PHR app. Other desired security protection features listed were data encryption and data backup. Some study participants even further indicated the user authentication methods, such as biometrics.

Implemented User-Desired Features of the New Mobile Personal Health Record App

The user-desired contents and features identified in the questionnaire study were implemented in the mobile PHR app (PittPHR). As shown in Figure 1, there are 6 major modules in this mobile app: Health Records, History, Trackers, Appointments, Contacts, and Resources. The *Health Records* module is used to manage frequently updated medical information, such as laboratory test and diagnostic test results, doctor visit notes, medications, and immunization records. The *History* module is used to manage relatively stable medical data, such as medical history, family history, surgical history, allergies, and social history. Users can use the *Tracker* module to track 12 different types of personal heath data, such as weight, blood pressure, physical activity, food, drink, sleep, period, and pain. The *Appointments*, *Contacts*, and *Resources* modules are used to manage all types of doctor's appointments, contacts, and links to health resources. Both the *Trackers* and *Resources* modules are customizable; users can customize the trackers according to their own needs by hiding or unhiding available trackers in a given list, and they can add or delete links in the Resources module according to their own needs. All 6 modules are supported by the cross-platform layer; therefore, they can run on all three major mobile operating systems (Android, iOS, and Windows Phone system). Data security protection features were implemented in the app to conduct user authentication and data encryption and decryption.

The users' preferences on data content and format were incorporated in the new mobile PHR app. Figure 2 shows eight screenshots of the mobile PHR app. The first 4 screenshots on the top will be described from left to right (a-d), and then the next 4 screenshots on the bottom will be described from left to right (e-h). This mobile app has a colorful and graphical user interface. The first screenshot (top left) in Figure 2 displays a list of modules in the app on the left-hand side and the contents of the dashboard (truncated) on the right-hand side. The dashboard shows a summary of recently entered data, for instance, a new medication—aspirin. The Health Records and the History modules can be expanded to show further details. The second screenshot in Figure 2 shows the screen that appear if the Test Results section in the Health Records module is selected. The third and fourth screenshots in Figure 2 display the screens that appear when each of the two buttons in the second screenshot is selected. The third screenshot has a list of commonly ordered laboratory tests, organized in alphabetical order. The fourth screenshot (top right) includes a list of commonly orders diagnostic procedures.

If any of these test items is clicked, a very brief form will be shown under the tab TRACK in the fifth screenshot (bottom left) in Figure 2 so that the app user can enter data items such as the date, test result (numbers or texts), and any additional notes the user wants to enter. The test results entered over time will be shown as a list under the tab HISTORY, shown in the fifth and sixth screenshots. If the test results are quantitative, the history can also be shown as curves under the tab CHART, as shown in the sixth screenshot. In other words, some quantitative test results can be shown either as a list or a graph according to the user's preference. For some tests, the normal range of test values has been incorporated into the app and can be shown as a shadowed band or a straight line in the chart. If the normal range of test results is not available or has not be incorporated into the app, only the test results will be shown in the chart.

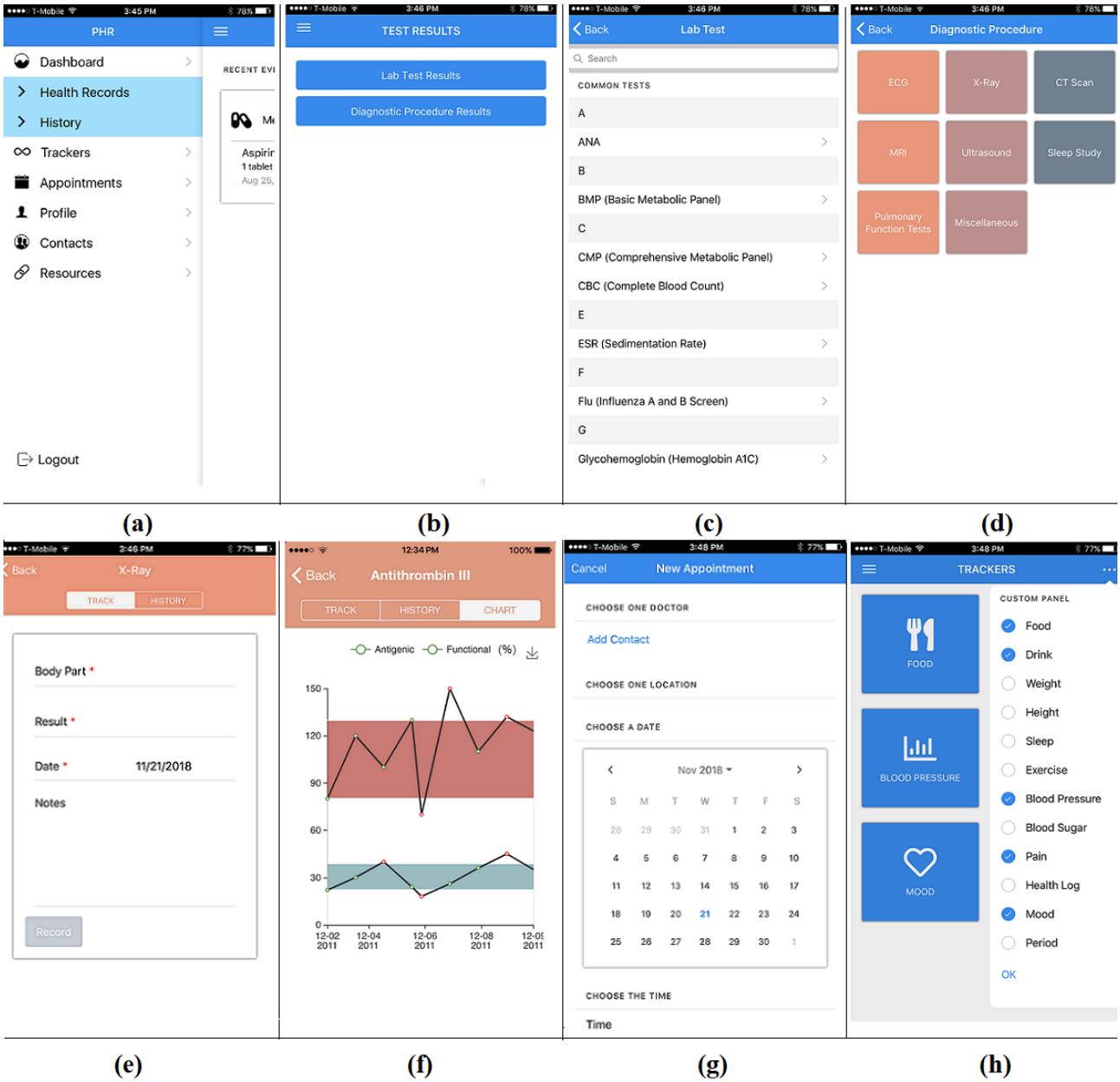
The seventh screenshot in Figure 2 displays the page for adding a new doctor's appointment. If the doctor's contact information is already stored in the Contacts module in the app, users can simply choose the doctor from the contact list and indicate the appointment date and time in the form and calendar shown in the seventh screenshot. If the chosen doctor has multiple office locations, users also have the option to select the location of that specific appointment. If the doctor's contact information is not stored in the Contacts module, users can add the contact information by clicking the *Add Contact* button in the seventh screenshot to fill out a form with the doctor's full name, office addresses, specialty, office phone number, and fax number (not shown).

The last screenshot (bottom right) in Figure 2 shows the page for health data tracker selection. Users can choose their desired trackers from the list on the right-hand side after they click the three dots at the top right corner of the page. Once users make their selection, only the chosen trackers will be shown in this page. To use a tracker, users can click the icon and fill out a brief form for the tracker. For instance, to report the blood pressure, users only need to provide the numbers for the systolic and diastolic readings plus the date and time.

The details of a few other modules are not shown in Figure 2. The Contacts module offers users a space to store several types of contact information, such as emergency contacts, family members, friends, and doctors. The Resources module allows users to manage website links to Web-based resources useful for themselves. There is also a Profile section in the mobile app, which is used to show users' basic information such as name, address, age, gender, phone number, and email address.

All the modules in this mobile app are designed to be extensible according to the needs of users. For instance, more laboratory tests, diagnostic procedures, and new trackers can be added to this app.

Figure 2. Screenshots of the new mobile personal health record app. (a) Dashboard. (b) Two types of tests in the Test Results section under the Health Records module. (c) A list of commonly ordered laboratory tests. (d) A list of buttons for commonly ordered diagnostic procedures. (e) A simple form for entering a typical x-ray exam result. (f) Graphical test results collected over time. (g) The page for adding a doctor's appointment. (h) The customizable tracker choices.



Usability Study Results

The usability study was performed with 15 participants from June 2018 to October 2018. These participants were selected from among 114 persons who expressed their interest in participating in this usability study on the Pitt + Me website. The demographics of the 15 usability study participants are summarized in Table 3.

Overall, 9 (60.0%) participants used mHealth apps regularly. Frequently mentioned mHealth apps were Apple Health, MyFitnessPal, Samsung Galaxy Health, Map My Ride, Cardiio, and Fitbit. One participant mentioned that she used a calorie intake app, a daily pill reminder, and a period tracker but did not provide specific names of these apps.

Table 3. Demographics of the usability study participants (N=15).

Demographics	Value
Age (years), mean (SD)	35.3 (15.24)
Gender, n (%)	
Male	8 (53.3)
Female	7 (46.7)
Race, n (%)	
African American	2 (13.3)
White American	8 (53.3)
Asian American	5 (33.3)
Education, n (%)	
High school or lower	2 (13.3)
Some college credits, no degree	1 (6.7)
Bachelor's degree	3 (20.0)
Master's degree	5 (33.3)
Professional degree	2 (13.3)
Doctoral degree	2 (13.3)
Marital status, n (%)	
Single	9 (60.0)
Married	6 (40.0)
Years used smart devices, mean (SD)	7.8 (2.4)
Used mobile health apps before, n (%)	
Yes	13 (86.7)
No	2 (13.3)
Self-assessed health status, n (%)	
Excellent	4 (26.7)
Very Good	7 (46.7)
Good	3 (20.0)
Fair	1 (6.7)

All study participants were able to finish the given tasks in the usability study easily, in approximately 15 min on average. The details of the study participants' responses to the PSSUQ statements in this usability study are provided in Table 4. Participants could choose from 1 to 7, where 1 means strongly agree, whereas 7 means strongly disagree. Therefore, the lower (closer to 1) the values of these statements, the higher the usability of the app because lower values indicate that these study participants agreed that the app was easy to learn, was easy to use, was effective to finish tasks, had all desired features, and had a good user interface and that they were satisfied with the app. This is also true for the overall average of the PSSUQ scale, that is, a lower overall average value corresponds to a higher usability of the app. In this study, the overall average of the participants' response in the PSSUQ was 1.90 (SD 0.526). Therefore, the usability of the app was shown to be high. The small SD indicates that these study participants' opinions were consistent.

The following are some comments from study participants about their overall impression of the PHR mobile app:

> *It was easy to use and easy to learn. I want to download the app and use it* [Participant 5]
>
> *I like this app and would like to use it if it were available for download. Overall, the app was easy to understand* [Participant 2]
>
> *It is a handy app to keep lab test results. I like the different color-coded sections.* [Participant 9]
>
> *This app is easy to use and user friendly* [Participant 12]
>
> *This is a pretty good and easy to use system* [Participant 15]

Table 4. Usability study results.

Statements	Mean (SD)
Overall, I am satisfied with how easy it is to use this system.	1.73 (0.704)
It was simple to use this system.	1.67 (0.724)
I could effectively complete the tasks and scenarios using this system.	1.53 (0.516)
I was able to complete the tasks and scenarios quickly using this system.	1.40 (0.507)
I was able to efficiently complete the tasks and scenarios using the system.	1.67 (0.724)
I felt comfortable using this system.	1.53 (0.640)
It was easy to learn to use this system.	1.40 (0.507)
I believe I could become productive quickly using this system.	1.73 (0.704)
The system gave error messages that clearly told me how to fix the problems.	3.47 (0.834)
Whenever I made a mistake using the system, I could recover easily and quickly.	2.40 (1.404)
The information (such as on-line help, on-screen messages and other documentation) provided with this system was clear.	2.67 (1.397)
It was easy to find the information I needed.	1.67 (0.900)
The information provided for the system was easy to understand.	1.67 (0.724)
The information was effective in helping me complete the tasks and scenarios.	1.67 (0.724)
The organization of information on the system screens was clear.	1.60 (0.632)
The interface of this system was pleasant.	2.00 (1.069)
I liked using the interface of this system.	1.97 (0.915)
This system has all the functions and capabilities I expect it to have.	2.40 (1.549)
Overall, I am satisfied with this system.	2.00 (1.254)

In addition to these general comments, study participants also provided specific suggestions for further improvement on the app. We assigned these suggestions to one of 4 common themes that emerged upon analysis. When multiple participants mentioned the same feature, only one representative comment is cited here.

- Theme 1 Connect to other information systems to reduce the data entry load and share the information with others, such as doctors:

  Would it be able to pair with sensors and show real-time data? [Participant 6]

  Can this be connected to the standard health records? [Participant 7]

  For social, family history etc., can you include "canned" items already, so that we may minimize the amount of data that we need enter? [Participant 8]

  Can you link this app to the phone's calendar and load the existing doctor's appointments? [Participant 14]

  It would be nice if my doctors could also see the data I entered in the app [Participant 15]

  Can you connect to the phone's camera so that I can upload photos? [Participant 17]

- Theme 2 Reminders and alerts:

  Would there be an alert going out to me when the medication needs to be re-filled? [Participant 12]

  It would be helpful to have a description for each vaccination so that the user is reminded when to do next ones [Participant 14]

  It would be helpful to have an alert for upcoming appointments [Participant 18]

- Theme 3 Standardization of patient-entered information:

  It would be nice to have a section saying what the normal range for each test result is. [Participant 12]

  If the medication names were from a database, users would not need to know the exact spelling of each medication. [Participant 12]

  A pre-populated drop-down list whenever possible on all occasions would be good, such as for medication names, test result units, food servings, and diagnosis [Participant 14]

- Theme 4 Other desired features for convenience and flexibility:

  Can the tracking data be graphed? For example, show the quality of sleep (episodic tracking). [Participant 8]

  For medication, add a notes section. [Participant 9]

  It would be helpful to track daily activity and provide on dashboard showing how much calories were consumed each day etc [Participant 14]

  Can you add QR code capability? [Participant 16]

Discussion

Principal Findings

In this project, a user-centered approach was used to design, implement, and evaluate the mobile PHR app, PittPHR. This app provides users with the ability to collect and manage all their health data in a single place, including the typical medical records and PGHD. The features of this app may encourage users to be more involved in their own health care and eventually improve health care quality [50-52]. Use of this mobile app to flexibly manage various types of patient health data may also fill the information gap currently existing between clinical visits.

Before designing and developing this app, to determine user's needs and preferences, a short questionnaire was created and distributed to approximately 2000 recipients. In total, 609 persons answered the questionnaire and indicated desired data items and features in the mobile PHR app. These collected preferences were then used to guide the design and development of the new mobile PHR app. Specifically, 6 app modules for frequently updated health information, records that are not updated so frequently, customizable trackers, contact information management, appointment management, and customizable resource links were implemented into the mobile app. These modules made it convenient for users to manage their health data. A study with 15 participants was performed to evaluate the usability of the app.

For the general population, EHR and PHR are two highly similar systems. Therefore, when they answered the questionnaire for the needs assessment, their desired data items in a PHR are similar to the ones in existing EHRs. One major difference is the desire for managing PGHD between typical clinical visits. The study participants want to use a PHR to manage their PGHD.

The app was designed to be easy to use. The individual pages in the new mobile PHR app were designed to be simple, with each page having only a specific purpose, for instance, entering laboratory test results, viewing the entered data, and making note of an appointment. Therefore, the usability of the app was high (1.90 out of 7 in PSSUQ) and the study participants were satisfied with the app.

This app is customizable and flexible to use for managing data collected from various types of wearable sensors. In the current version of the app, there are 12 trackers, including food, drink, weight, height, sleep, exercise, blood pressure, blood sugar, pain, mood, period, and health notes. Users can choose the trackers according to their needs. As there are many types of wearable sensors and each of them has its own API and this field itself is changing quickly [35,53], it is challenging to integrate all these APIs into this mobile app and keep them updated all the time. Therefore, in the current version of this mobile PHR app, we chose the simplest approach for data collection, providing a list of trackers and asking the user to choose the trackers they use and then enter the data items from those trackers manually [6]. In the future, after the wearable sensor market is mature and APIs used are relatively stable, we can integrate them into this mobile app and make the data collection automated.

This app has strong security measures to protect user data. Although it is not the major focus of this study, user information security and privacy has been a top priority throughout the design process. In this mobile PHR app, users are required to register their own accounts with a strong password (a combination of upper-case and lower-case letters, digits, and special symbols) before they can start to use the app. All user-entered data are encrypted before they are transmitted on the internet and stored on a remote secure server behind a firewall. The user-entered data are decrypted after the app retrieves the data to display on the local device, and only authorized users can enter, view, or change the data in the app. In this design, the mobile PHR app cannot be used when an internet connection is not available. In other words, it requires a Wi-Fi signal or cellular service to work. All the collected data are only stored in an encrypted format on the remote secure server. No health record is stored on the local storage of the mobile device. Therefore, even if the user loses the mobile device, there will not be any health data breaches. The user can continue using the app on a different mobile device without losing any data.

PittPHR is a Web-based app; therefore, the resources required on the mobile device are similar to those for other Web-based apps. The scalability of the app is determined by the capacity of the remote secure server. At this moment, it is a typical Dell server. If the number of users increases to a large number (a few thousand or more), a cloud-based server may be needed. PittPHR can run on any major mobile operating system (iOS, Android, and Windows Phone system). This is one advantage when compared with the *operating system–specific* Health apps offered by Apple and Google. Further details are provided in the next section.

With the availability of this mobile PHR app, users will be able to conveniently manage all of their health data in one place, including the typical medical record data and the patient data generated between their typical clinical visits, data that are often unavailable to medical professionals. As a result, the information gap will be filled, and health care providers may obtain more reliable and comprehensive patient data, which may help them to better understand the reasons for the ineffectiveness of certain therapies. Health care providers can utilize the information in their decision making, which may lead to improvements in the quality of health care provided.

The design and implementation of the app also have integrated some solutions to the PHR adoption barriers. As mentioned in the Introduction section, the adoption rate for PHRs is still low, with barriers to adoption including factors such as the demographic characteristics of users and security and privacy concerns [28,54]. With respect to demographics, women and the older adults tend to actively use PHRs less often [55]. The questionnaire study for needs assessment allowed us to consider this issue as there were more than 100 respondents in each age group and the average age of the 609 participants was 43.3 years. More specifically, we obtained opinions from a large number of people older than 56 years, including 26 participants

who were 65 years or older. Moreover, among all of the respondents, 78% (473/609) were female, meaning opinions from women are reflected in the questionnaire study results. We addressed the second barrier to adoption, security and privacy concerns, by including strong security measures in the app. These features may help this new mobile PHR app to achieve a higher adoption rate than others.

This mobile app is designed to be extensible, and therefore, it will be convenient to add new features according to users' needs and feedback. The intention of this study is not to create a mobile app to meet the needs of everyone but to build the mobile app and provide it to users to use. Once the users have used the app for a period of time, they will have a better idea of what they want. We will collect feedback from these actual users and update the app to make it better [15,20,56,57], changing existing features and adding new features into the app, for instance, creating more types of trackers, adding more laboratory tests, incorporating normal ranges of test results, and providing a more meaningful summary of patient data by conducting data analytics on the data.

Comparison With Previous Work

As indicated in the Introduction section, a number of mobile PHR apps exist, such as MyChart, MyHealthKeeper, and My HealtheVet; however, these were mainly created by hospitals and EHR vendors. As a result, these PHRs obtain patient health data primarily from the corresponding EHR systems. In addition, the major purpose of these PHRs is to make some preselected patient data items available to patients cared for by the corresponding hospitals or with records in the EHR systems. These mobile PHR apps have many useful functions; for instance, they make laboratory test results easily accessible to patients, allow patients to making appointments with their doctors, and provide a platform for secure messaging between patients and their doctors [20-22,58]. However, if a person does not have an existing account with those hospitals or the specific EHR system, he/she cannot use those mobile apps. More importantly, these existing mobile PHR apps only allow patients to enter a very limited number of data items, such as blood pressure and glucose level, which makes it difficult for patients to manage other health data that may be collected from many sources, such as wearable sensors, Web-based screening tools, and self-assessment mobile apps. In other words, these existing mobile PHR apps lack the flexibility for managing various types of patient-generated data, and therefore, they cannot fill the information gap between typical clinical visits.

It is true that on both iOS and Android systems, there is a Health app (Apple Health and Samsung Galaxy Health) in which users can enter various types of patient-generated data and test results. The Health apps also offer an option to access the user's other mHealth apps so that collect data can be shared among apps. Therefore, if the user has both this Health app and multiple mHealth apps, the user will be able to manage many data items included in this new mobile PHR. However, if the user does not have those mHealth apps, the user can only use this Health app to manage some patient-generated data and test results, such as blood pressure and number of steps. Even for these patient-generated data, these mobile operating system–specific Health apps have one major drawback, that is, the entered data will become inaccessible if the user wants to switch to a different mobile operating system. This new mobile PHR app, PittPHR, is cross-platform. In other words, the stored patient data can be accessed by any mobile device on any major mobile operating systems.

This new mobile PHR app offers a more flexible and comprehensive alternative. It is a standalone app, and it is not required to be associated with any specific EHR systems. Therefore, it has the flexibility to manage any type of health data desired by patients, instead of being limited by the rules and regulations determined by hospitals and health care providers. Patients have full control over the data managed by the app. Moreover, anyone can use this app—users do not need to have an existing account in an EHR system before they can use this app. One disadvantage is that patients have to enter all their health data manually. Although we have intentionally made the data input pages simple, it still can be burdensome when patients have to enter a specific type of data the first time or when patients have a lot of health records to manage. However, once the existing records are entered into the app, it is easy to update or enter new data items. In the future, we will consider ways to make some data input easier, for instance, making it possible for patients to scan a barcode or QR (quick response) code for items such as food, drink, and medications, a feature suggested by some of the usability study participants.

Limitations and Future Work

A current limitation to this project is the lack of a Web portal for sharing the patient-entered information with health care providers. Currently, to share the data with providers, patients have to physically bring their mobile devices to their providers to show the information to them. In the next phase of this project, a Web portal will be created to make the PGHD readily available to providers.

The current version of this app did not help users to determine whether the entered data are normal or not in most cases. Users need to infer that from the data they obtain from their health care providers. In the next version of the app, databases and decision rules will be created and incorporated into the app to help users determine the normality of the laboratory and diagnostic test results. These databases and decision rules will help us to improve the accuracy of user-entered health data as they will determine which values are allowed for a specific test. After extensive PGHD are entered in the mobile app, it will even be feasible to make predictions and give personalized recommendations to patients, which may be helpful for improving health care quality [20,37,59-62].

The current version of the mobile PHR app simply helps users to collect and manage various types of health data. It does not provide any reminders or alerts, which is desired by some study participants in the usability study. Reminders and alerts can be very useful for some users, for instance, elderly people, cognitively impaired patients, and people with very busy schedules. However, it can be annoying for some users as well if many reminders and alerts are generated according to a schedule. Those reminders and alerts may interrupt things they are doing or pop highly sensitive information up on the screen

of their mobile device while they are surrounded by a group of people, which may be a violation of the user's privacy [63]. In the future, alerts and reminders for highly important issues may be implemented in the app, for instance, to remind users to take medications on time and at the correct dosage.

In the questionnaire study for needs assessment, there was only a small number of participants (15/609, 2.5%) with high school or lower education. Therefore, the results obtained in this study may not reflect the opinion of people with high school or lower education. The reason for this bias is probably because the questionnaire was distributed via an email, and the primary communication method for people with lower education may not be email. To recruit people with lower education into this study, other approaches, such as mailers, text messages, and posted flyers, may need to be used. The questionnaire itself may also need to be administered in a paper-based format.

The self-assessed health status of participants in the questionnaire study is also a limitation of this study. More than 90% of the study participants (550/609, 90.3%) in the questionnaire study reported that they had good, very good, or excellent health. Therefore, the needs and preferences identified in the study were only for people with at least good health status. The results could be different if the study participants were a group of people with chronic disease or some other major health issues to manage.

Conclusions

In this project, a questionnaire was created and used to understand users' needs, preferences, and expectations with respect to a proposed mobile PHR app. An mHealth app (PittPHR) was created according to the needs assessment results using a user-centered approach. A usability study on the app indicated that potential users were satisfied with the implementation of PittPHR and would like to use PittPHR in their personal health data management. The flexibility and customizability of this mHealth app may facilitate better personal health data management and fill the information gap between clinical visits. Further development will be conducted on this mobile app to allow it to serve users better. This mobile PHR app may help users to become more involved in their own health care and eventually improve the quality of the health care.

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Conflicts of Interest

None declared.

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Abbreviations

AES: Advanced Encryption Standard
API: application programming interface
EHR: electronic health record
HITECH: Health Information Technology for Economic and Clinical Health
ISO: International Organization for Standardization
JSON: JavaScript Object Notation
mHealth: mobile health
NIDILRR: National Institute on Disability, Independent Living, and Rehabilitation Research
ONC: Office of the National Coordinator for Health Information Technology
PGHD: patient-generated health data
PHR: personal health record
PSSUQ: Post-Study System Usability Questionnaire
QR: quick response
REST: REpresentational State Transfer

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Original Paper

Physical Activity Behavior Change Driven by Engagement With an Incentive-Based App: Evaluating the Impact of Sweatcoin

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Abstract

Background: Physical inactivity, now the fourth leading cause of death, is a primary element of noncommunicable diseases. Despite a great number of attempts, there is still a lack of effective approaches that can motivate sedentary populations to increase their levels of physical activity over a sustained period. Incentives for exercise can provide an immediate reward for increasing activity levels, but because of limited funding to provide rewards, previous programs using this approach have only shown short-term changes in behavior. Sweatcoin (Sweatco Ltd, UK) is an app-based platform that converts physical movement into virtual currency. The currency can be exchanged for goods and services on their marketplace, providing a continuous incentive to be active. This study investigates the physical activity behavior change observed in Sweatcoin users over a 6-month period of app usage.

Objective: The aim of this study was to investigate the change in physical activity (measured using daily step count) of a sample of Sweatcoin users, the longevity of the change, and whether this change can be predicted by demographic and other lifestyle variables.

Methods: Activity data from a sample of 5892 Sweatcoin users were used to analyze daily step count. Activity change was measured in terms of the percentage change in average daily step count for each month after registration, relative to that in the 3 months before using the app. Users were grouped according to having no or negative, moderate, or high activity change. A subset of users completed a questionnaire that allowed differences between groups in terms of activity and demographic status to be investigated using regression analyses.

Results: Daily step count increased by 19% on average over the 6 months following registration (P<.001). Of the questionnaire respondents, 728 were valid responses. A multinomial logistic regression identified the key drivers of moderate and high activity behavior change relative to no or negative change based on the defined groupings. There was a clear impact of seasonality, with those registering for the app in winter (odds ratio [OR] 4.67; P=.001) and spring (OR 5.05; P=.001) being more likely to show high positive activity behavior change than those registering in summer. More striking were the results identifying those classified as overweight (measured through body mass index [BMI]; OR 1.83; P=.02) and less active (based on a self-reported scale of physical activity; OR 0.88; P=.048), being most likely to show high levels of physical activity change following registration with the app.

Conclusions: The results highlight that an incentives-based app can induce significant physical activity behavior change, sustained over a 6-month period. Importantly, the results suggest that those typically lacking motivation to exercise (sedentary and high BMI) are most likely to be incentivized to increase their activity levels.

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KEYWORDS

physical activity; incentives; rewards

Introduction

High levels of sedentary behavior increase the risk of cardiovascular disease, some types of cancer, and type 2 diabetes, particularly when combined with low levels of physical activity [1]. Europe has the highest levels of sedentary behavior, with nearly two-thirds of the population estimated to spend an average of 4 hours or more per day sitting [2]. Globally, the prevalence of insufficient physical activity was 27.5% in 2016 [3], with an estimated cost to health care systems of US $53.8 billion in 2013 [4]. The thresholds for improving the levels of physical activity for benefit are relatively low: regular bouts of walking have long been identified to be advantageous to many aspects of physical and mental health [5,6]. Yet, for sedentary individuals, there is often a lack of motivation to increase the levels of exercise, despite its value in terms of quality of life.

Adherence to physical activity programs has been found to be higher in individuals who exercise for enjoyment and social interaction rather than for fitness and appearance [7]. This can be aligned to the long- and short-term rewards leading to motivation levels: those focusing on longer-term rewards (fitness and appearance) are less likely to continue with a physical activity program than those focusing on the instant rewards of enjoyment and social interaction. This can be explained by systematic biases toward immediate reward in human behavior, known as present bias [8]. Therefore, providing immediate rewards to inactive individuals, in the form of incentives, could be a way of providing the necessary motivation to increase activity [9]. Evidence to date has shown this to be effective in a number of studies, albeit over short periods. Extending incentives-for-exercise programs beyond short-term trials is costly; however, because of the extrinsically motivated approach, there is a risk that individuals engaged with such short-term programs could regress soon after the incentive structure has been removed [10]. The lack of continuous engagement with program participants makes it more difficult to drive sustainable levels of activity behavior change, even if the program delivers behavior change in the short run. Therefore, a program of sustained goals and rewards is required that will continue to motivate sedentary populations to become more active. Wearable and smartphone technologies provide an opportunity for these programs to be implemented on a large scale, at relatively low cost. Adopting this approach, Sweatcoin is a concept and an app that converts the step count recorded on smartphones into a virtual currency. Hence, the users generate financial rewards through physical activity, which can be used to purchase products and services from an in-app marketplace. Sweatcoin has had more than 20 million users installing the app in the United Kingdom and United States and, most recently, in Canada, Australia, and Europe.

In this study, we investigated the behavior change exhibited by users of Sweatcoin and analyzed the change in physical activity following engagement with the app. In addition, we used a survey from a subsample of users to identify which populations were most likely to show the biggest activity change.

We hypothesized that users who will be motivated to increase their physical activity following engagement with the app can be predicted through a range of demographic and other self-reported lifestyle variables.

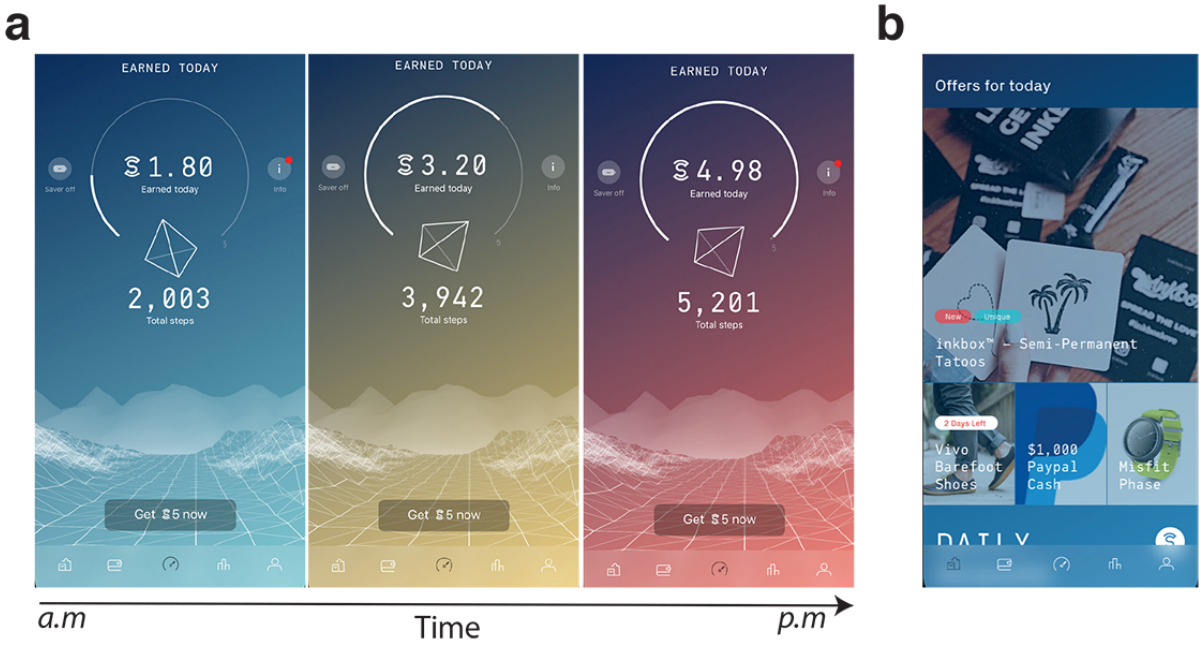
Methods

The Sweatcoin App

Sweatcoin is a free app available on iOS and Android platforms. The concept of Sweatcoin is to convert a user's step count, as recorded by the sensors on a smartphone, into virtual currency [11]. To ensure the value of the reward is maintained, the app incorporates a second layer of step verification. This operates by ensuring the distance moved (calculated from global positioning system [GPS] measurements) is representative of the number of steps recorded over a time period. Consequently, the app will convert validated outdoor steps (where a GPS signal is available) into Sweatcoins (Figure 1). Currently, 1000 steps will earn 0.95 Sweatcoins.

Users accumulate Sweatcoins that can subsequently be spent on the marketplace, accessible through the app (Figure 1). The marketplace usually has 3 to 4 daily offers and a similar number of *marathon* offers available. The daily offers are low cost and have short-term availability, with a new offer added each day (with the oldest product removed so that each product remains on sale for around 4 days). The offers can be for free products, services, or subscriptions. Sweatcoin currently has over 300 commercial partners who offer products and services on the marketplace. Marathon offers are a fixed set of high-value products (smartphones and televisions) that are priced such that it would take a user 12 to 18 months to accumulate enough Sweatcoins to make a purchase.

Figure 1. (a) Screenshots from the Sweatcoin app (as of December 2018). As a user's step count (recorded by their smartphone) accumulates over the day, it is verified and converted into Sweatcoins. (b) The Sweatcoins are stored in the user's wallet and can be subsequently used to purchase products, services, or subscriptions that are available on the marketplace.

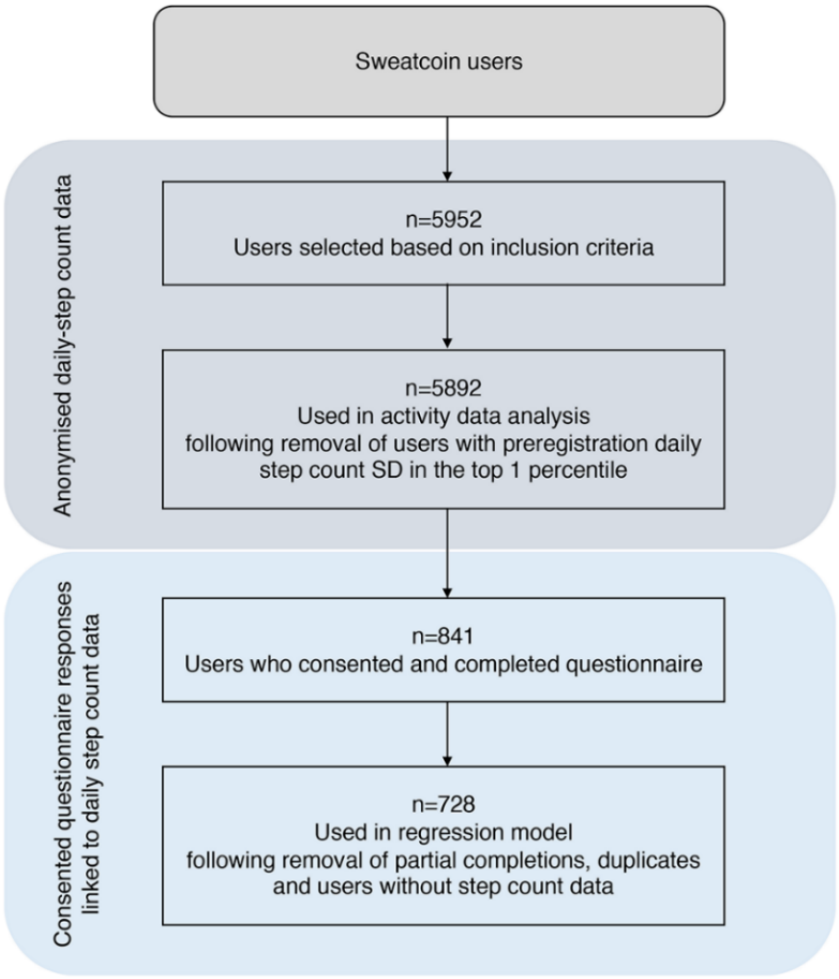


Activity Dataset

A dataset containing daily step count for each user was used for the analysis of this study. The dataset contained no identifiable information, with the exception of a *Sweatcoin user identification number* such that only those internal to the company could identify which users were included in the analyses. The dataset was acquired through the Sweatcoin app from Apple iPhone users who had agreed to share their step count data, captured by Apple HealthKit, with the app. To ensure a consistent sample of user data, additional inclusion criteria were applied to the dataset. In particular, we only collated data from users who had daily step count data for a minimum of 6 months after originally registering with Sweatcoin, and an additional 3 months data before registration. It was important that we only analyzed data from users who were engaging with the app to get the best assessment of the app's impact on physical activity change. Therefore, users included in the dataset also had to have opened the app within the last week.

On the basis of these inclusion criteria, 5952 Sweatcoin users were included in the daily step count dataset (Figure 2). The data were split approximately equally between UK and US residents. The raw data consisted of a unique Sweatcoin user identification number, date of registration, number of steps recorded (for 1 day), and the date of the recording.

Figure 2. Flowchart of analysis stages with corresponding sample sizes.



Activity Data Processing

Processing and analysis of the activity data were completed using R (version 3.4.1), a programming language specifically designed for statistical data analysis [12]. For each user, the daily step count data were split into the days occurring before Sweatcoin registration and the days occurring after registration. Additional fields of weekday versus weekend and season were added to each entry based on the date of the recorded steps. Similarly, the data were subgrouped into monthly (30-day) periods relative to registration, with negative months (−1 through −3) reflecting periods before registration and positive months (1 through 6) reflecting the period after registration. It should be noted that there was no *month 0*; the date of registration was defined as the first day of month 1. Any entries that were more than 90 days before registration or 180 days after registration were discarded.

For each 30-day period within each user's data, we calculated the mean, median, maximum, minimum, upper quartile, lower quartile, and SD of the daily step counts. However, for this study, we focused only on the mean values recorded. In addition to the mean daily step count recorded over the whole 30-day period, we further measured the mean value across all weekend days (Saturdays and Sundays only) occurring within the 30-day period along with the mean of the weekdays only (Monday through Friday) in that period.

Physical Activity Change Analyses

The aim of the initial analysis was to quantify the change in physical activity (in the context of daily step count) after registering with the Sweatcoin app, relative to the 3-month period before registration. We did this by taking the mean across months −1 to −3 and subtracting this value from the mean daily step count of all 9 months. This resulted in a relative daily step count that was centered around zero for the period before registration and quantified any increase or decrease in the 6 months after registration. These relative step counts for the period after registration were subsequently converted to a percentage of the mean daily step count measured across months −1 to −3 to normalize against the large variation in activity levels across the sample.

We excluded users who had highly variable step counts in the 3-months preregistration period as the variability would impact the calculations of activity change in the postregistration period. This was achieved by ranking users according to the SD of their mean steps per day across months −1 to −3 and excluding those in the top percentile (equating to a SD >4020 steps/day). The final sample size for analysis was 5892 after removing these users (Figure 2).

Users were finally classified into groups according to their level of *physical activity behavior change* following registration of the app, measured as the mean percentage change over 6 months. Overall, 3 groups were defined: no or negative change, where the average percentage change was zero or less; moderate change, where the average percentage increase was greater than zero, but less than or equal to the overall mean observed across the sample (18.7%, see Results); and high change, where the average percentage increase was greater than the overall mean observed across the sample.

Demographics Questionnaire

On the basis of the grouping of users according to their change in activity following app registration, we wanted to determine if there were any demographic differences between these groups. To achieve this, we defined a set of demographic variables of interest to be tested (Table 1).

Table 1. Demographic and other variables included in the questionnaire, along with options or categories.

Variable	Options or categories
Gender	Male, Female
Age	<18 years [excluded], 18-24 years, and then 10-year increments up to 85 years or older
Height	1 m or less, increments of 10 cm up to 2 m. Equivalent feet and inches measurements also shown
Weight	40 kg or less, increments of 10 kg up to 120 kg, or >120 kg. Equivalent stones and pounds measurements also shown
Education	High school (or equivalent), Grammar school, College degree, Bachelor's degree, Master's degree, Professional degree, Doctoral degree, or Other
Employment	Student, Retired, Unemployed, Homemaker, Self-Employed, Private sector, or Public sector
Income	<£10,000, then £10,000 increments up to £100,000, £100,000-£149,999, £150,000-£200,000, over £200,000, or would rather not say. (Equivalent US dollar amounts also shown.)
Marital status	Living with another, Married/civil partnership, Separated, Divorced, Widowed, Would rather not say, or Other
Dog owners	Yes, No
Have children	Yes, No
Regularly use a wearable fitness tracker	Yes, No
Home location	Urban, Suburban, or Rural
Commute type	Car, Bus, Train, Tram/Tube, Walk, Cycle, or Other/None
Commute distance	No commute/no fixed place of work, <5 km, 5-10 km, 11-15 km, 16-20 km, 21-30 km, or >30 km
Motivations to exercise	Respondents chose one option from: Increase my overall health, Lose weight, Gain strength, Improve my skills, Have fun, Spend time with friends, To look good, or Other
Self-reported physical activity	On the basis of the General Practice Physical Activity Questionnaire [13], respondents state level of activity at work (multiple choice, from "most of time sitting" through to "vigorous physical activity") and number of hours (between 0 and 3 or more) spent on a range of different activities in the last week
Rigidity score	On the basis of the compulsive exercise test [14], respondents state how often each of 4 statements is true, ranging from never to always on a 6-point Likert scale. The statements cover organization and structure of activities
Walking pace	Slow (<3 mph), Steady, Brisk, or Fast (>4 mph)
Other health/fitness apps used	Respondents chose from Never, Sometimes, or Regularly from the following apps: 7-Minute Workout, 8fit Planner, Calm Meditation, Calorie Counter, Fitbit, Headspace, MyFitnessPal, Nike, Strava, and Weight Watchers

Recruitment

To recruit for the questionnaire survey, all users included in the original sample were shown an advert on the Sweatcoin marketplace inviting them to participate. Users who registered to participate were provided a link to the questionnaire (hosted on the Google Forms platform). Participant information and ethical approval information were provided on the first screen. Consent was registered by participants explicitly ticking a box to register their consent to take part and then continuing to the questionnaire. Those who completed the questionnaire were sent a £10 (United Kingdom) or US $10 retail voucher. The questionnaire typically took participants around 10 min to complete.

Over a period of 4 weeks, a total of 841 users completed the questionnaire (Figure 2). Of these, 728 users remained after removing partial completions, duplicates, and users who were not in the original activity dataset (Figure 2). The corresponding daily step count data were then linked to the resulting sample of questionnaire responses.

Analysis

The questionnaire data were coded and restructured as required to make each variable suitable for regression analysis. Dummy variables were created for multiple-choice responses. Self-reported activity and rigidity scores were calculated as per guidelines. However, it should be noted that rather than limiting the General Practice Physical Activity Questionnaire (GPPAQ) score to a maximum of 3, we used the total score from all activities. In addition to the questionnaire variables, the season of registration was added as a further set of dummy variables to ensure seasonality would be accounted for in the analysis.

The physical activity change class (Table 2) was used as the dependent variable in a multinomial regression, with the questionnaire and other variables described above used as the independent variables. Using this model, we were able to investigate the predictor variables that differentiated the moderate and high behavioral change groups from the no or negative change group. A total of 728 participants were included in the regression analysis (Figure 2). All variables were entered simultaneously into the regression (see Multimedia Appendix 1 for full regression results including nonsignificant variables).

Table 2. Classification of physical activity behavior change based on percentage change in daily step count relative to the 3 months preregistration period. The number of samples in each class is shown for both the daily step count data and the combined questionnaire responses with daily step count.

Class	Label	Range, %	Number of users in class, n (%)	
			Activity dataset (N=5892)	Questionnaire responses (N=728)
0	No or negative change in activity	<1	2172 (36.86)	258 (35.4)
1	Moderate positive change in activity	1-18.7	1542 (26.17)	196 (26.9)
2	High positive change in activity	>18.7	2178 (36.96)	274 (37.6)

Ethical Approval

Ethical approval was received from the University of Warwick Biomedical and Scientific Research Ethics Committee (Approval Number: REGO-2017-2086). In addition, 2 members of the academic research team received honorary contracts with Sweatcoin to oversee the analysis of the anonymized activity data. Recruitment for the demographic questionnaire was further handled by employees of Sweatcoin to ensure participants' activity data were not made identifiable outside of the company until they had provided consent to merge their activity data with the questionnaire responses.

Results

Change in Daily Step Count Following App Registration

Initially, mean daily step count was examined across three 3-month periods. In particular, we contrasted the mean daily step count for the 3 months before registration with the app and for two 3-month periods following app registration (months 1-3 and 4-6; see Figure 3). This was further split into both weekday and weekend activity. Overall activity levels were higher during the week than at weekends. Importantly, we found a significant rise in daily step count following app registration for both weekend and weekday activities, with weekend step counts showing a greater increase than those on weekdays (interaction effect, $F_{2,11782}$=101.49; P<.001). Post hoc analysis confirmed that the increase remained consistent over the 6-month period, with no significant difference between months 1-3 and months 4-6 following app registration for either weekdays (P>.99) or weekends (P=.30).

For the remaining analyses, we no longer contrasted weekend and weekday activity and, hence, averaged the daily step count across continuous 30-day periods. The relative percentage activity change following app registration was calculated as described in the Methods section, revealing an overall mean increase of 18.7% (47.9%) in daily step count across the sample (Figure 4). Across the 6 months, this increase ranged from 15.4% (month 1) up to 20.9% in month 5. Plotting the percentage change against the mean daily step count across the 3 months before registration (Figure 4) reveals that those who were less physically active (in terms of step count) before using the app had a higher range of increased activity after registration. Individuals who were already physically active tended to show minimal further increase following registration. Reduced levels of physical activity after registration (negative percentage change) did not appear to vary according to previous levels of activity.

Figure 3. Mean daily step count across the sample (N=5892) was analyzed for the 3 months before app registration (Pre) and 6 months after registration (Post). (a) For analysis, these were grouped into 3-month periods; the results highlight the consistent increase in mean daily step count after registration. (b) The same measure is broken down over 30-day periods. Both plots show the data separated into weekday and weekend activity. Although weekend activity is lower, the overall pattern of increase after registration is similar. Error bars represent SE of the mean.

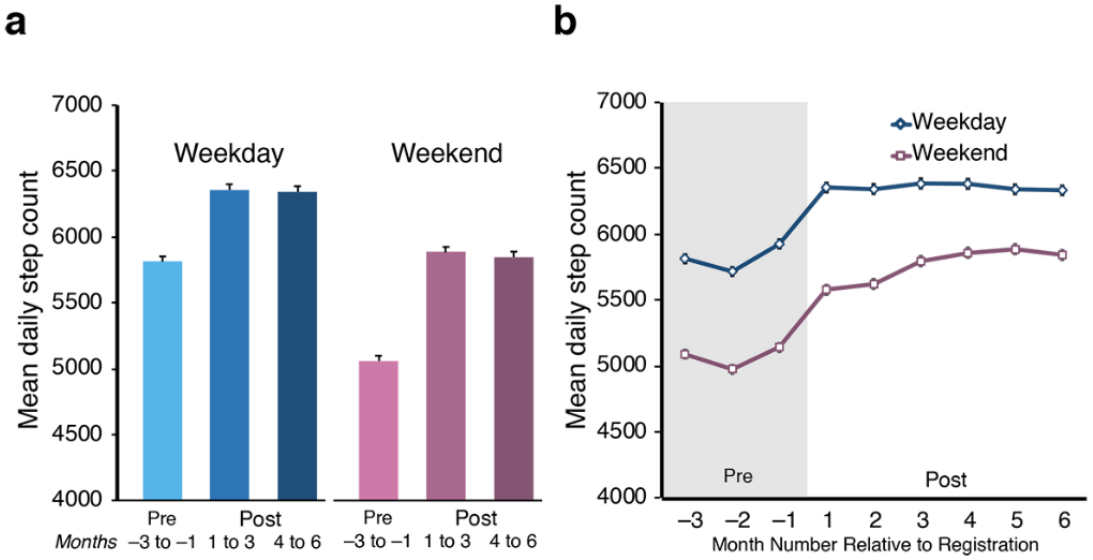
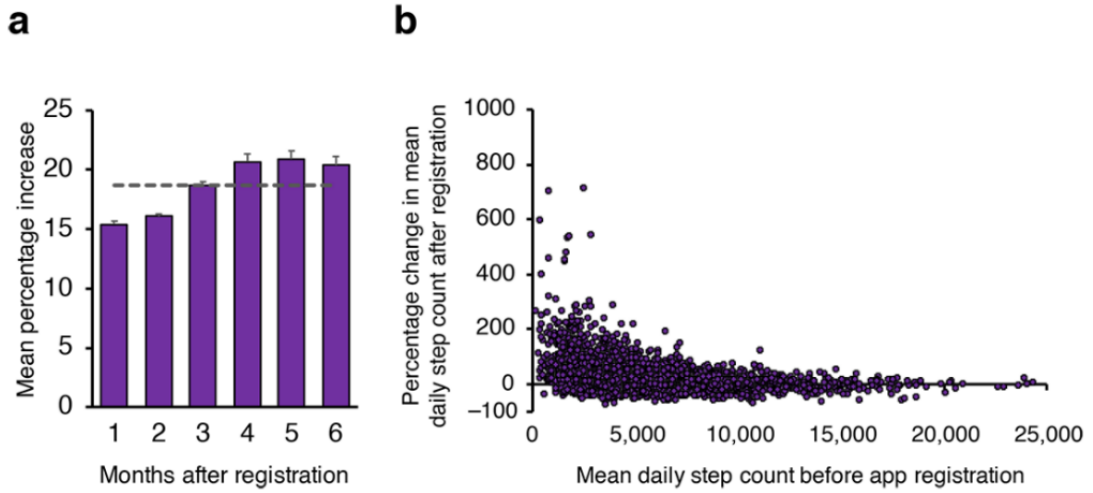


Figure 4. (a) Percentage change in daily step count for the period after registration, relative to the 3 months before registration (N=5892). The horizontal dashed line (gray) represents the overall average percentage increase of 18.7%. Error bars represent SE of the mean. (b) Individual data points (N=5892) of mean daily step count before app registration against the subsequent percentage change after registration.



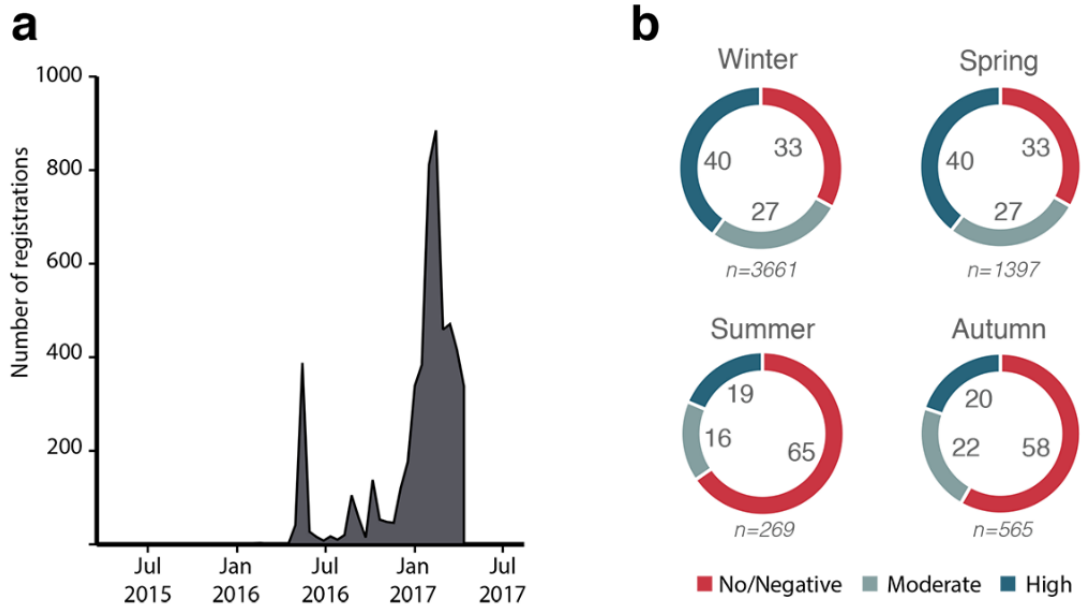
Classification Thresholds

From the overall mean activity change of 18.7% across 6 months, we defined user activity behavior change classifications as shown in Table 2. Users were then split into these classes based on their overall activity change for the 6 months after registration.

Seasonality Effects

Figure 5 shows the distribution of user registrations for the dataset analyzed and highlights the accelerating rate of registration over a short period of time. This provides a relatively skewed dataset in terms of most people registering over the winter or spring period. Seasonality effects were investigated to examine the distribution of registrations among classes. This was to evaluate the risk that activity change classifications were based primarily on season rather than engagement with the app. For the winter and spring data (when the majority of users registered) we observed that, despite a relatively even split of classifications, there is a greater proportion of high activity change users than no or negative change users (Figure 5). In contrast, summer and autumn registrations are more over-representative of no or negative change users. However, the overall sample from these 2 latter seasons was much smaller. The season of registration of each user was also added as a dummy variable to the later regression model to ensure any seasonality was accounted for in the analysis.

Figure 5. (a) Histogram showing distribution of user registrations in the sample data (N=5892). The main app launch can be identified in May 2016, whereas there is a further rapid acceleration around December 2016, which skews the data toward the winter and spring seasons. (b) User classifications of activity behavior change broken down across seasons; numeric values inside the circles represent the percentage of users in the associated class; sample sizes for each season are shown in italics under each chart. For winter and spring, there is a higher proportion of high activity change users than no or negative change users. Summer and autumn show an over representation of no or negative change users.



Demographic Survey Profile

In Table 3, the descriptive statistics of the main demographic variables are listed. In addition, the sample was split evenly geographically, with 49.6% of respondents from the United Kingdom and 50.4% from the United States. Measures of exercise rigidity [14] were low on average, with means of 2.40 (like days to be organized and structured), 2.25 (pattern of exercise is repetitive), and 2.12 (set routine for exercise). In addition, respondents were asked about which other fitness-related apps they used, either occasionally or on a regular basis (Table 4).

Table 3. Descriptive statistics of key variables in the questionnaire (N=728).

Variable	Frequency, %
Gender	
Male	64.7
Female[a]	35.3
Age (years)	
18-24	39.7
25-34	38.9
35-44	17.3
Over 45[a]	4.1
Weight status (based on body mass index estimate)	
Underweight	3.2
Healthy weight[a]	49.2
Over weight	21.6
Obese	26
Has a degree	
Yes	67.7
No[a]	32.3
Employment status	
Not in employment	6
Student	29
Employed (private sector)[a]	38.3
Employed (public sector)	19.4
Self-employed	7.3
Annual household income	
Less than £20k	17.4
£20k-£39k	22.4
£40k-£59k[a]	33.7
£60k-£79k	12.8
£80k or more	13.7
Marital status	
Married/civil partnership	27.2
Cohabiting	15.7
Divorced/separated	4.3
Single[a]	52.8
Have a dog	
Yes	31
No[a]	69
Have children	
Yes	31.9
No[a]	68.1
Use a wearable device	

Variable	Frequency, %
Yes	46.4
No[a]	53.6
Home location	
Urban[a]	38.2
Suburban	44.4
Rural	17.4
Commute/transport type	
Walk	19.6
Cycle	4.3
Bus	9.5
Car	46.8
Train	6.6
Tube/tram	7.4
Other	5.8
Commute distance	
None/no fixed location	10.7
<5 km	28.3
5-10 km	22
11-15 km	11.4
16-20 km	8.9
21-30 km	7.8
>30 km	10.9
Motivation to exercise	
Increase overall health[a]	37.4
Lose weight	29.8
Gain strength	12.1
Look good	10.9
Improve skills	3.2
Have fun	4.3
Spend time with friends	2.3
Activity level (self-reported GPPAQ[b] score [13])	
Inactive	13.3
Moderately inactive	13.6
Moderately active	19.8
Active	53.3
Walking pace	
Slow (<3 mph)	7.1
Steady	44.5
Brisk	38.6
Fast (>4 mph)	9.8

[a]Response options were used as the reference response with which the other responses for that variable were compared in the regression model.
[b]GPPAQ: General Practice Physical Activity Questionnaire.

Table 4. Frequency of usage of other fitness- and well-being–related apps (N=728).

App	Never use, %	Sometimes use, %	Regularly use, %
7-Minute Workout	76.1	19.2	4.7
8fit Planner	88.7	8.1	3.2
Calm Meditation	76.2	17.7	6.0
Calorie Counter	81.6	12.9	5.5
Fitbit	72.1	10.2	17.7
Headspace	79.8	15.0	5.2
MyFitnessPal	60.0	25.3	14.7
Nike	74.0	18.1	7.8
Strava	77.7	11.1	11.1
Weight Watchers	88.6	7.3	4.1

Predictors of Activity Behavior Change

On the basis of the classification of users according to their change in activity following app registration, we investigated the main predictors of this behavior change based on the demographic questionnaire variables. A multinomial logistic regression was run to compare users in the moderate and high activity change classes with respect to those in the no or negative activity change class. Independent variables included the demographic and other variables captured by the questionnaire (see Tables 3 and 4).

The results (N=728, χ^2_{146}=197.6 *P*=.003; Nagelkerke pseudo R^2=26.8%) report the predictors of both moderate change and high change with respect to no or negative change. Significant results are reported in Table 5 (moderate) and Table 6 (high) with associated ORs and significance levels; full results are provided in Multimedia Appendix 1. The seasonal skew identified above was present for both moderate and high change groups, with those registering in autumn (OR 4.17; *P*=.04), winter (OR 11.54; *P*<.001), and spring (OR 10.88; *P*=.001) seasons being more likely to show a moderate increase in activity after downloading the app, relative to those registering in summer. Similarly, those exhibiting high levels of activity increase were more likely to have registered in winter (OR 4.67; *P*=.001) or spring (OR 5.05; *P*=.001). After accounting for seasonality, a further significant predictor variable was found, with regular users of MyFitnessPal being significantly less likely to show moderate activity change (relative to no or negative change). For the high change group, users were more likely to be classed as *overweight* (relative to *normal weight*, calculated using body mass index) compared with those in the no or negative change group (OR 1.83; *P*=.02). Similarly, those with lower self-reported activity levels were more likely to be in the high change group (OR 0.88; *P*=.048). We also noted a slight positive relationship between rigidity score and high behavior change (OR 1.07; *P*=.02).

Table 5. Multinomial logistic regression results for predictors of moderate activity behavior change classification versus no or negative activity change (N=728). Results show the odds ratios of the significant predictor variables (*P*<.05). Odd ratio values less than 1 represent negative relationships.

Variable	Model coefficients (B)	SE	Wald	Odds ratio	*P* value
Registered in winter	2.45	.67	13.36	11.54	<.001
Registered in spring	2.39	.69	11.92	10.88	.001
Registered in autumn	1.43	.71	4.05	4.17	.04
Regular user of MyFitnessPal	−0.89	.37	5.77	0.41	.02

Table 6. Multinomial logistic regression results for predictors of high activity behavior change classification versus no or negative activity change (N=728). Results show the odds ratios of the significant predictor variables (*P*<.05). Odds ratio values less than 1 represent negative relationships.

Variable	Model coefficients (B)	SE	Wald	Odds ratio	*P* value
Registered in winter	1.54	.46	11.13	4.67	.001
Registered in spring	1.62	.49	11.08	5.05	.001
Overweight	0.61	.27	5.18	1.83	.02
Rigidity score	0.07	.03	5.72	1.07	.02
GPPAQ[a] score	−0.13	.07	3.90	0.88	.048

[a]GPPAQ: General Practice Physical Activity Questionnaire.

Discussion

In this study, we have investigated physical activity behavior change in users engaging with an app that converts step count into virtual currency (Sweatcoins). Using an initial sample of 5892 users who had been registered with the app for 6 months or longer, we used anonymized daily step count data to analyze activity levels for the 6-month period following registration and compared it with that recorded for the 3-month period before registration. Importantly, our results found a significant and consistent increase in step count following app registration, which averaged 18.7% across the period and across all users. In an earlier pilot analysis, we previously reported a figure of 19.5% because of a slight variation in inclusion criteria [11].

The respondents to the subsequent questionnaire were mainly from the young adult population, which is likely to be representative of Sweatcoin's overall user demographic. Therefore, our results do not necessarily generalize across all age groups. However, the captured demographic is an important generation to target, with many physical activity programs focusing specifically on children or older adults but few targeting young adults and capitalizing on their engagement with smartphone technologies [15]. Therefore, there is potential for this app to be used as an intervention aimed at young and middle-aged adults who are at an important transition period for weight gain and development of obesity [16].

The classification of users into levels of activity behavior change and subsequent demographic survey data allowed us to examine in detail which users are most likely to increase activity following registration with the app. Despite the wide range of variables captured, the equivalent variance accounted for by the logistic regression model was relatively low at 26.8%, highlighting that there are likely additional lifestyle events not captured that could contribute to increased activity behavior. In particular, we did not capture any medical conditions the respondents may have had at the time that may impact the levels of physical activity. Weather-based effects [17,18] and holiday periods [19] can also have a strong influence on an individual's activity levels. Although it was not practical to factor in daily weather patterns, seasonality was included in our regression model, with winter and spring showing as strong predictors of activity change. This is most likely to relate to an effect of *New Year's Resolutions* creating an uplift in activity. On the basis of the change in activity observed that aligned with the registration with the app (Figure 3), it is likely that users were using the rewards as a motivational tool during this period.

Taking seasonality into account, we found additional variables that distinguished moderate and high activity change groups from those showing no or negative change. Regular users of MyFitnessPal were significantly less likely to be in the moderate change group compared with the no or negative change. MyFitnessPal [20] is primarily a dietary monitoring app where users can accurately measure food intake, and it was the second most regularly used app by the Sweatcoin users surveyed (Table 4). It is possible that users of this app are more focused on changing their food intake behavior than increasing physical activity levels, although we did not observe a similar relationship in the high change group.

For the high change group, we found that a number of variables were significant predictors of this group relative to no or negative change. We found a small positive relationship to a user's rigidity score [14], suggesting that those with a more structured lifestyle and exercise routine were more likely to increase activity behavior. Importantly, users classified as *overweight* and self-reporting lower levels of physical activity were also more likely to be in the high change group. Therefore, the motivation to increase physical activity based on the rewards offered by the app was greatest in a group of users who were inactive, highlighting that the app was motivating the target demographic of sedentary individuals to become more active. The relationship between the mean daily step count before app registration and percentage change after registration also highlights this, with those with already high step counts showing little increase after registration (Figure 4). We cannot totally rule out that our measure is showing some *regression to the mean* effects, where the extreme low and high values measured in the preregistration phase are naturally more likely to be closer to the average in a follow-up phase. However, although we observed higher positive change in those with low daily step count before registration, we did not see a correspondingly large negative shift after registration in those who initially had a very high step count. In addition, the predictor variables that were significant in the high change group indicate self-reported sedentarism (ie, lower GPPAQ score and overweight), suggesting those users were not just captured in an unusually inactive period before app download. Therefore, we suggest that those who are already active will accumulate rewards at a reasonable rate anyway, and hence, the extrinsic motivation is limited relative to their intrinsic motivation levels to exercise, similar to that observed with fitness tracker usage [21]. Individuals who are defined as obese (rather than overweight) are more likely to require more formal interventions to change physical activity behavior. As such, individuals who are overweight, but not obese, appear to be those who can most benefit from incentive-based physical activity programs because of low intrinsic motivation, but with minimal physical barriers to increasing activity levels.

The overall consistent increase in physical activity over the 6-month period following registration highlights a differentiation from other incentive-based and goal-oriented programs reported, which typically show only short-term behavior change effects [10]. A common cause of people failing to maintain physical activity over the long term is the fading novelty effect of activity trackers and apps. Most fitness trackers allow users to set goals and compete with other users, providing *badges* and other virtual rewards once a goal has been achieved. These incentives to change behavior are successful in the short term, but over one-third of US citizens stop using fitness trackers within 6 months of purchase [22]. In a similar example, Pokemon GO, an app-based game that requires users to search out rewards in specific geographic locations, resulted in a large increase in activity levels [23]. However, users reverted to previous activity levels after just 6 weeks. The Sweatcoin concept in this study allows users to be continuously and immediately rewarded for

their activity. Although a reduction in novelty over time is still a risk, the effect is minimized by daily rotations of products available on the marketplace. In addition, a wide range of product types and prices allow users to make regular purchases of low-cost items or save toward larger purchases. The results we have reported suggest this concept leads to a maintained increase in physical activity over a 6-month period.

Monetary and other tangible incentives have been effective in increasing physical activity behavior in sedentary populations [9,10,24]. However, often, incentive programs are only funded for a short period either because of being trial-only programs or because of limited funding available to provide the rewards. Incentives provide an extrinsic motivation to exercise, and therefore, unless an individual develops intrinsically motivated attitudes to exercise [7] (ie, self-motivated) within the period that rewards are offered, participants are at risk of returning to their previous behavior once the Sweatcoin app has developed a sustainable business model, where users are continuously generating their own virtual currency that companies are willing to accept in exchange for their goods and services (because of the exposure to a large customer base). As the Sweatcoin platform continues to grow, the associated datasets will increase timewise, and future analyses could investigate incentive-based engagement over much longer periods—something that has not been possible with other programs.

There are some limitations to this study. In particular, we were unable to establish a control group as a direct comparator to the intervention group we analyzed. This would have required the recruitment of a similar sample (ie, N>5000) of non-Sweatcoin app users who would share their daily step count data over matched 9-month periods. However, the dataset we used included both pre- and postregistration data, such that the preregistration data provided an objective baseline measure of activity. Furthermore, during the period that the data were generated, users were unaware that it would be used for this kind of analysis, and hence, there was no risk of experimental bias in the data.

There was also risk of bias being introduced because of sampling of users. We only used data from iPhone users because of the limitation of the app only being able to access daily step count data via Apple HealthKit on these devices. This could have potentially skewed the demographic profile of the sample recruited, although it has recently been reported that there are few demographic and personality differences between iOS and Android users [25]. We further only recruited users that had recently opened the app. This was to ensure we were only analyzing engaged users and, hence, measuring the effect of incentives as much as possible (ie, avoiding users who may have downloaded the app, opened it once and never opened again). It is possible that there was some overlap between a user that is engaged with the app and their motivation to increase their exercise. However, the distribution of users across the different groupings of activity change was fairly equal. Similarly, bias could have been introduced in the users selecting to complete the survey, again recruiting those more motivated to change. However, the distribution of users in the activity change groups in the survey sample was almost identical to those in the original activity dataset (Table 2), suggesting that recruitment did not bias the sample, at least in terms of level of activity change.

In conclusion, the Sweatcoin concept allows users to continuously be incentivized to be physically active through generation of virtual currency from steps. Through analysis of a sample of Sweatcoin users, we have observed a sustained increase in physical activity (measured by daily step count) over a 6-month period, with users identified as overweight and less active most likely to show the highest increases in activity after registering with the app.

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Authors' Contributions

All authors contributed to the design of the study. FE and EK led data processing and analysis of step count data. ME, FE, and EK worked on data processing and analysis of survey data. ME wrote the manuscript. All the authors commented on and edited the manuscript.

Conflicts of Interest

ME received a grant in partnership with Sweatco Ltd from Innovate UK. He was provided with an honorary unpaid research position within Sweatco Ltd for the period of the project. FE was provided with an honorary unpaid research position within Sweatco Ltd for the period of the project. AD and OF are directors and shareholders of Sweatco Ltd. Sweatco Ltd received a grant in partnership with ME (University of Warwick) from Innovate UK to conduct the study. EK is an employee and shareholder of Sweatco Ltd.

Multimedia Appendix 1

Full regression results.

[PDF File (Adobe PDF File), 100KB - mhealth_v7i7e12445_app1.pdf]

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Abbreviations

BMI: body mass index
GPPAQ: General Practice Physical Activity Questionnaire
GPS: global positioning system
OR: odds ratio

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Original Paper

A Pilot Randomized Controlled Trial of a Web-Based Growth Mindset Intervention to Enhance the Effectiveness of a Smartphone App for Smoking Cessation

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Abstract

Background: Although smartphone apps have shown promise for smoking cessation, there is a need to enhance their low engagement rates. This study evaluated the application of the growth mindset theory, which has demonstrated the potential to improve persistence in behavior change in other domains, as a means to improve engagement and cessation.

Objective: This study aimed to explore the feasibility, utility, and efficacy of a Web-based growth mindset intervention for addiction when used alongside a smoking cessation app.

Methods: Daily smokers (N=398) were all recruited on the Web and randomly assigned to receive either a cessation app alone or the app plus a Web-delivered growth mindset intervention. The primary outcome was engagement, that is, the number of log-ins to the smoking cessation app. The secondary outcome was 30-day point prevalence abstinence at 2-month follow-up collected through a Web-based survey.

Results: The 2-month outcome data retention rate was 91.5% (364/398). In addition, 77.9% (310/398) of the participants in the experimental arm viewed at least 1 page of their growth mindset intervention, and 21.1% (84/398) of the group viewed all the growth mindset intervention. The intention-to-treat analysis did not show statistically significant differences between the experimental and comparison arms on log-ins to the app (19.46 vs 21.61; *P*=.38). The experimental arm had cessation rates, which trended higher than the comparison arm (17% vs 13%; *P*=.10). The modified intent-to-treat analysis, including only participants who used their assigned intervention at least once (n=115 in experimental group and n=151 in the control group), showed that the experimental arm had a similar number of log-ins (32.31 vs 28.48; *P*=.55) but significantly higher cessation rates (21% vs 13%; *P*=.03) than the comparison arm.

Conclusions: A growth mindset intervention for addiction did not increase engagement rates, although it may increase cessation rates when used alongside a smartphone app for smoking cessation. Future research is required to refine the intervention and assess efficacy with long-term follow-up to evaluate the efficacy of the mindset intervention.

Trial Registration: ClinicalTrials.gov NCT03174730; https://clinicaltrials.gov/ct2/show/NCT03174730

(JMIR Mhealth Uhealth 2019;7(7):e14602) doi:10.2196/14602

KEYWORDS

addictive behavior; smoking behaviors; smoking cessation; health technology; mobile apps; psychological theory

Introduction

Background

Cigarette smoking is the leading cause of preventable death and disease in the United States [1]. To reduce the public health burden of smoking, there is an ongoing need for low-cost, high reach public health interventions for tobacco cessation [1]. In response to this need, smartphone app–based smoking cessation interventions have become increasingly prevalent [2]. Although this area of research is still nascent, clinical trials evaluating smoking cessation apps have shown that apps such as *Smokefree28* [3], *SmartQuit* [4,5], *Clickotine* [6], and other apps [7] have yielded promising quit rates over 2 to 6 months. Although app-based interventions are promising because of their high potential reach and low cost, smokers' engagement with these interventions remains low, and there is much room for improving their efficacy [3,8]. Increased engagement with apps is a key target for improving efficacy because smokers who engage more tend to have higher quit rates [6,8]. Overall, there is a need for theory-based approaches to improve the efficacy of existing cessation apps. This study evaluated the application of the growth mindset theory [9], which has demonstrated the potential to improve persistence in behavior change in other domains, as a means to improve engagement and cessation.

Application of the Growth Mindset Theory to Engagement

People develop lay theories about the nature of human attributes such as intelligence and personality [10]. These lay theories, also referred to as fixed and growth mindsets, are fundamental belief systems about the malleability of different human attributes. A person holding a *fixed mindset* about an attribute (eg, intelligence or addiction) considers that it is a permanent entity that is firmly entrenched in an individual's personality. Contrasting this, a person holding a *growth mindset* about that attribute believes that the attribute is malleable [10].

A belief system about the malleability of addiction is referred to as an addiction mindset [11]. A person can have a *fixed mindset* about addiction, in which they believe that addiction is a permanent attribute of a person and cannot change. Alternately, they can have a *growth mindset* about addiction, whereby they believe that addiction is changeable. Survey research suggests that smokers with a growth mindset about addiction to cigarettes (nicotine) tend to be more motivated and willing to persist with quitting [11]. In addition, as the literature suggests that a mindset is particularly effective at changing behavior by improving participants' persistence in goal-oriented behavior [12], the addiction mindset was chosen as a possible target for an intervention to improve both engagement with apps and cessation.

Experimental research has shown that interventions fostering a growth mindset show promise for behavior change. In educational contexts, interventions fostering a growth mindset of intelligence have been an effective way to improve academic performance in students [13-15]. Growth mindset interventions have been applied in other domains including reducing aggressive behavior [16], reducing stress, and improving coping behaviors [17]. Growth mindset interventions have also been beneficial for improving health behaviors in both young and adult groups, including preventing weight gain among overweight participants [18] and improving mental health [19]. Despite the promise of changing mindsets to change behavior, no work to date has explored the application of this theory to interventions for addictive behavior.

This Study

The goal of this study was to evaluate a growth mindset intervention for improving engagement with and effectiveness of an established smoking cessation app (*SmartQuit*) for adult daily smokers. The SmartQuit app was ideal for this study because its effectiveness for engagement and cessation has been reported in 2 clinical trials [4-5]. Furthermore, engagement with different features of SmartQuit and engagement patterns associated with successful cessation have been identified in previous research [8,20]. This study evaluated the addition of a growth mindset of addiction (to nicotine) component by randomly assigning adult current smokers to either SmartQuit plus a Web-delivered growth mindset intervention or a comparison arm (only SmartQuit). The intervention was specific to addiction to nicotine, referring only to cigarette smoking. The primary outcome measure was engagement with SmartQuit, and the secondary outcome was cessation.

Methods

Design and Randomization

Participants were randomized (1:1) to either the experimental group (growth mindset intervention+SmartQuit app, n=199) or the control group (SmartQuit app only, n=199) using randomly permuted block randomization, stratified by heavy daily smoking (yes or no to 20 cigarettes per day or more) and education (yes or no to high school or less), as these are common predictors of cessation [21,22]. The growth mindset intervention was delivered through an emailed link to a website. Participants were blinded to the exact nature and conditions in the study (see section *Blinding*) to minimize any potential placebo effect of 1 group receiving an additional intervention. The study was registered on ClinicalTrials.gov (NCT03174730).

Recruitment

Eligibility Criteria

The eligibility criteria were as follows: (1) aged ≥18 years, (2) smoked ≥5 cigarettes per day for the past 12 months, (3) ready to quit in the next 30 days, (4) lived in the United States and planned to remain for next 3 months, (5) could read English, (6) had access to a smartphone (running iOS version 8 or higher or running Android version 4.4 or higher) and could download an app, (7) had access to the internet and personal email, (8) not currently enrolled in other smoking cessation treatment, (9) never participated in previous studies by the same research group, and (10) willing to be randomized to treatment and willing to complete surveys at baseline and follow-up.

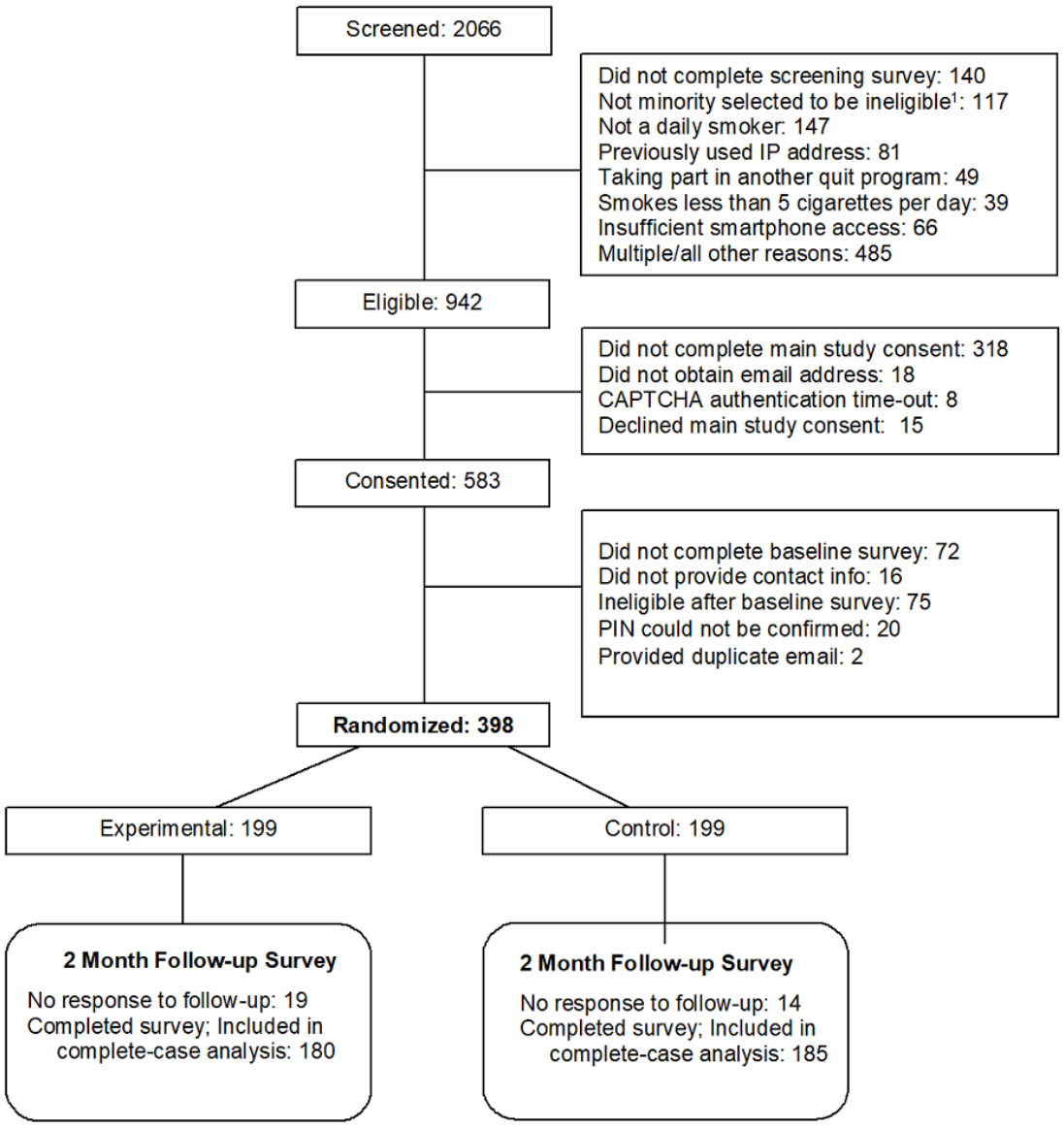
Sample Size

Consistent with the aims of this pilot trial, the sample size was determined using a precision-based approach [23] with the main outcome of engagement with the smoking cessation app. Using available preliminary data on SmartQuit app log-ins [4,5], a sample size of 300 was determined to provide 80% power to detect the differences in number of log-ins between study arms. A threshold minimum effect size of Cohen d=0.2 was used to provide precision toward estimating the engagement effects in a large phase 3 trial. Although the target sample was 300, the sample size was increased to 398 after 2 months of recruitment to account for data loss from participants not accessing SmartQuit (27% of the first 150 participants). See section *Implications for Engagement* for further detail.

Participants and Enrollment

Adult smokers (N=398) were recruited between June and October 2017. Figure 1 shows the study participant flow diagram (Consolidated Standards of Reporting Trials). Recruitment strategies included the use of an internet survey panel and Facebook advertisements to recruit a national sample. Targeted advertisements and website content were used to ensure that the sample reached the minimum 25% male and the minimum 25% minority enrollment targets. A minimum inclusion level for men was added to recruitment criteria because studies using similar recruitment methods tend to overrecruit women [24]. Potential participants completed a Web-based screening survey to assess eligibility. If they screened eligible, they provided Web-based consent and completed a baseline survey and a contact form. Enrollment fraud deterrence included CAPTCHA authentication and review of internet protocol addresses for duplicates or non-US origin participants.

Figure 1. Participant flow diagram. To increase the enrollment of racial and ethnic minorities, some nonminorities who were otherwise eligible for study enrollment were randomly selected to be excluded. IP: Internet Protocol; PIN: personal identification number.



Blinding

The study was presented to participants as *a research study comparing 2 technology-based quit-smoking programs* to maintain blinding of treatment group assignment. Neither research staff nor study participants had access to randomized study arm assignments. Participants were debriefed at the end of the study with the full purpose and differences between groups in the study.

Follow-Up Assessment

Participants completed a follow-up survey at 2 months after randomization. Moreover, 2 weeks before the survey, participants received US $2 as a preincentive and a letter notifying them to expect the survey. Participants received US $25 for completing the survey and an additional US $10 bonus if they completed the Web-based survey within 24 hours of receiving the invitation. Participants who did not complete the Web-based survey within 18 days were sequentially offered opportunities to do so by phone and a mailed survey. Further noncompleters were finally sent a postcard after 30 days with the option to provide their smoking status. Details of our recruitment and retention techniques used in this study are identical to our other electronic health (eHealth) studies described elsewhere [24]. This assessment method yielded a 91.5% (364/398) follow-up rate at 2 months, with 65.9% (240/364) of those responding within 24 hours of survey receipt.

Description of the Growth Mindset Intervention: MIND Tips

The theoretical basis used for all the materials in the MIND tips was the mindset theory [9]. The goal of the intervention was to influence participants' beliefs about the permanence of addiction. Toward this goal, the first step was to identify the specific aspects of addiction that are considered permanent. The literature on nicotine and tobacco addiction was reviewed, and *permanence belief* themes were extracted qualitatively from the review process by all authors (see Multimedia Appendix 1 for additional references). These were refined into 6 specific beliefs with input from subject matter experts (additional scientists in tobacco treatment and counselors). The review was limited to nicotine/tobacco addiction and not expanded to addiction in general. The final 6 beliefs used for creating the intervention content included the following: *addiction is permanent because it is genetic*, *some people will always be addicted because they have an addictive personality*, *addiction is permanent because it irreversibly changes the brain*, *addiction is permanent because withdrawal symptoms may persist after cessation*, *addiction is permanent because people can feel like smoking even years after quitting*, and *failure to quit smoking is indicative of a permanent habit*.

Next, 6 packets of information called MIND Tips (MIND is an acronym for Mindset Intervention for Nicotine Dependence) were created by the authors of this paper in the form of Web-based lessons to counteract each of these 6 beliefs. Moreover, 2 additional lessons were created to provide an introduction and summary for the program. Similar to growth mindset interventions in education and weight loss [13,18], these lessons were constructed to provide scientific evidence for the capacity to change addiction. For example, the lesson discussing genes for addiction explained that having specific genes does not guarantee that a person will always be addicted [25,26]. Furthermore, every tip featured both a testimonial of a (fictional) former smoker demonstrating a growth mindset, consistent with recommendations about their persuasiveness from health communication research [27]. An example of a testimonial from the study showed a person's struggle with their belief in an addictive personality (an intrinsic aspect that cannot change or a fixed mindset of addiction). After presenting scientific information about personality, their quote changes to say that learning this new information showed that personality does not prevent successful quitting, and anyone can quit (growth mindset). The quote is as follows:

> *I've always liked trying new things just for the experience. Unfortunately, the one thing I tried and could not stop was cigarettes. When I struggled to quit, my mom said I've always had an addictive personality. After learning that my personality does not matter for quitting, I was able to kick the habit for good. It wasn't easy, but it was worth all the effort because it feels so good to be free at last.*

A user-centered design process for psychological interventions [28] was used to create and test the MIND content. To make it user-friendly, each lesson was 300 to 500 words long and was at an eighth grade or lower reading level. Remote user testing with 25 current daily smokers for *each* lesson tested the acceptability, usability, and feasibility of remote administration of the MIND content.

These 8 lessons were delivered to participants via an emailed link to a website in the experimental group. Participants in the intervention group received their first MIND Tip email (containing the link of the first lesson) on the same day that they enrolled. They did not have to complete reading it to receive the following content or gain access to SmartQuit. The remaining lessons were sent, one at a time, every 3 days in a preset order (introduction, withdrawal, genes, changes in the brain, personality, urges and cravings, failure to quit, and summary). In this way, the MIND Tips were spaced out over 24 days to prevent overloading participants with content at the time of enrollment. When participants finished reading each lesson, they were provided a link to download the PDF file of the lesson if they wished. The links to the MIND content were active from the day they were pushed out until the end of the study period (2-month window for each participant). Participants could read the MIND Tips content any time during this window and as frequently as they wished.

Description of the SmartQuit Program

Participants in both groups received access to SmartQuit, a smartphone app created to facilitate smoking cessation [29]. As soon as they were confirmed enrolled in the study, participants in both groups were provided a log-in and password to open the app by email. Once they logged in, the app helped them create a quit plan, set a quit date, and establish why they wish to quit. Full details of the app are described elsewhere [4,5,8]. Participants were informed they could use the app as they wished for 2 months.

Measures

Demographics and Smoking History

Participants reported demographic information including their age, gender, race and ethnicity, sexual orientation, education, and employment. Participants who were marked eligible in a short screener were provided up to a week to complete the baseline measures online. Participants reported the number of cigarettes they smoked per day in the past 30 days, as well as the number of years they have been a regular smoker, and the number of quit attempts in the past 12 months. They also completed the Fagerström Test of Nicotine Dependence (FTND) [30].

Mindset and Motivational Variables

Participants completed, at baseline and 2-month follow up, the 6-item Addiction Mindset Scale (AMS; baseline alpha=.68 and follow-up alpha=.73) [11]. The AMS consists of 6 statements that measure beliefs that addiction is permanent (eg, *a person's addiction can never fully leave them*) on a strongly agree to strongly disagree scale. Participants received instructions to consider only addiction to nicotine (ie, from cigarette smoking) only for all statements. Participants completed the 8-item measure of motivation using the Commitment to Quitting Smoking Scale [31], which assesses their willingness to persist in staying quit despite discomfort or other difficulties at both baseline (alpha=.91) and follow-up (alpha=.93). As a measure of self-efficacy for quitting smoking, participants reported their confidence in staying abstinent at the 2-month follow-up using an adapted single item, "On a 0-100 scale, where 0 is not at all and 100 is extremely confident, how confident are you that you will be abstinent 2 months later?" [32].

Utilization of the Growth Mindset Intervention

Objective measures of website utilization were tracked through server-recorded, time-stamped page views.

Outcome Measures: App Engagement

Participants' use of the SmartQuit app was automatically recorded for the duration of the study, that is, 2 months from the date of enrollment for each participant. The main indicator of use recorded for this study was the number of log-ins. Additional metrics of interest included the number of days of use and whether participants received the certificate of completion awarded inside the app (participants who completed a quit plan, viewed the 8 main exercises, used the urge tracking feature, and viewed additional content from a help menu received this certificate), which predicted 4 times higher odds of cessation in a previous trial [8].

Outcome Measures: Cessation and Smoking Behavior

Two months after the date of randomization, participants completed the FTND and reported the last time they smoked a cigarette, how many cigarettes per day they smoked on average in the last 30 days, and how many quit attempts they made. Cessation was defined as self-reported 30-day point prevalence abstinence (PPA; ie, no smoking at all in the past 30 days) at the 2-month follow-up. Biochemical validation of quit status was not used in this study. However, research suggests that biochemical verification is not required in studies where data are collected through Web or mail without any face-to-face contact and which present limited demand characteristics [33,34].

Statistical Analysis

All analyses were conducted with the analysis software R Studio version 3.4.0 [35]. For all analyses, a significance level of .05 was used. Differences between demographic variables across arms at baseline were examined using *t* tests and Fisher exact tests for continuous and categorical variables [36,37]. If any baseline variables were found imbalanced across arms, *and* these variables were predictive of the outcome of the analysis, they were included as covariates in analyses comparing study arms [38]. Logistic regression models were used to examine differences in cessation between groups. The primary analysis method was a complete case analysis with the intent-to-treat sample, which covers 91.5% (364/398) of the recruited sample. A secondary sensitivity analysis was included, with missing cessation data coded as smoking to allow comparison with other trials [39]. In addition, a modified intent-to-treat analysis was conducted on the sample that accessed their assigned intervention materials at least once. This includes only those participants who had logged in at least once to SmartQuit (both arms) and had viewed at least 1 page (out of the 8 page views required for complete adherence) of the MIND content (experimental arm only; n=266).

Negative binomial regression models were used for predicting 2 engagement outcomes (number of log-ins and number of days logged in) to account for zero inflated distributions [40]. All analyses exploring group differences between the control and experimental groups controlled for the randomization factors of education and heavy smoking to avoid loss of power [41]. Further covariates were included only if they were significantly and independently associated with both the predictor and outcome variables in models [42].

Results

Description of Sample

Table 1 shows the demographics of the sample across the intervention and control arms. The only significant difference in characteristics at baseline was self-efficacy to quit. The control group had significantly higher baseline self-efficacy to abstain from smoking (P=.002). As self-efficacy is predictive of smoking cessation in this study (P<.001), models predicting cessation from group assignment controlled for baseline self-efficacy.

Table 1. Baseline demographics, self-reported mental health, smoking history, and behavior of participants in the Mindset Intervention for Nicotine Dependence study for the intention-to-treat sample.

Characteristics	Total (N=398)	Control (n=199)	Intervention (n=199)	*P* value[a]
Demographics				
Age (years), mean (SD)	42.0 (12.3)	42.0 (12.5)	42.1 (12.0)	.88
Male, n (%)	165 (41)	84 (42)	81 (41)	.84
Caucasian, n (%)	309 (79)	157 (79)	152 (78)	.99
African American, n (%)	60 (15)	32 (16)	28 (14)	.75
Asian, n (%)	1 (<1)	1 (<1)	0 (0)	>.99
Native American or Alaska Native, n (%)	3 (1)	1 (<1)	2 (1)	.98
Native Hawaiian or Pacific Islander, n (%)	1 (<1)	0 (0)	1 (<1)	.99
More than 1 race, n (%)	19 (5)	8 (4)	11 (6)	.60
Hispanic, n (%)	45 (11)	20 (10)	25 (13)	.53
Married, n (%)	125 (31)	57 (29)	68 (34)	.28
Working, n (%)	195 (49)	99 (50)	96 (48)	.84
High school or less education, n (%)	156 (39)	78 (39)	78 (39)	>.99
Lesbian, gay, or bisexual, n (%)	68 (17)	39 (20)	29 (15)	.23
Self-reported mental health, n (%)				
Anxiety disorder	146 (37)	77 (39)	69 (35)	.47
Depression	144 (36)	76 (38)	68 (34)	.47
Bipolar disorder	56 (14)	30 (15)	26 (13)	.67
Schizophrenia	9 (2)	3 (2)	6 (3)	.50
Alcohol abuse	16 (4)	7 (4)	9 (5)	.80
Drug abuse	24 (6)	9 (5)	15 (8)	.29
No mental health conditions	199 (50)	94 (47)	105 (53)	.32
Smoking behavior				
Fagerström Test for Nicotine Dependence score, mean (SD)	5.84 (2.1)	5.87 (2.1)	5.82 (2.0)	.81
High nicotine dependence, n (%)	234 (59)	117 (59)	117 (59)	>.99
Cigarettes per day, mean (SD)	19.0 (16.2)	19.0 (16.5)	19.1 (15.9)	.94
Smokes more than half pack per day, n (%)	279 (70)	137 (69)	142 (71)	.66
Smokes more than 1 pack per day, n (%)	84 (12)	43 (22)	41 (21)	.90
Used electronic cigarettes at least once in past month, n (%)	85 (21)	37 (19)	48 (24)	.22
Quit attempts in the past 12 months, mean (SD)	1.0 (2.5)	0.8 (2.0)	1.1 (2.9)	.33
Self-efficacy, mean (SD)	71.6 (22.6)	75.2 (21.2)	68.0 (23.4)	.002
Commitment to quitting, mean (SD)	4.00 (0.7)	4.04 (0.7)	3.96 (0.7)	.31
Friend and partner smoking				
Close friends who smoke, mean (SD)	2.5 (1.8)	2.5 (1.8)	2.4 (1.8)	.48
Number of adults in home who smoke, mean (SD)	1.5 (0.8)	1.6 (0.9)	1.5 (0.8)	.27
Living with partner who smokes, n (%)	136 (34)	63 (32)	73 (37)	.34
Theory-based measures				
Addiction Mindset Scale score, mean (SD)	3.33 (0.8)	3.31 (0.8)	3.35 (0.8)	.69

[a]*P* values are reported for *t* tests (for continuous variables) and Fisher exact tests (for categorical variables) comparing demographics across groups.

Intention-to-Treat Analyses

Treatment Adherence and Change in Mindset

In the intervention group, 78.4% (156/199) of the participants viewed at least 1 page of the MIND tips, and 21.1% (42/199) of the group viewed all 8 tips. On average, participants in the intervention group viewed 4.16 (SD 3.38) tips out of 8 total tips. Controlling for the baseline level of growth mindset, the intervention group's mean AMS score after 2 months (3.42 [SD 0.90]) was not significantly different from the control group (3.35 [SD 0.93]; *B*=0.05; 95% CI −0.13 to 0.22; *P*=.59). We also found no group-level differences between AMS score at follow-up (control group 3.35 [SD 0.93] vs intervention group 3.42 [SD 0.90]; *P*=.46).

Engagement: Primary Outcome

The results are shown in Table 2. Across both groups, 72% of the participants logged in at least once to the SmartQuit app. Participants in the control arm logged in an average of 21.61 (SD 37.74) times (median 6.00; interquartile range [IQR] 25.50) and in the experimental arm, 19.46 (SD 30.20) times (median 5.00; IQR 25.00). Participants in the experimental arm did not log in to the app more than control arm participants (*P*=.38).

Engagement: Additional Metrics of Interest

Intervention group participants logged in for an average of 11.73 days (median 4.00; IQR 17.5) compared with the control group's 12.19 days (median 5.00; IQR 5.00), and this difference was not significant (*P*=.97). The proportion of participants receiving certificates of completion was highly similar in the intervention (31%) and control (30%) groups (*P*=.74).

Cessation: Secondary Outcome

In complete case analysis, the 30-day PPA rates at 2-month follow-up in the experimental and control conditions were 17% and 14%, respectively (odds ratio [OR] 1.64; 95% CI 0.90-3.00; *P*=.10), representing a 64% increase in the odds of quitting in the experimental group relative to the control group. The results did not change when missing data were treated as smoking (OR 1.54, 95% CI 0.88-2.76; *P*=.14).

Cessation: Progress Metrics

For cessation progress, the smokers in the intervention group reported nonsignificant decreases in smoking (mean decrease in number of cigarettes per day=4.66 vs 3.01, *B*=−1.90; *P*=.07;) and marginal reduced dependence as measured by the FTND score (mean score decrease=1.55 vs 1.11; *B*= −.53; *P*=.05) compared with participants in the control group.

Modified Intention-to-Treat Analyses

Results for modified intention-to-treat (ie, participants with ≥1 SmartQuit log-in for both arms and at least 1 page view of the 58 total pages of MIND content for participants in the experimental arm) are summarized in Table 3. When examining only the participants included in this analysis, the intervention group (n=115) did not differ from the control group (N=151) in number of log-ins to the SmartQuit app (M=32.31 vs 28.48; *P*=.55). Descriptively, the participants in the intervention group tended to log in more days (mean 20.10 days) compared with the control group (mean 15.46 days; *P*=.06) and were more likely to receive the certificate of completion in SmartQuit (50% vs 38%; *P*=.07) although these differences were nonsignificant.

Table 2. Smoking cessation and engagement with cessation program at 2-month follow-up. Results are adjusted for 2 stratification factors (heavy smoking and education). Cessation results are adjusted for baseline self-efficacy.

Outcome variable	Overall (N=398)	Control (n=199)	Intervention (n=199)	OR[a]/IRR[b]/estimate[c] (95% CI)	*P* value
Engagement with SmartQuit app					
At least one log-in, n (%)	287 (72)	151 (76)	136 (68)	0.69 (0.44 to 1.07)	.10
Number of log-ins, mean (SD)	20.54 (34.16)	21.61 (37.74)	19.46 (30.20)	0.90 (0.61 to 1.21)	.38
Number of days used, mean (SD)	11.96 (16.90)	11.73 (16.14)	12.19 (17.64)	1.00 (0.72 to 1.37)	.97
Completion certificate, n (%)	119 (30)	58 (30)	61 (31)	1.08 (0.70 to 1.65)	.74
Number of Acceptance and Commitment Therapy[d] exercises completed, mean (SD)	11.92 (19.93)	11.74 (17.03)	12.12 (22.50)	0.95 (0.69 to 1.32)	.77
Smoking cessation					
30-day PPA[e], complete case, n (%)	56 (15)	25 (13)	31 (17)	1.64 (0.90 to 3.00)	.10
30-day PPA, missing=smoking, n (%)	56 (14)	25 (12)	31 (16)	1.54 (0.86 to 2.76)	.15
Change in cigarettes per day, mean (SD)	−3.81 (7.88)	−3.01 (8.37)	−4.66 (7.27)	−1.90 (−4.00 to 0.18)	.07
Change in Fagerström Test for Nicotine Dependence, mean (SD)	−1.33 (1.92)	−1.11 (1.73)	−1.55 (2.08)	−0.53 (−1.07 to 0.01)	.05

[a]OR: odds ratio in logistic regression for binary variables.

[b]IRR: incident rate ratio in negative binomial regression for count variables (ie, number of times logged in and length of use of website).

[c]Point estimate: difference between arms for continuous variables.

[d]Modules inside SmartQuit.

[e]PPA: point prevalence abstinence.

Table 3. Smoking cessation and engagement with cessation program at 2-month follow-up with the Modified-Intention-to-Treat analysis. Results are adjusted for 2 stratification factors (heavy smoking and education). Cessation results are adjusted for baseline self-efficacy.

Outcome variable	Overall (N=266)	Control (n=151)	Intervention (n=115)	OR[a]/IRR[b]/estimate[c] (95% CI)	*P* value
Engagement with app					
Number of log-ins, mean (SD)	30.14 (38.13)	28.48 (41.13)	32.31 (34.00)	1.08 (0.83 to 1.42)	.55
Number of days used, mean (SD)	17.46 (18.10)	15.46 (16.91)	20.1 (19.31)	4.14 (−0.23 to 8.50)	.06
Completion certificate, n (%)	116 (44)	58 (38)	58 (50)	1.58 (0.86 to 2.59)	.07
Number of Acceptance and Commitment Therapy[d] exercises completed, mean (SD)	17.41 (22.32)	15.48 (18.02)	19.96 (26.82)	3.72 (−1.66 to 9.11)	.18
Smoking cessation					
30-day PPA[e], complete case, n (%)	42 (17)	19 (13)	23 (21)	2.13 (1.06 to 4.27)	.03
30-day PPA, missing=smoking, n (%)	42 (16)	19 (13)	23 (20)	2.10 (1.45 to 4.19)	.03
Change in cigarettes per day, mean (SD)	−4.15 (7.74)	−3.53 (7.57)	−4.96 (7.96)	−1.26 (−3.97 to 1.27)	.33
Change in Fagerström Test for Nicotine Dependence	−1.48 (1.91)	−1.18 (1.69)	−1.88 (2.12)	−0.78 (−1.45 to −0.11)	.02

[a]OR: odds ratio in logistic regression for binary variables.

[b]IRR: incident rate ratio in negative binomial regression for count variables (ie, number of times logged in and length of use of website).

[c]Point estimate: difference between arms for continuous variables.

[d]Modules inside SmartQuit.

[e]PPA: point prevalence abstinence.

Regarding cessation outcomes, the intervention group participants significantly differed from the control group on quit rates (21% vs 13%) at 2-month follow-up (OR 2.13, 95% CI 1.06-4.27; *P*=.03). The results were the same when missing data were coded as smoking (OR 2.10, 95% CI 1.45-4.19; *P*=.03). For cessation progress, descriptively similar patterns were observed for reduction of smoking, although the difference was not significant (mean decrease in number of cigarettes per day=4.96 vs 3.53; *B*=−1.26 , *P*=.33). The participants in the intervention group also showed greater reduction in nicotine dependence (mean score decrease=1.88 vs 1.18; *B*=−.78; *P*=.02) than the control group.

Discussion

Summary of Results

This study evaluated a randomized trial of a growth mindset intervention on engagement with SmartQuit, an app-based cessation program, and successful cessation among daily smokers. On average, participants viewed half of their assigned growth mindset tips in the intervention condition. Contrary to the hypothesis that the growth mindset intervention might improve persistence with the SmartQuit program, there were no significant differences between study arms in engagement with SmartQuit. There was a nonsignificant trend for higher odds of cessation in the intervention group compared with the control group. A modified intention-to-treat analysis was also conducted as a sensitivity analysis to evaluate the impact of including data from participants who never accessed their assigned intervention. In this analysis, there were no significant differences on engagement to SmartQuit, although cessation rates were significantly higher for the MIND intervention group compared with the control group. Thus, the results were similar, but with a stronger signal for efficacy of the MIND intervention.

Implications for Engagement

Overall, participants in the intervention arm viewed about half of their assigned MIND tips, and about one-fifth of them viewed the entire content provided. A Web-delivered growth mindset intervention, although feasible to implement, did not yield higher log-ins to SmartQuit when compared with the control arm. There are some possible explanations for this. First, the mindset scores were not different between groups at the end of the study (controlling for the baseline mindset), possibly because the growth mindset intervention did not sufficiently increase the growth mindset or participants did not view enough of the growth mindset intervention content to demonstrate a significant overall increase in their mindset score. Given that an overall increase in the growth mindset was hypothesized to improve engagement, this could explain why there were no overall differences in engagement with SmartQuit. To explore this further, a follow-up analysis showed that viewing more MIND tips was significantly associated with increased growth mindset scores in the intervention group (*B*=0.04; *P*=.03). Therefore, future iterations of this work should explore ways to improve the adoption and efficacy of the growth mindset intervention.

Second, it is possible that MIND intervention group participants who received the combination of an app-based and a Web-based intervention might have simply been provided too much content over 2 different modalities such that they did not have time for both. Furthermore, participants in the intervention group may have been responsive to the MIND tips over the app because the emails proactively reached out to them and served as a cue for participation, whereas app use has to be driven by the

participant's own actions. Future work implementing a growth mindset intervention for engagement should take these into consideration for improving on intervention design and delivery. Perhaps, combining all the interventions into a single modality will ease participant burden and improve engagement rates.

In general, there was less engagement across both arms than desired. Although all participants signed up for a technology-based smoking cessation study, more than one-fifth of the sample did not use their assigned programs even once. This study did not require the participants to log in to be enrolled, as imposing that condition would have proven costly and difficult to implement, and our goal was to mimic real-world conditions where participants are free to access their app. Other digital interventions that have not required 1 log-in as an enrollment condition have found that 57% to 82% of the recruited sample did not download/log in to their digital interventions [43,44]. These behaviors may be characteristics of technology-delivered interventions, where factors intrinsic to technology itself (eg, lack of space in a participant's phone, knowledge needed to install the app, and steps involved in acquiring a password from email to input into a phone) may have affected participant engagement [45]. Although characteristic of mobile health and eHealth studies, the problem of low engagement remains challenging and contributes to difficulties in interpreting study results. Programs using app-based and/or Web-based interventions should carefully consider mitigation strategies for these factors including improving ease of access and early engagement strategies. To address the interpretive issues that arise from failure to engage with any aspect of the intervention, we used a modified intention-to-treat analysis to explore outcomes among users who did engage at least minimally to the treatment protocol. This analysis was intended as a sensitivity analysis, and its conclusions are limited by the absence of random assignment; thus, it cannot be used to draw causal conclusions [46].

Results of the modified intent-to-treat analysis showed no differences in log-ins. Descriptively, participants in the intervention subgroup logged in for a greater number of days and were more likely to achieve the certificate of completion. Half of all participants in the intervention subgroup received a certificate of completion to the SmartQuit program compared with 38% in the control group. Although nonsignificant, the descriptive differences in achieving the certificate of completion are important from a treatment perspective, as previous research has found that smokers who achieved certificate of completion were 4 times more likely to quit. The descriptive difference in results between number of log-ins and number of days logged in also suggests the readers of the mindset tip may have been using the app differently. Additional exploration of the data is needed to examine the nature of this difference (eg, intervention participants logging in to get tips before, during, and after their quit attempt to sustain behavior change instead of consuming large amounts of content at once). Greater number of days logged in may also indicate greater persistence toward behavior change, which would be consistent with the mindset theory.

Another explanation for the differential outcomes is the greater participant exclusion in the experimental subgroup (the experimental subgroup needed at least 1 page view of the MIND content (of 58 total pages of content) and 1 log-in to SmartQuit (relative to the control group, which only needed 1 log-in to SmartQuit), which may have excluded participants who differed in motivation or other variables predisposing them to engagement. However, a post-hoc analysis of the 2 subgroups revealed no significant differences in demographic variables or commitment to quit smoking between them at baseline. There was still a significant difference in baseline self-efficacy to quit between the intervention and control subgroups, but this difference was not related to engagement with SmartQuit. On the basis of available data, then, it is more likely that exposure to a growth mindset intervention is related to the difference between arms than baseline demographic difference. However, we cannot rule out the possibility that other unmeasured variables may have contributed to this difference as well.

Implications for Cessation

There was a trend toward greater cessation (30-day PPA at 2 months) and reduction in the number of cigarettes smoked per day and in nicotine dependence in the experimental arm compared with the control arm. These results were also mirrored more strongly in the modified intent-to-treat results when examining participants with at least minimal adherence to their assigned interventions. The differences in cessation were present despite the lack of differences in number of log-ins. Reflecting on the fact that mindset interventions most commonly affect behavioral persistence, perhaps a measure of the number of log-ins does not fully capture that variable. A different measure of digital engagement or other external measures that connects more to persistence in behavior toward cessation would be beneficial to investigate in future studies as a mechanism of action.

Viewing all the data on cessation and cessation progress together, there is evidence that the combination of the growth mindset intervention and the SmartQuit app may be more helpful for smokers wanting to quit smoking than the app alone. This result warrants further investigation. When scaled to a population level and considering the cost-effectiveness of technological interventions and health benefits accrued from each additional person who quits or reduces smoking, even a 1% improvement in quit rates can be considered clinically significant [47]. From the results of this study, a 4% improvement (in the intention-to-treat analysis) and an 8% improvement (in the modified intention-to-treat analysis) are considerable when scaled to a population level [47]. Therefore, there is a need to learn from this pilot trial and iterate and improve on the adoption and efficacy of a growth mindset intervention.

Limitations and Future Directions

This pilot study of a growth mindset intervention has some important limitations to note. The experimental group received a growth mindset intervention in addition to an app, whereas the control group did not receive anything in addition to the app. Future work should explore alternative study designs in addition to the pilot design demonstrated here and compare the growth mindset intervention to other interventions to evaluate its comparative efficacy. Adherence to the MIND Tips remained lower than desired in the intervention arm, and there was no

measure of knowledge gained from the MIND Tips included in this study. The sample size limits power to draw inferences on cessation, and pretreatment attrition, although more realistic of real-world use, limits the amount of data available for a full exploration of an intention-to-treat analysis. Although the modified intent-to-treat analysis provides important insight into the outcomes of participants who at least accessed their programs, the selection of participant subgroups cannot be used to draw causal conclusions because of loss of true random assignment [48]. Future studies should focus on making technology-delivered interventions easier to adopt and investigate ways to reduce attrition from participants never engaging with an intervention. Delivering all the intervention content over the same technology may alleviate some burden on participants instead of having tips linked by email and skills delivered through a smartphone app. Future work should also follow up participants for 6 months or more to identify efficacy over the long term. Future studies can also improve on recruiting a diverse sample. Despite targeted enrollment efforts, the study population was still largely white (79%) and had greater than high school education (61%). Finally, future work should also explore the different mechanisms through which the intervention influence engagement and/or cessation, including changes in self-efficacy and commitment to quit smoking.

Conclusions

A Web-delivered growth mindset intervention for nicotine addiction is feasible to implement but did not enhance engagement with smartphone app for smoking cessation. The combined Web-delivered growth mindset intervention and app may have a beneficial effect for cessation or progress toward cessation. More research is required to improve on the growth mindset intervention, remove barriers to and enhance its adoption, and evaluate its effectiveness in combination with existing cessation programs.

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Conflicts of Interest

JB has served as a consultant for GlaxoSmithKline and serves on the advisory board of Chrono Therapeutics. JH has received research support from Pfizer. None of the other authors have financial conflicts to disclose.

Multimedia Appendix 1

Additional references used to create intervention material.

[PDF File (Adobe PDF File), 72KB - mhealth_v7i7e14602_app1.pdf]

Multimedia Appendix 2

CONSORT - EHEALTH checklist (V 1.6.1).

[PDF File (Adobe PDF File), 2MB - mhealth_v7i7e14602_app2.pdf]

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Abbreviations

AMS: Addiction Mindset Scale
eHealth: electronic health
FTND: Fagerström Test of Nicotine Dependence
IQR: interquartile range
IRR: incident rate ratio
MIND: Mindset Intervention for Nicotine Dependence
OR: odds ratio
PPA: point prevalence abstinence

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Original Paper

Specialized Smartphone Intervention Apps: Review of 2014 to 2018 NIH Funded Grants

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Abstract

Background: The widespread adoption of smartphones provides researchers with expanded opportunities for developing, testing and implementing interventions. National Institutes of Health (NIH) funds competitive, investigator-initiated grant applications. Funded grants represent the state of the science and therefore are expected to anticipate the progression of research in the near future.

Objective: The objective of this paper is to provide an analysis of the kinds of smartphone-based intervention apps funded in NIH research grants during the five-year period between 2014 and 2018.

Methods: We queried NIH Reporter to identify candidate funded grants that addressed mHealth and the use of smartphones. From 1524 potential grants, we identified 397 that met the requisites of including an intervention app. Each grant's abstract was analyzed to understand the focus of intervention. The year of funding, type of activity (eg, R01, R34, and so on) and funding were noted.

Results: We identified 13 categories of strategies employed in funded smartphone intervention apps. Most grants included either one (35.0%) or two (39.0%) intervention approaches. These included artificial intelligence (57 apps), bionic adaptation (33 apps), cognitive and behavioral therapies (68 apps), contingency management (24 apps), education and information (85 apps), enhanced motivation (50 apps), facilitating, reminding and referring (60 apps), gaming and gamification (52 apps), mindfulness training (18 apps), monitoring and feedback (192 apps), norm setting (7 apps), skills training (85 apps) and social support and social networking (59 apps). The most frequently observed grant types included Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) grants (40.8%) and Research Project Grants (R01s) (26.2%). The number of grants funded increased through the five-year period from 60 in 2014 to 112 in 2018.

Conclusions: Smartphone intervention apps are increasingly competitive for NIH funding. They reflect a wide diversity of approaches that have significant potential for use in applied settings.

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KEYWORDS

smartphone; intervention; funded grants; mobile phone

Introduction

Public Health Interventions

Through its various federal agencies, the US government has evolved a broad public health mandate to prevent disease and improve health. Part and parcel of this mandate is to find creative and innovative ways to enhance the public's health and reduce the burdens of disease and disability. In recent years, the National Institutes of Health (NIH) and its 27 Institutes and Centers have searched for promising ways to capitalize on the public's use of mobile phone technology to service its mission. Otherwise known as mobile health (mHealth), the use of cellular

and smartphone technology has provided a platform to extend the reach of health promotion and disease prevention activities. We differentiate mHealth technology, which is defined as "mobile communications for health information and services" from electronic health (eHealth), the latter which primarily involves the use of the Internet for delivery of behavioral and health-related interventions [1-4]. Mobile communication can include, but not be limited to, smartphones, tablets, patient monitoring devices, personal digital assistants, and bodily or household sensors that rely on wireless communication. Given the widespread presence of mobile technology, potential users are no longer bound by periodically showing up for clinic visits and the inconvenience of waiting rooms and stalled scheduling. The monitoring and reporting of behavior, tracking events that precipitate disease conditions, or monitoring adherence can all be conducted in real-time, and a wide assortment of pertinent information can be transported electronically to medical records or even stored in comprehensive research databases.

Several systematic reviews and meta-analyses have reinforced the utility of mobile phones and smartphones (including wireless hand-held tablet devices and cellular phones) in a variety of health domains. These include application of mHealth technology in care delivery and chronic disease management [5,6] with specific applications monitoring hypertension [7,8], medication adherence support [9], obesity and weight loss [10], diabetes mellitus [11], substance use prevention [12,13], mental health [14-16] and physical activity [17,18], to name a few. Apps have also been developed for asthma self-care management [19], smoking cessation [20], maternal and neonatal care [21], and stress reduction using mindfulness strategies [22], all of which include provision of biofeedback [23]. Additional reviews have focused more exclusively on mobile apps targeting diseases identified by the WHO as major global health priorities [24]. For the most part, these reviews support promising results with potential healthcare benefits for a wide selection of evidence-based mobile and smartphone app interventions.

There is a considerable upside to the plethora of mobile phone apps now available. According to the trade organization GSMA Intelligence, which tracks trends in mobile phone usage worldwide, cell phone use worldwide has topped five billion, with roughly 67% market penetration and 3.2% annual projected growth [25]. In the United States alone, there are over 262 million mobile phone subscribers [25]. Increases in mobile phone usage are slated for the traditionally developing or low-income countries where expansion of mobile phone infrastructure (ie, 4G networks, cell transmission towers, and LTE broadband transmission) is taking place [26]. Using digital distribution platforms like Apple's AppStore for iOS products or Google's Google Play for Android products, approximately 1500 apps are downloaded daily with 178 billion downloaded in 2017 and 205 billion in 2018 [27]. A mobile app industry tracking company reports there are 318,000 health-related mobile phone apps with approximately 200 new ones added daily [28]. Based on Apple Store statistics, health and fitness apps represented 3.0% of the total downloads, lifestyle represented 8.3% of the downloaded apps, medical was 1.8% and the leading app download category was games at 24.9%.

More importantly, availability of free and low-cost health-related applications has dramatically increased as well. FitBit, a digital healthcare company, is the leading fitness tracking app among those labeled as wireless-enabled wearable sensor technology and that are used specifically for monitoring health and vitals. The free, downloadable app monitors health and vitals like heart rate, pulse, sleep quality, and calories burned, and can both accurately measure steps using a pedometer, as well as monitor activity through an accelerometer-based motion sensor. A new sector is growing to handle digital biomarkers that can instantly regulate a patient's insulin intake or monitor their breathing capacity (ie, smart inhalers) and report this to clinical providers. The availability of apps in general as well as the increased market for health-related apps all speaks volumes regarding demand. One barometer of this demand is revenue from global mobile app sales. In 2014, revenues from mobile app sales hovered around 35 billion US dollars. In 2018, these sales skyrocketed to 92 billion US dollars [29] with the duo of Samsung and Apple sharing the lion's share of revenues at 50%. This number is projected to reach 188.9 billion US dollars in 2020.

The use of mobile phone apps for healthcare piggybacks onto several emerging trends. Smartphone sales have skyrocketed in the past decade, and with their advanced features they now practically function like a handheld computer. This is due to improved technological capabilities which include wireless connectivity allowing Internet access, faster chip processors and download speeds, longer battery life, finer digital pixilation, and multimedia graphic imaging capability, all at a lower cost to subscribers. Freeware apps like Skype, Fring, and iCall utilize Voice of Internet Protocol (VoIP) to achieve real-time synchronous remote teleconferencing (ie, video chat). The global positioning system (GPS) capability enables remote location monitoring, making it possible to monitor disease vectors as part of public health surveillance [30,31], to track physical activity in cardiac rehabilitation [32] and to find dementia patients who wander outside of care facilities [33].

Smartphone camera technology has improved dramatically, and with higher resolution digital imaging it can now enable bio-optical sensing and real-time synchronous sharing of pictures of patients' skin with their dermatologist or sharing of medical conditions with healthcare staff for diagnosis, treatment and remediation. Connectivity to cloud computing allows physicians, for example, to exchange laboratory or radiographic images for medical consultations using servers that are compliant with data privacy regulations [15]. More and more, even in resource limited countries, mobile technology provides a bridge to healthcare connectivity, making it possible for patients (or their families) to receive educational materials, monitor their health, track symptoms or conduct self-assessments [34].

Smartphone apps allow users to connect with their healthcare provider and share patient experiences as well as receive individualized instruction by transmitting data in real-time. This may help individuals overcome resource limitations that may arise from the large distances between their residence and their provider (access to care) and structural barriers that arise from cultural or behavioral factors that limit care provision. There are now numerous projects underway supporting public health

surveillance in Sub-Saharan Africa that are leveraging mobile health-related apps [35,36] to increase treatment adherence, improve delivery of care [30], and monitor communicable diseases (ie, malaria) and other health problems (eg, child malnutrition). Even physician providers themselves are using mobile apps to learn about care delivery in remote areas of Africa [37], and this is part of an ongoing, worldwide trend for health care professionals who require greater access to point of care tools for decision making [38]. The burgeoning use of mobile phones for provision of healthcare is coupled with what is termed lab-on-a-chip technology that allows biochemical and diagnostic assays (eg, blood glucose monitoring or cholesterol testing) to be performed with sweat, saliva, urine or blood using the smartphone in vivo [39]. In all these examples, the portability, ease of use, flexibility, customization, convenience, and privacy of information was highly attractive to users.

Missing Pieces of the Mobile Phone Healthcare Puzzle

What is missing from this picture, however, is a deeper understanding of the organization of mobile apps, in particular whether there are common themes underlying mobile app intervention strategies (ie, treatment adherence, behavior modification, appointment reminders, and data collection using self-reporting or remote bio-sensors for symptom tracking), service delivery strategies (ie, platforms used to deliver interventions), the medical and behavioral conditions that apps emphasize, their intervention goals, integration with other service platforms (ie, web or in person), and characterization of the target populations, all of which can help clarify the event horizon. To our knowledge, this type of summarization has not been previously conducted, with the few research-based systematic reviews of mHealth applications highly topic dependent (ie, focusing on at most one disease or health focus with a specific target population). It is particularly relevant to understand the US government's scientific research investment portfolio, which through various grant mechanisms supports app development that specifically addresses the nation's stated public health agenda [40]. Therefore, in the current study, we undertake the synthesizing of NIH-funded mobile phone apps between 2014 and 2018 based on a set of organized criteria that will inform the future of public health initiatives using mHealth strategies.

Methods

Sample

We searched NIH Reporter [41] using the following key terms in the text search field: (1) *mHealth* or *smartphone* or *mobile* or *phone* or *Android* or *iOS* or *game* or *gaming* or *gamification* and (2) *intervention* or *treatment* or *randomized* or *RCT* or *program*. We limited the search period to the five fiscal years of 2014 through 2018. At times, insufficient information was available on the NIH Reporter that made it hard to detect whether an app was being used in the research. This prompted us to widen the search engines (Google) and to include Grantome.com (an independent resource for searching for grant awards) as a means of locating additional information. In some cases, we used Google Scholar to track down publications, when available, that could clarify the research focus and utilization of a true app.

We completed this search for each of the following agencies:

1. National Institute on Alcohol Abuse & Alcoholism (NIAAA)
2. National Institute on Aging (NIA)
3. National Institute of Allergy and Infectious Diseases (NIAID)
4. National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)
5. National Institute on Drug Abuse (NIDA)
6. National Institute on Deafness and other Communication Disorders (NIDCD)
7. National Institute of Dental and Craniofacial Research (NIDCR)
8. National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
9. National Institute of Biomedical Imaging and Bioengineering (NIBIB)
10. National Institute of Environmental and Health Sciences (NIEHS)
11. National Eye Institute (NEI)
12. National Institute of General Medicine Sciences (NIGMS)
13. National Institute of Child Health and Human Development (NICHD)
14. National Human Genome Research Institute (NHGRI)
15. National Heart, Lung, and Blood Institute (NHLBI)
16. National Library of Medicine (NLM)
17. National Institute on Minority Health and Health Disparities (NIMHD)
18. National Institute of Mental Health (NIMH)
19. National Institute of Nursing Research (NINR)
20. National Institute of Neurological Disorders and Stroke (NINDS)

For each funded grant, we retrieved the abstract, title, start date, activity code, and first year funding amount. We subsequently retained only the following grant activity codes: R01, R03, R15, R21, R34, R35, R41, R42, R43, R44, R56 and R61. We excluded all D, F, K, O, P, S, U and Z awards as well as R13, R25, R36, R37 and R90 awards. This left us with the bulk of peer reviewed research grant mechanisms that included technology-related research [42].

Initial Documentation

For each grant we reviewed the abstract, the only publicly available description of the project that might elucidate the content and methods. We first eliminated grants that did not have a planned intervention. We also eliminated grants that only used standard features of smartphones, such as SMS or text messaging, although if there were added features that were novel in any way those grants were retained.

We read through each abstract and provided brief summaries about: (1) the topic of the app (eg, the specific disease or behavior addressed); (2) the specific strategy employed by the app (ie, how the app was to be used for intervention); (3) the intended outcome (ie, goals of the intervention); (4) whether the app was applied to a standalone intervention or used in an

ancillary way in conjunction with other forms of care; (5) the age group targeted by the app; (6) the population on which it would be tested or used; and (7) the name of the app.

Categorization Scheme

Review proceeded agency by agency. Following an initial review of specific strategies employed in four behavior focused (NIAAA, NICHD, NIDA and NIMH) and four disease focused agencies (NCI, NIDDK, NHLBI and NIA), we developed a tentative list of categories that summarize the kinds of interventions that we noted in the abstract review process. When a subsequently reviewed grant had an approach that could not be easily accommodated within the existing list of categories, we added a new category. For each grant, the proposed categories were noted as present or not present. Single grants could include multiple categories. All grants included at least one category.

Artificial Intelligence

In the context of smartphone apps, artificial intelligence implies the use of embedded computational algorithms that give the user guidance for making ideal or maximally satisfying decisions [43]. The user provides input either by defining situations and selecting options provided by the app or through data provided from wearable devices. The intent is to guide the user in taking next steps toward enhancing prevention or engaging in treatment [44]. Included in this category are apps that feature tailoring to meet an individual's personalized needs.

Bionic Adaptation

This category of apps included grants that intend to develop smartphone assisted or adaptive technologies and prosthetic devices to compensate for a variety of biological limitations or disease conditions. Conceivably, bionic adaptations can be used to compensate for challenges with vision [45,46], vestibular balance [47,48], speech and hearing [49,50], and the use of artificial limbs [51,52]. The goal is often to replace a missing component of normal human functioning or enhance a component that has been damaged due to aging, illness or injury. Included in this category are wearable and injected devices that communicate wirelessly with smartphones.

Cognitive and Behavioral Therapies

This category includes a wide variety of interventions. Among these, cognitive behavior therapy (CBT) involves treatments that seek to change behavior by modifying how people process self-relevant information [53]. The underlying assumption is that people have dysfunctional thoughts and that these thoughts lead them to behave in maladaptive ways that can be corrected with supportive counseling. The CBT approach seeks to challenge a person's assumptions and how they interpret events around them. The goal of CBT is to replace negative or self-defeating beliefs, thoughts, and feelings with positive and self-enhancing cognitions. Therapeutic treatments involving CBT typically train individuals to self-monitor and identify harmful thoughts as well as eliminate distorted cognitions (eg, unnecessary worry) that lead to dysfunctional behaviors. Core features include developing problem solving and coping strategies, anxiety reducing techniques, progressive relaxation, cognitive restructuring, activity scheduling, and other skills training approaches (eg, assertiveness) that reduce the influence of unhelpful thinking patterns. An added approach, behavioral activation (BA) [54] specifically addresses scheduling positive activities. We categorized grants as having cognitive and behavioral therapy components even if CBT or BA were not mentioned, but cognitive interventions falling under the CBT rubric were addressed.

Contingency Management

This generally refers to interventions that provide overt consequences, typically in the form of rewards, when behavior standards are met [55,56]. Apps that address contingency management often provide some form of monetary reward. Using rewards is most common in cases where app users are required to forego behavior, such as in treating different forms of addiction [57], or users want to promote a behavior, such as physical exercise among sedentary individuals [58] or individuals recovering from surgery [59]. The provision of financial incentives (ie, the carrot and stick approach in behavioral economic theory), suggests that human beings are rational agents that will deliberate consciously when faced with a decision, and if offered a valued incentive, change their behavior [60-64].

Education and Information

Apps in this category provide information and serve to educate patients about their disease, condition, or disorder. One of the primary aspects that characterize apps in this category is providing access to research on the disorder in a manner that is acceptable and understandable to a lay audience [65]. There may be a variety of reasons for providing this information, including increasing understanding of and countering misperceptions about the course of a disease [66-68], increasing beliefs about negative consequences of inaction or dysfunctional action [69,70] and increasing beliefs that taking proper action will be beneficial [70,71].

Enhanced Motivation

This merits an umbrella classification because it involves interventions that attempt to increase a user's inherent desire to behave in a manner that improves health behaviors. Included in this rubric is motivational interviewing (MI) [72-74] as well as a variety of other strategies. The focus of motivational enhancement is to increase a person's desire to align their behaviors with their primary values and reduce their ambivalence through a focus on the pursuit of goal directed activities. This approach assumes that people can articulate their thinking about goals and aspirations. Aligning their behavior with goals, priorities and values helps individuals reduce cognitive dissonance [75]. Thus, instead of focusing on changing or developing new cognitions, motivational approaches capitalize on and strengthen existing cognitions. Apps that focus on motivation often focus on helping users remember their overarching life goals and engage in goal setting activities.

Facilitating, Reminding, and Referring

These smartphone apps provide a means for users to connect with resource providers, primarily clinicians and testing facilities, and they address improving access to healthcare [76,77]. This can involve finding resources as well as providing

reminders and scheduling alerts to assist users in remembering appointments, when to take medication [78] and finding relevant resources they need [79,80].

Gaming and Gamification

This category of apps involves users in some form of imaginative (ie, virtual simulation) and competitive play [81-83]. The goal is to provide a basis for active learning and foster skill development. This can include stealth learning, where the user is not entirely aware of the game logic but acquires new cognitive skills while playing the game [84,85]. This is typically done irrespective of directly providing instruction. Rather, users are expected to learn through the experiences provided by the game's design. Games include a variety of formats including timed challenges, simulations, and exercises in which users earn points (ie, rewards) through correct responses.

Mindfulness Training

An alternative cognitive approach that encourages individuals to be introspective and pay attention to moment by moment experiences and heed one's inner voice [86-89]. The goal of mindfulness training in smartphone apps is to heighten users' awareness, encourage them to live in the moment and be aware of their surroundings in a more relaxed and contemplative state of mind [90]. Meditation is a core feature of mindfulness training, using deep relaxation and breathing exercises to accompany skills and strategies that target defeating negative thoughts and reducing temptations to overreact to nonessential stimuli.

Monitoring and Feedback

This a broad catchall for apps that collect biological data (from sources such as saliva, blood or urine), activity data (from telemetry or accelerometer devices that detect movement or location) or detect vital signs (involving sensors), as well as self-report data (from ecological momentary assessments). Apps that are linked with wireless wearable devices or subcutaneous embedded sensors [91-93] are also included. In part, the value of monitoring is that, without adequate information, errors in diagnosis and treatment may occur [94]. Thus, there is a clear benefit to the clinician who intends to understand how the patient responds or acts when not present in the clinic.

A second value of monitoring is that it creates opportunities for clinic staff to keep patients and other non-clinical parties informed and provide them feedback. Many apps address monitoring as well as provide the app user feedback about their performance, such as adherence to medication and prescribed health promotion routines based on the monitoring just received. Indeed, without monitoring, feedback would not be possible, so it became a corollary activity of these apps. Research has demonstrated the potential that positive feedback can have on health outcomes [95,96].

Norm Setting

These apps draw from the literature in which these norm setting approaches have been tried with adolescents [97] and college-age populations [98,99]. The hypothesis underlying these approaches is that many people overestimate the prevalence and acceptability of negative behaviors, such as alcohol and drug use. Interventions reduce risk by providing accurate information about the prevalence and unacceptability of behaviors among referent peer groups. Correcting misperceptions regarding social acceptability and prevalence also serves to modify expectancies about perceived benefits that underlie engaging in risky behavior.

Skill Training

Apps in this category tend to focus on stress and emotional self-regulation. These apps provide cues on how to respond to challenging situations. Apps often focus on pain, anxiety, stress and emotion management [100,101]. Skills taught may also include how to be assertive and refuse unwanted offers to participate in risky behaviors [102]. These apps walk users through different strategies they can apply when handling challenging situations. Examples of skills frequently taught include general life skills such as decision making, goal setting and communication skills.

Social Support and Social Networking

This category of apps provides ways to link a patient or app user to family and friends [103]. These apps may provide access to a network of individuals similar to the user who share similar health conditions and who can provide support and information. The implied effect by increasing support and including a user's social network is that there will be both an empathetic response and the potential for those in the network to provide some type of instrumental support or assistance. Apps that fall under this broad rubric are in part driven by the literature linking social support with better health outcomes [104,105].

Results

Based on the search criteria, a total of 1524 grants met the activity code requirements. After reading the abstract for each grant to verify that a smartphone intervention app was indeed proposed, and that enough detail was provided to categorize the intervention, the resulting qualifying pool included 397 grants in the final sample.

The most common activity codes represented were Research Project Grants (R01) (103 grants; 25.9%) and R43 Phase I Small Business Innovation Research (SBIR) grants (also 104 grants; 26.2%). Together SBIR (R43 and R44) and Small Business Technology Transfer (STTR) (R41 and R42) grants accounted for 162 (40.8%) of the grants. Two categories of exploratory grants, R21s (70 grants; 17.6%) and R34s (37 grants; 9.3%), were also prominent. R03 (10 grants), R15 (5 grants), R56 (5 grants), R61 (3 grants), R35 (1 grant) and R37 (1 grant) together accounted for 6.2% of the grants.

Table 1 summarizes the number of grants that met the selection criteria and shows the total first grant year dollars awarded for these grants for the years 2014 through 2018 (dollars are not adjusted for inflation.) Total funding for the first year of projects increased steadily and the percentage these grants represent doubled throughout the five-year period. While this represents a sizable investment in absolute dollars, funding for smartphone intervention apps was a miniscule part of overall NIH funding for the agencies that sponsored this research.

Table 1. Year of funding and one-year grant awards.

Year	Number of Grants	Total Dollars ($)	Average Grant ($)	Agency Funding, %
2014	60	16,783,541	279,726	0.06
2015	75	25,871,328	344,951	0.09
2016	69	26,493,472	383,963	0.09
2017	81	29,533,319	364,608	0.10
2018	112	39,428,610	352,041	0.12
Total	397	138,110,270	345,058	0.09

All NIH agencies reviewed, except for NHGRI, contributed projects to our sample. Table 2 presents the number of smartphone intervention app grants awarded by each NIH agency. NIA awarded a large number of grants (76). Several other agencies were also prolific in awarding grants for developing and testing smartphone intervention apps: NCI (47), NIMH (41), NIDDK (37), NIDA (31) and NHLBI (31). During any given year, the size of an agency's budget was not significantly associated with how many smartphone intervention app grants were funded (r=.018).

The next step involved coding each grant's abstract based on the 13 intervention categories. All grants could be coded based on single or multiple categories, should such evidence exist. In the 397 grant applications, the number of categories of intervention ranged from 1 to 5 with a mean of 1.99. Most grants proposed either one (139 grants, 35.0%) or two (155 grants, 39.0%) intervention approaches.

Table 2. Smartphone 1-year grant awards by NIH agency.

Agency	Grants	Grants Awarded, %	Total Funding ($)	Average Grant ($)
NIAAA	22	5.8	8,067,120	366,687
NIA	76	18.5	25,487,479	335,362
NIAID	6	1.8	2,509,169	418,195
NIAMS	4	0.6	862,077	215,519
NCI	46	11.8	16,363,863	355,736
NIDA	31	7.1	9,842,481	317,499
NIDCD	18	4.3	5,910,960	328,387
NIDCR	1	0.2	223,252	223,252
NIDDK	37	11.0	15,219,500	411,338
NIBIB	4	0.8	1,158,194	289,549
NIEHS	9	1.0	1,396,922	155,214
NEI	3	0.5	664,506	221,502
NIGMS	9	1.8	2,548,240	283,138
NICHD	15	3.4	4,657,284	310,486
NHLBI	31	11.1	15,283,691	493,022
NLM	3	0.6	777,482	259,161
NIMHD	21	3.7	5,144,671	244,984
NIMH	41	11.2	15,487,235	377,737
NINR	18	4.4	6,106,917	339,273
NINDS	2	0.3	399,227	199,614
Total	397	100.0	138,110,270	307,283

Table 3. Relative emphasis of intervention strategies in NIH-funded smartphone apps (N=397).

Content Category	Number of Apps	Total Apps, %	Rank
Artificial Intelligence	57	14.4	7
Bionic Adaptation	33	8.3	10
Cognitive and Behavioral Therapies	68	17.1	4
Contingency Management	24	6.0	11
Education and Information	85	21.4	3
Enhanced Motivation	50	12.6	9
Facilitating, Reminding and Referring	60	15.1	5
Gaming and Gamification	52	13.1	8
Mindfulness Training	18	4.5	12
Monitoring and Feedback	192	48.4	1
Norm Setting	7	1.8	13
Skills Training	85	21.4	2
Social Support and Social Networking	59	14.9	6

Table 3 summarizes the relative emphasis placed on the types of intervention approaches that were coded. By far, the most commonly included intervention approach provided monitoring and feedback to targeted individuals (48.4%). In 15.7% of cases, monitoring and feedback apps included some form of a wearable device that provided data that was transmitted through the smartphone. Also included were apps that used geo-sensors that could relay information about a user's location as well as self-report functions. Contingency management that would involve some form of monetary reward or incentive was much less frequently observed but was always tied to monitoring. Providing education and information (21.4%) and separately providing skills training (21.4%) were each represented in about one in five proposed apps. Apps that intended to provide cognitive and behavior therapies (17.1%), facilitating, reminding and referring (15.1%), social support and opportunities for joining social networks (14.9%), enhancing a user's motivation to improve their behaviors or comply with prescribed regimens (12.6%) and apps that proposed to use some form of game (13.1%) were also observed with some frequency. On the rare side were apps that focused on norm setting (1.8%) and mindfulness training (4.5%). Bionic adaptation apps that proposed linking smartphones to prosthetic devices were also relatively rare (8.3%).

Discussion

Principal Results

It is worth emphasizing that all abstracts represented proposed projects that had undergone rigorous peer review and been funded. NIH funds anywhere between 10% and 20% of submitted applications on an annual basis. Successfully competing for NIH funding therefore provides some assurance that the abstracts reviewed represent the state of the science.

Smartphone intervention apps are increasing in popularity among researchers being funded by NIH. The increase in numbers of grants funded between 2014 and 2018 attests to the belief in the potential for smartphone technology to be useful in health promotion and disease prevention. It is conceivable that this increase is due primarily to the increased technology capability that smartphones offer, their broad reach, ease of use by potential users, flexibility, and increasing ease of app programming.

The current review found that each NIH agency's research agenda was matched with possible smartphone intervention apps that addressed their programmatic goals. The behaviorally focused agencies (eg, NIAAA, NICHD, NIDA and NIMH) funded grants that emphasized psychosocial interventions. However, disease focused agencies also included funding for smartphone intervention app projects that addressed behavioral concerns, notably focusing on monitoring and feedback. The diversity of app categories and intervention strategies was interesting given that we identified 13 discrete intervention categories in comparison to the four categories suggested by Abraham and Michie [106]. Their categories included: (1) adherence and remote monitoring; (2) remote dissemination of information; (3) data collection and disease outbreak surveillance; and (4) diagnostic treatment and support. Their classification scheme was specific to physical activity and dietary interventions and not extended to a broad variety of smartphone apps.

There are yet many approaches to intervention that are currently less robustly represented in the current taxonomy. For example, smartphones have significant potential to deliver interventions that can augment participant engagement through gamification. In the grants reviewed, gamification (13.1%) was most often included with grants that also addressed skills training (34.6%), monitoring and feedback (26.9%), and education and information (25.0%). Less frequently it was coupled with cognitive and behavioral therapies (17.3%), contingency management (11.5%), social support and social networking (11.5%), artificial intelligence (7.7%), bionic adaptation (5.8%), enhanced motivation (7.7%), mindfulness training (1.9%) and facilitating, reminding and referring (1.9%). It was never

coupled with norm setting. This coupling of strategies may indicate the desire to utilize fun gaming logic with other active program ingredients. Conceivably, strategies could be more frequently coupled to more robustly utilize the gamification potential of smartphones.

Grant review has been noted as fostering conservatism in its outcomes [107], with relative ease in providing fundable scores to traditional topics and difficulty in assigning equally meritorious scores to novel approaches. When examined from this point of view, norm setting and mindfulness training were the least utilized approaches for interventions. Perhaps these may represent newer approaches for which researchers have not yet successfully competed for grant funding.

The creation of a categorization scheme is intended to provide a simplified structure by which topics covered can be grouped for analysis. NIH funded grants are truly multifarious, covering a wide array of diseases and conditions that are addressed through an equally diverse set of interventions. The categorization scheme presented reflects both our understanding of the underlying theoretical and practical assumptions investigators used when crafting their grant applications. The diversity of wording used in abstracts, even within a topic area, presents a challenge to anyone who would attempt to simplify an entire field. We note especially that there were many cases where abstracts were somewhat vague about the approach being proposed. Nonetheless, the resulting classification system provides an initial way in which intervention types may be characterized and meets the needs of our analysis.

Limitations

NIH grant summaries and abstracts presented in NIH Reporter are the only freely available descriptions of grant applications that can be accessed without making a freedom of information request. They are abbreviated descriptions that, under current guidelines, are limited to 30 lines of text. As a result, they often lack sufficient detail that would otherwise be found in a grant's research plan section. Because of this, it is likely that details about interventions in an abstract may be missing or underspecified. Nonetheless, abstracts provided enough information for the purpose of the current paper to construct a general picture of the state of the science in funded grants.

Our review was limited to examining funded grants and not the outcomes of these grants. Future research will need to examine the strategies proposed to determine if researchers' planned interventions were successful at achieving intended results.

Access

Our classification results are publicly available for download [108].

Conclusion

Our review of NIH-funded abstracts over a five-year timeframe suggests that there is growing interest in using smartphone apps as either standalone or auxiliary components of health promotion and disease, as well as injury prevention and treatment. While smartphone intervention apps being developed with NIH grants are no longer novel, there is still great opportunity for innovation and rigorous science to provide a body of evidence-based strategies.

Conflicts of Interest

None declared.

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Abbreviations

BA: behavioral activation
CBT: cognitive behavior therapy
eHealth: electronic health
GPS: global positioning system
mHealth: mobile health
MI: motivational interviewing
NEI: National Eye Institute
NHGRI: National Human Genome Research Institute
NHLBI: National Heart, Lung, and Blood Institute
NIA: National Institute on Aging
NIAAA: National Institute on Alcohol Abuse & Alcoholism
NIAID: National Institute of Allergy and Infectious Diseases
NIAMS: National Institute of Arthritis and Musculoskeletal and Skin Diseases
NIBIB: National Institute of Biomedical Imaging and Bioengineering
NICHD: National Institute of Child Health and Human Development
NIDA: National Institute on Drug Abuse
NIDCD: National Institute on Deafness and other Communication Disorders
NIDCR: National Institute of Dental and Craniofacial Research
NIDDK: National Institute of Diabetes and Digestive and Kidney Diseases
NIEHS: National Institute of Environmental and Health Sciences
NIGMS: National Institute of General Medicine Sciences
NIH: National Institutes of Health
NIMH: National Institute of Mental Health
NIMHD: National Institute on Minority Health and Health Disparities
NINDS: National Institute of Neurological Disorders and Stroke
NINR: National Institute of Nursing Research
NLM: National Library of Medicine
VoIP: Voice over Internet Protocol

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Original Paper

Nutrition-Related Mobile Apps in the China App Store: Assessment of Functionality and Quality

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Abstract

Background: There are an increasing number of mobile apps that provide dietary guidance to support a healthy lifestyle and disease management. However, the characteristics of these nutrition-related apps are not well analyzed.

Objective: This study aimed to evaluate the functionality and quality of nutrition-related apps in China.

Methods: Mobile apps providing dietary guidance were screened in the Chinese iOS and Android app stores in November 2017, using stepwise searching criteria. The first screening consisted of extracting information from the app descriptions. Apps that (1) were free, (2) contain information on diet and nutrition, and (3) were last updated after January 1, 2016, were downloaded for further analysis. Nutritional functionalities were determined according to the Chinese Dietary Guidelines framework. Market-related functionalities were developed from previous studies and tailored to downloaded apps. The quality of apps was assessed with the user version of the Mobile App Rating Scale (uMARS).

Results: Out of 628 dietary guidance apps screened, 44 were nutrition-related. Of these, guidance was provided on diet exclusively (11/44, 25%), fitness (17/44, 39%), disease management (11/44, 25%), or maternal health (5/44, 11%). Nutritional functionalities included nutritional information inquiry (40/44, 91%), nutrition education (35/44, 80%), food record (34/44, 77%), diet analysis (34/44, 77%), and personalized recipes (21/44, 48%). Dietary analysis and suggestions mainly focused on energy intake (33/44, 75%) and less on other factors such as dietary structure (10/44, 23%). Social communication functionalities were available in 42 apps (96%), user incentives were supported in 26 apps (59%), and intelligent recognition technology was available in 8 apps (18%). The median score for the quality of the 44 apps, as determined on a 5-point uMARS scale, was 3.6 (interquartile range 0.7).

Conclusions: Most nutrition-related apps are developed for health management rather than for dietary guidance exclusively. Although basic principles of energy balance are used, their nutritional functionality was relatively limited and not individualized. More efforts should be made to develop nutrition-related apps with evidence-based nutritional knowledge, comprehensive and personalized dietary guidance, and innovative technology.

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KEYWORDS

mobile phone; mobile apps; apps; nutrition; diet; food; behavior change

Introduction

Chronic and noncommunicable diseases (NCDs) are an increasing global health challenge. According to the World Health Organization (WHO), over 14 million deaths of people between the ages of 30 and 69 years are caused by NCDs each year, of which 85% occur in developing countries [1]. Dietary risks are now the leading risk factors for NCDs, accounting for 12.2% of disability-adjusted life years (DALYs) for men and 9.0% for women [2]. Since the 1990s, WHO has called on all countries to take action to promote healthy lifestyles to prevent NCDs [3,4]. Many countries including China have developed dietary guidelines and recommendations encouraging people to keep a healthy diet in their daily life [5]. However, overall dietary patterns around the world have not improved over the past decades [6]. There remain gaps in translating knowledge into actions and achieving behavior changes toward a healthy lifestyle.

With an ever-growing telecommunications industry, mobile technology is increasingly used for health education and assistance in behavior change around the globe and in China. The number of mobile-cellular subscriptions worldwide now exceeds the global population [7]. In China, there were 772 million internet users in 2017, 97.5% of whom were mobile phone users, and almost 4 million mobile apps users [8]. People use mobile apps for games, shopping, public services, and for health counseling. There is a growing interest in mobile health (mHealth) apps for health promotion and chronic diseases prevention, mostly because of their cost effectiveness and innovations in changing behaviors [9,10]. It has been suggested that mobile phone apps have the potential to provide evidence-based health information to help people make better decisions about diet and physical activity [11]. Compared with conventional approaches, nutrition apps perform better in increasing adherence to self-monitoring [12]. These apps can also push personalized educational articles or messages to the users [13].

Although there are an increasing number of mobile apps that provide dietary guidance, their features and quality have not been thoroughly studied. The objectives of this study were to review nutrition-related apps available in China and evaluate their nutritional and market-related functionalities with the ultimate aim of identifying gaps for further improvement.

Methods

Search Strategy

Apps for both the iOS and Android platforms were searched, and their inclusion ot exclusion was recorded according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow diagram [14]. We searched iOS apps through the iOS App Store and Android apps through Tencent MyApp, the number one Android app store in China [15]. We screened apps in the following app categories: Food & Drink and Health & Fitness in the iOS App Store and Food & Takeout, Activity & Fitness, and Health & Nourishment in the Tencent Android app store. To avoid omission, we also used search keywords as a supplementation. The following Chinese search keywords, extracted from the aims of apps searched in the above categories, were used in both platforms: nutrition, diet, food, food product, dietary, catering, calorie, energy, nourishing, obesity, slimming, weight loss, weight, fitness, activity, diabetes, hypertension, hyperlipidemia, and hyperglycemia. For each category and each keyword search result, the top 100 results were included for screening, which could be regarded as the most popular apps [16]. Apps in either Chinese or English were eligible.

Primary Analysis: Dietary Guidance App

The description and screenshots of each app were used for screening. The inclusion criteria for the primary analysis were the following: apps providing dietary advice (eg, diet plan or meal planning), food advice (eg, cooking process or characteristics of food), or nutrient information (eg, nutrient content, recommended intakes), all of which were considered to be apps providing dietary guidance. The following type of apps were excluded: (1) notebooks for dietary record without dietary analysis or nutritional advice; (2) apps for restaurant booking, take-away orders, or food sales; (3) camera apps to take pictures or videos; (4) apps designed for doctors, nurses, or nutritionists to conduct professional work; (5) educational apps for children to learn food-related words; and (6) apps providing paid offline health management service. Two pairs of reviewers screened all apps available in the iOS App Store and the Tencent Android app store on one day (November 10, 2017). The two reviewers in each group first screened independently and then reached a consensus on which apps were to be included in the primary analysis through discussion.

We extracted data on the primary purpose of each app (eg, guidance on cooking, diet, fitness, disease management, or maternal health), the developer, cost, size (MB), date of last update, number of reviews (ie, how many people rated the app), number of rating stars (0-5), number of downloads (available for Android apps only), and whether the app could be connected to peripheral devices (eg, watch or scale). For apps available on both platforms, data were extracted from the Tencent Android app store, as the iOS App Store does not display the number of downloads.

In-Depth Analysis: Nutrition-Related Apps

Of all apps providing dietary guidance, a subsample of apps that were more closely related to nutrition, relatively integrated, informative, and accessible were selected for download in order to study their design and functionality. To identify these nutrition-related apps, the following inclusion criteria were applied: (1) contained diet, food, and nutrient information; (2) last updated after January 1, 2016; and (3) can be used free of charge. The selected nutrition-related apps were downloaded and installed on iPhones and Android phones (Huawei and Xiaomi). Apps with different names or developers but the same content were regarded as duplicates.

The 2016 Chinese Dietary Guidelines put forward the concept of a balanced diet based on the principle of energy balance. According to this, energy metabolism includes two aspects: energy intake and energy expenditure. Energy balance means keeping energy intake equivalent to energy expenditure, which

is vital to maintain a healthy body weight. Dietary intake and physical activity are two important factors in energy intake and energy expenditure. Therefore, we must balance our diet and physical activity to keep a healthy body weight [5]. The Guidelines also suggested the following balanced dietary advice when providing dietary guidance: (1) "design balanced dietary recipes that follow the guidelines: keep food diversity; practice healthy cooking with recommended fat, salt, and sugar; and control energy intake to balance energy expenditure"; (2) "compare and evaluate meals by keeping rational dietary structure; that is, the intake of whole grains, deep color vegetables, milk, and beans is adequate; the energy resource from carbohydrate, fat, and protein is suitable; and the micronutrients reach the reference intakes"; and (3) "nutritional education and promotion follow the key points: promote the principle of balanced diet, encourage intake of recommended food, and suggest to eat less of some food" [5]. Accordingly, we defined five nutritional functionalities an app could provide to help follow those recommendations: (1) provide options to search for food and nutrient information; (2) record daily dietary intake using different record indicators such as weight, portion, and picture; (3) provide personalized and detailed recipes; (4) provide dietary analysis and advice, including energy-related analysis and analysis of dietary structure; and (5) push messages with nutrition-related educational materials.

We selected which technological features and market-related functionalities to study based on previous analyses and tailored this to the characteristics of our downloaded apps [17,18]. Market-related functionalities thus included social networks, interactivity, business model, intelligence technology, and connectivity to another smart device.

We recorded details of items of nutritional and market-related functionalities for each app and decided the subtotal functionalities as long as one of the detail items is positive (eg, there are four items under energy analysis functionality, including total energy intake, energy balance information, energy ratio of three meals, and energy source; if an app provided one or more of these items, it could be regarded as providing energy analysis).

Quality Assessment of the Nutrition-Related Apps

We selected the user version of the Mobile App Rating Scale (uMARS) to assess the scientific quality of the apps [19]. uMARS is adapted for users of MARS, which has been widely used to assess apps in different fields such as mental health and cardiovascular disease [18,20-21]. uMARS presents similar key sections as those in MARS but is relatively simple to use. Although we have two reviewers doing the evaluation, they evaluated each app representing common users rather than expert developers. So we chose uMARS instead MARS to assess the apps from the user perspective and avoid understanding bias by using the simpler uMARS version. uMARS is composed of four sections: engagement, functionality, aesthetics, and information. In the engagement section, reviewers could assess whether the app was fun, interesting, customizable, interactive, or had prompts (eg, alerts, messages, reminders, feedback, enabled sharing). In the functionality section, they could assess whether the app was functional, easy to learn, easy to navigate, flowed logically, and was designed gesturally. In the aesthetic section, reviewers could score the apps according to their graphic design, overall visual appeal, color scheme, and stylistic consistency. In the information section, reviewers could assess whether the app contained high-quality information (eg, text, feedback, measure, reference) from a credible source. Overall and section-specific scores ranged from 0 to 5. During the in-depth analysis, two reviewers used uMARS to assess the apps, first independently, then reaching a consensus on the scores through discussion.

Statistical Analyses

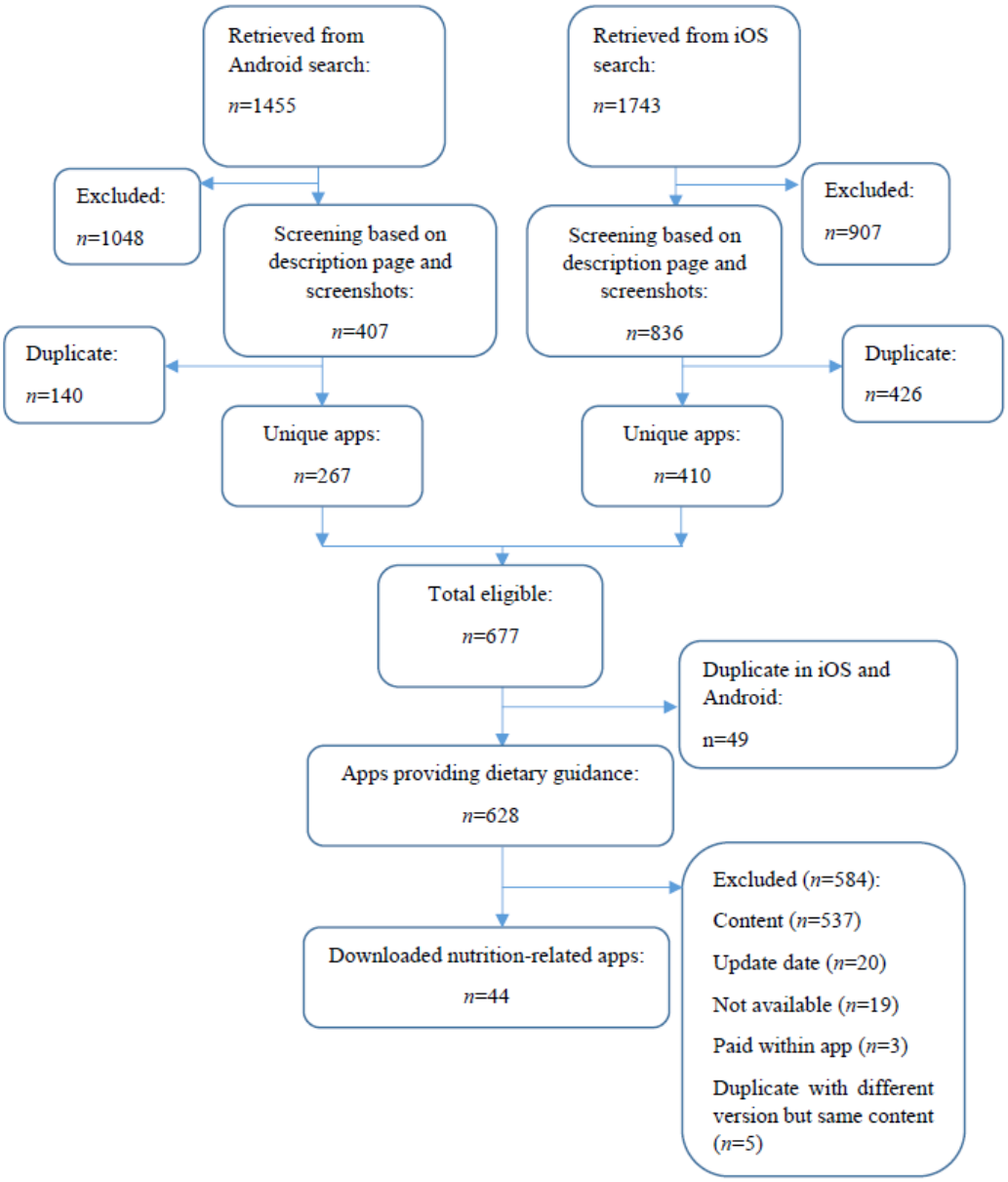
The number and percentage of apps with each nutritional and market-related functionality were calculated. Overall and section-specific uMARS scores were described by their maxima, minima, means, medians, and interquartile ranges. All data analyses were conducted using Stata 14.0 (StataCorp LLC).

Results

Search Results

Our search found a total of 3198 apps (Figure 1). After removing duplicates, 1243 apps were screened, and 628 apps met the inclusion criteria as apps providing dietary guidance (iOS n=361; Android n=267) and were included in the primary analysis. Of these, 44 met the inclusion criteria as nutrition-related apps and were downloaded for the in-depth analysis.

Figure 1. Flowchart of the selection of apps providing dietary guidance (for primary analysis) and nutrition-related apps (for in-depth analysis).



Characteristics of the Selected Apps

The majority of the 628 apps providing dietary guidance were for cooking (219/628, 34.9%), dietary guidance exclusively (114/628, 18.2%), fitness guidance (118/628, 18.8%), or disease management (95/628, 15.1%; Table 1). The apps released by individuals and corporations accounted for 42.8% (269/628) and 57.2% (359/628), respectively. User ratings with 4 and 5 scores accounted for 52.5% (330/628), while 46.8% (294/628) of the rating numbers have been rated by fewer than 100 users. Of the 267 apps with a download count available, over 50% had been downloaded more than 100,000 times (135/267, 50.1%). Most apps were last updated after January 1, 2016 (455/628, 72.5%) and were available for free (606/628, 96.5%).

Of the 44 downloaded nutrition-related apps, 41 (93%) were in the Chinese language and 42 (96%) were released by corporations; 11 (25%) were specifically aimed for dietary guidance while the rest were developed for other purposes, including fitness guidance (17/44, 39%), disease management (11/44, 25%), and maternal health (5/44, 11%). Most received a user rating of 4 or 5 stars (30/44, 68%), and of the 30 apps with a download count available, 26 (87%) had been downloaded more than 10,000 times (Table 1).

Table 1. Characteristics of the selected nutrition-related mobile apps.

Characteristics	All dietary guidance apps (n=628), n (%)	Downloaded nutrition-related apps (n=44), n (%)
Aim		
Cooking guidance	219 (35)	—
Dietary guidance	114 (18)	11 (25)
Fitness guidance	118 (19)	17 (39)
Disease management	95 (15)	11 (25)
Maternal health	54 (9)	5 (11)
Traditional Chinese medicine	28 (4)	—
Platform		
Android	267 (43)	30 (68)
iOS	361 (57)	14 (32)
Developer		
Individual developer	269 (43)	2 (4)
Corporation	359 (57)	42 (96)
User rating (stars)		
0	2 (0)	—
1	19 (3)	1 (2)
2	19 (3)	2 (5)
3	45 (7)	3 (7)
4	169 (27)	15 (34)
5	161 (26)	15 (34)
Missing	213 (34)	8 (18)
Number of ratings		
0-99	294 (47)	19 (43)
100-999	110 (17)	10 (23)
1000-9999	53 (8)	7 (16)
≥10000	16 (3)	0 (0)
Missing	155 (25)	8 (18)
Download count[a]		
0-99	18 (7)	1 (3)
100-999	42 (16)	1 (3)
1000-9999	72 (27)	2 (7)
10,000-99,999	51 (19)	9 (30)
100,000-999,999	56 (21)	10 (33)
≥1,000,000	28 (10)	7 (24)
Available for free		
Yes	606 (96)	44 (100)
No	22 (4)	—

[a]Download count for Android apps only (n=267 for all dietary guidance apps and n=30 for nutrition-related apps).

Nutritional Functionalities of the Nutrition-Related Apps

In the in-depth analysis of the 44 nutrition-related apps, 91% (40/44) contained food databases to support the nutritional information provided on various foods, some of which used standard graphical displays (eg, traffic lights, stars) to show how healthy the food was. Other nutritional functionalities included nutrition education (35/44, 80%), food records (34/44, 77%), dietary analysis (34/44, 77%), and recommended recipes (21/44, 48%; Table 2). Energy was the most frequently provided nutritional information (38/44, 86%), and energy intake analysis was also the most common dietary analysis function (33/44, 75%). Only 10 out of 44 (23%) apps gave feedback and advice on dietary structure. No apps provided an analysis of protein, fat, salt, or sugar intake.

Table 2. Nutritional functionalities of the nutrition-related apps (n=44).

Functionalities	n (%)
Searching food and nutrition information	40 (91)
Items available in database	
Prepackaged food	32 (73)
Single food	40 (91)
Recipe	32 (73)
Nutritional information available in database	
Energy	38 (86)
Energy-yielding nutrients	33 (75)
Vitamins and minerals	22 (50)
Fiber	27 (61)
Other information	
Graphical healthy rating	18 (41)
Glycemic index	6 (14)
Recording food intake	34 (77)
Quantified by weight (g)	31 (71)
Quantified by portion	27 (61)
Using graph to estimate amounts	9 (21)
Providing recommended recipes	21 (48)
With energy requirement	19 (43)
With specific food	21 (48)
With amount of food	18 (41)
With cooking guidance	12 (27)
Dietary analysis and suggestions	34 (77)
With energy analysis	33 (75)
Total energy	32 (73)
Energy balance (balance intake and expenditure)	19 (43)
Energy ratio of three meals	23 (52)
Energy source (ratio of three macronutrients)	15 (34)
With dietary structure analysis	10 (23)
Arrangement of food groups (eg, grains, vegetables, dairy products)	6 (14)
Estimates of micronutrients intake	7 (16)
Nutritional education	35 (80)
Independent education module	26 (59)
Intake of oil, salt, and sugar	6 (14)
Suitable dietary structure	4 (9)

Market-Related Functionalities of the Nutrition-Related Apps

In the in-depth analysis of the 44 nutrition-related apps, 41 (93%) enabled users to register and/or log in. Almost all apps (42/44, 96%) had at least one interaction function, such as communicating with other users or expert advisers. More than half of the apps (26/44, 59%) provided incentives such as sign-in points, badges, coupons, or rankings to improve retention of users. Eight (18%) apps offered intelligent recognition technology through identifying barcode, QR code, or photo. Eighteen (41%) apps could be connected to other health devices (eg, weighing scales, smart watches, wristbands, Bluetooth heart rate devices, blood glucose meters) (Table 3).

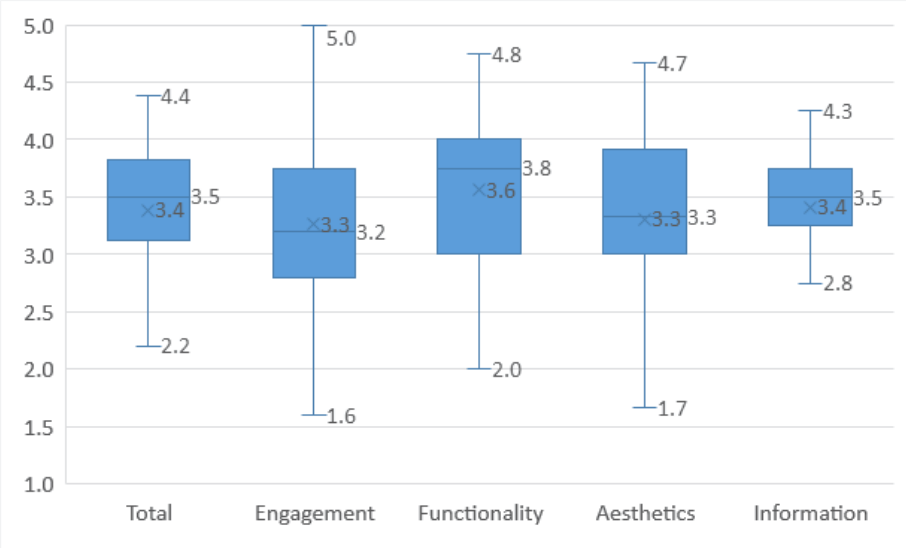
Table 3. Market-related functionalities of the nutrition-related apps (n=44).

Functionalities	n (%)
Enable user registration and/or log-in	41 (93)
Interaction function	42 (96)
Blog (in app)	25 (57)
Advice from officials and/or experts	25 (57)
Reminder (personalized)	41 (93)
Communicate among users	27 (61)
Offline activity	6 (14)
Sharing (out of app)	30 (68)
User incentive	26 (59)
Selling products	28 (64)
Advertisement	34 (77)
Crowd sourcing for data upload	2 (5)
Intelligent recognition technology	8 (18)
Barcode	4 (9)
QR code	4 (9)
Photo	1 (2)
Peripheral applications and/or devices	18 (41)

Quality of the Nutrition-Related Apps (uMARS Score)

On the uMARS scale, nearly 80% (35/44) of the nutrition-related apps scored higher than 3 out of 5. The highest score was 4.4, with 6 (14%) apps receiving scores above 4. Most apps had an overall and a section-specific score between 3 and 4 (Figure 2). The median for the overall score was 3.5 (interquartile range [IQR] 3.1, 3.8) and the medians for the section-specific scores were as follows (in descending order): functionality (3.8), information (3.5), aesthetics (3.3), and engagement (3.2). There was also a large variety in the scores; the total uMARS score ranged from 2.2 to 4.4, uMARS engagement score ranged from 1.6 to 5.0, uMARS functionality score ranged from 2.0 to 4.8, and uMARS aesthetics score from 1.7 to 4.7. The uMARS information score had the smallest range, from 2.8 to 4.3, but its maximum 4.3 score was the lowest among the four section scores.

Figure 2. The user version of the Mobile App Rating Scale overall and section-specific scores of the nutrition-related apps (n=44). Note: The bottom and top edge of the boxes represent the first and third quartiles; the lines within the boxes represent the medians; the crosses represent the means; and the ends of the bottom and top whiskers represent the minimum and maximum values.



Discussion

Principal Findings

This study reviewed the features of apps providing dietary guidance and nutrition-related apps in China from nutritional and marketing perspectives. It has shown that instead of providing dietary guidance exclusively, most nutrition-related apps were developed for broader health management, including fitness guidance, disease management, and maternal health, which reflects the important role of diets in overall health [22]. It has been demonstrated that adhering to the Chinese Dietary Guidelines reduces total mortality from chronic diseases in Chinese adults [23]. The Chinese Dietary Guidelines also provide practical advice to keeping a healthy diet through recipe design, dietary analysis, and nutritional education. Dietary analysis includes the analysis of the food structure, energy sources, protein sources, nutrient intake, and use of fat and salt [5]. To review the features of the nutrition-related apps, we defined the nutritional functionalities following the principle of the Chinese Dietary Guidelines.

From the in-depth analysis, we found that the most common functionality of nutrition-related apps was the search function for food and nutrient information, while the least common was the provision of recommended recipes. This could be due to the fact that in terms of information acquisition and technology, food databases and educational functions are relatively easy to deploy in apps [24], whereas recommended recipes need to be designed by professionals. However, the reliability of the information contained in the food databases and the number of foods covered have not been assessed in this study. As the developers are primarily corporate entities, there are no authoritative organizations to participate in the development, and the accuracy of apps is worthy of verification.

In addition to providing evidence-based dietary guidance, the app design and presentation are also important to attract users [25]. Some apps used graphical forms to represent whether a food was healthy or suitable for specific groups of users or used portion sizes or reference pictures to help users record the amount food they eat. Some apps also used visual charts to display their user's food and nutrition intake. If these kinds of visual presentations are evidence-based, they have the potential to reduce user burden and improve user experience [26]. As the graphical forms were dispersed in different functionality panels, we didn't sum up the graphical forms of the apps and analyze their relationship with uMARS. But our informal result showed that the apps with graphical healthy rating information had higher uMARS scores (mean 3.7) than the apps without graphical healthy rating information (mean 3.2).

When the apps provided dietary analyses, the most common functionality (in 75% of the nutrition-related apps) was to calculate energy, with more than 40% of the apps using their user's energy intake and energy expenditure to determine whether they eat too much. A likely reason for this is that the algorithm of energy balance (estimating energy intake through food and energy expenditure primarily through physical activity) is relatively easy to compute and visualize. However, a healthy diet also requires variety and dietary structure. The Dietary Guidelines for Chinese Residents recommend the consumption of at least 12 types of foods each day and more than 25 types per week. In terms of rational dietary structure, the Guidelines recommend amounts for five categories of food including cereals, animal foods, beans and nuts, vegetable and fruits, and foods only providing energy such as fats, sugars, and alcohol drinks [5]. A study has shown the positive effect of consuming a variety of foods on health [3]. However, very little information was available in the nutrition-related apps on dietary structure and the recommended intakes of different types of foods, fat, salt, and sugar. This was similar to the nutrition-related apps found in the United Kingdom [27].

In terms of app design and business operations, the nutrition-related apps provided most of the basic market

functionalities, including incentives, which are important to motivate users to keep using the app [28]. In addition, several apps were able to connect to other smart devices, and a few apps supported intelligent recognition technology. With the rapid development of intelligent technology around the world, there are great opportunities for their use in nutrition-related apps.

The quality of the nutrition-related apps was considered acceptable (median overall uMARS score 3.5) with the functionality section being the best rated of the four sections assessed in uMARS (median 3.8). But the uMARS scores also showed great variety in app quality. The total uMARS score ranged from 2.2 to 4.4, and the uMARS engagement score had the widest range, from 1.6 to 5.0. According to the developers of uMARS, the score represents 1-inadequate, 2-poor, 3-acceptable, 4-good, and 5-excellent. Therefore, there were a certain proportion of apps that had low quality. In addition, for the same app there could be variety in the four section scores, which may be covered by the total score. The reason for the variety of apps is likely that there is no professional benchmark or verification for the development and release of apps in the app stores, and the quality of apps is mainly related to the ability of the developers. We found a relatively narrow range of the uMARS information score, from 2.8 to 4.3. This, to some degree, may show the homogeneity of nutrition-related information provided in the app stores. It is important to note, however, that another grading scale may be needed to more specifically assess the quality of nutrition-related information from a nutritional perspective.

Limitations

First, our search was not exhaustive as we performed the search on only one day and only retrieved the first 100 results from each search. However, even though the apps included in our study may not be representative of the totality of apps providing dietary guidance or nutrition-related apps, the top 100 results could be regarded as the most popular apps [16]. So the functionalities reviewed here could reflect the main characteristics of the apps on the market. Second, unlike many analyses based on app markets, we did not account for download counts or user ratings (which could be used as indicators of app popularity). Our priority was to assess nutritional and market-related functionalities in order to inform future app development; therefore, all apps related to nutrition that were relatively active were included. Nevertheless, most of the nutrition-related apps we analyzed could be considered popular from a market perspective, as 85% of them have been downloaded over 10,000 times and almost 70% had a rating of 4 stars or more. Additionally, it may be inappropriate to judge the popularity of an app solely based on download counts or user ratings as both can be greatly influenced by promotional strategies of developers. In addition, download counts were not displayed in the iOS App Store. Third, even though the uMARS has been validated with 2 mHealth apps, its application to nutrition-related apps has yet to be validated, especially regarding the quality of the nutrition information.

Conclusion

This article gave a comprehensive overview of the nutrition-related apps available on the Chinese market. Using the Chinese Dietary Guidelines as a framework to define nutritional functionalities, we found that although basic energy analysis and visual presentations were available in some apps, a limited number of apps provided comprehensive functionalities to help users adhere to dietary guidelines. On the other hand, the commercial functions of those nutrition-related apps are generally complete and some innovative technologies were attempted. The quality of the nutrition-related apps, as evaluated by uMARS, was fair but showed great variety. To improve the quality of nutrition-related apps, more effort should be made to equip them with evidence-based nutritional knowledge, comprehensive and personalized dietary guidance, and innovative technology.

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Authors' Contributions

PZ and YL designed the study. YL, JD, YW, and CT were responsible for the app search, analysis, and data collection. YL and JD drafted the manuscript. All authors contributed to the review and editing of the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

DALY: disability-adjusted life year
IQR: interquartile range
NCD: noncommunicable disease
uMARS: user version of the Mobile App Rating Scale
WHO: World Health Organization

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Original Paper

Attitudes, Beliefs, and Willingness Toward the Use of mHealth Tools for Medication Adherence in the Florida mHealth Adherence Project for People Living With HIV (FL-mAPP): Pilot Questionnaire Study

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Abstract

Background: Antiretroviral (ART) adherence among people living with HIV (PLWH) continues to be a challenge despite advances in HIV prevention and treatment. Mobile health (mHealth) interventions are increasingly deployed as tools for ART adherence. However, little is known about the uptake and attitudes toward commercially available, biprogrammatic mobile apps (ie, designed for both smartphone and short message service [SMS] messaging) among demographically diverse PLWH.

Objectives: The Florida mHealth Adherence Project for PLWH (FL-mAPP) is an innovative pilot study that aimed to determine the acceptability of a commercially available, biprogrammatic mHealth intervention platform to ensure medication adherence and gauge the current attitudes of PLWH toward current and future mHealth apps.

Methods: A predeveloped, commercially available, biprogrammatic mHealth platform (Care4Today Mobile Health Manager, Johnson & Johnson, New Brunswick, NJ) was deployed, with self-reported ART adherence recorded in the app and paper survey at both short term (30-day) or long-term (90-day) follow-ups. Consented participants completed baseline surveys on sociodemographics and attitudes, beliefs, and willingness toward the use of mHealth interventions for HIV care using a 5-point Likert scale. Chi-square tests and multivariate logistic regression analyses identified correlations with successful uptake of the mHealth platform.

Results: Among 132 PLWH, 66% (n=87) initially agreed to use the mHealth platform, of which 54% (n=47) successfully connected to the platform. Of the 87 agreeing to use the mHealth platform, we found an approximate 2:1 ratio of persons agreeing to try the smartphone app (n=59) versus the SMS text messages (n=28). Factors correlating with mHealth uptake were above high school level education (adjusted odds ratio 2.65; *P*=.05), confidence that a clinical staff member would assist with mHealth

app use (adjusted odds ratio 2.92, *P*=.048), belief that PLWH would use such an mHealth app (adjusted odds ratio 2.89; *P*=.02), and ownership of a smartphone in contrast to a "flip-phone" model (adjusted odds ratio 2.80; *P*=.05). Of the sample, 70.2% (n=92) reported daily interest in receiving medication adherence reminders via an app (80.4% users versus 64.7% nonusers), although not significantly different among the user groups (*P*=.06). In addition, 34.8% (n=16) of mHealth users reported a theoretical "daily" interest and 68.2% (n=58) of non-mHealth users reported no interest in using an mHealth app for potentially tracking alcohol or drug intake (*P*=.002).

Conclusions: This commercially available, biprogrammatic mHealth platform showed feasibility and efficacy for enhanced ART and medication adherence within public health clinics and successfully included older age groups. Successful use of the platform among demographically diverse PLWH is important for HIV implementation science and promising for uptake on a larger scale.

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KEYWORDS

mHealth; mobile phone app; app; HIV; antiretroviral therapy adherence; persons living with HIV; HIV care continuum; digital health; medication adherence; mobile health

Introduction

Antiretroviral therapy (ART) adherence is a recognized cornerstone in suppressing HIV viral load (VL) and thus achieving positive health outcomes in people living with HIV (PLWH) and their partners. As per the 2020 Joint United Nations Programme on HIV/AIDS target, 90% of all people with diagnosed HIV infection will receive sustained antiretroviral therapy (ART) and 90% of all people receiving antiretroviral therapy will have viral suppression [1]. As PLWH successfully complete longer lifespans, it becomes critical to optimize medication adherence for cardiovascular disease, cancer, diabetes mellitus, and hypertension in addition to overall health outcomes for PLWH, especially with the increasing overall pill burden and increasing requirement for care management by multispecialty health care providers.

In the United States, 70% of PLWH were estimated to have HIV VL suppression (defined as <200 copies/mL) when linked to care, as per the Centers for Disease Control and Prevention Medical Monitoring Project 2016 report [2]. ART adherence continues to be a challenge in the HIV treatment cascade, especially among those with poor social support, increased stigma, comorbid alcohol and substance use, and mental health challenges, all of which often are exacerbated by the challenges of poverty, housing and food instability, and inadequate transportation [3,4]. Optimal ART adherence is needed to help reduce the number of new HIV infections, improve health outcomes, and reduce health disparities [5,6]. Although much progress has been made in HIV prevention in the United States [7], and the ability of mobile phone technologies to provide medication reminders and further engage PLWH in care has increased [8-11], little is known about the implementation of pre-existing mHealth tools in routine HIV treatment and prevention beyond the initial development or pilot stages.

No previous studies have explored the merits of a widely commercially available predeveloped app to lay the foundation for wide-scale implementation of this evidence-based practice. Thus, within the field of HIV medication adherence, there is a great need to expand beyond the translational, iterative T1 and T2 developmental app stage focused on subgroups of PLWH and into broader implementation of predeveloped mobile health (mHealth) apps such as in a state-wide initiative that is inclusive of a diverse and potentially older population.

mHealth can best be thought of as modern mobile phone platforms that facilitate health interventions through a variety of mobile phone apps. Mechanisms for increasing adherence to mHealth platforms include not only smartphone apps but also interactive voice response reminders and short message service (SMS; eg, digital text messages) [12-20]. Much of the previous work has focused on the development and acceptability of mHealth platforms from the patient's perspective for HIV care linkage and prevention using both iterative models and the information systems research framework [10,13,16,18-24], mostly with at-risk populations such as men who have sex with men (MSM) [25,26] or youth [27,28]. There is scant literature on the acceptability of a ready-made, commercially available mHealth platform for addressing ART adherence. Further, there are scant data on PLWH aged above 55 years who may not be as likely to own smartphones and may have limitations to data and internet access [29,30]. Therefore, today's inclusive mHealth platforms also need to include SMS messaging (texting) in partnership with apps that require internet access in order to reach vulnerable populations, known as "biprogrammatic"; we define this term as an app program that functions with both smartphone and texting-only (ie, feature or "flip" phone) platforms. Little is currently known about biprogrammatic platforms and how SMS text interventions are useful in this paradigm, as results have been previously mixed [8,11,15,31-42]. To our knowledge, no study has offered a previously developed, free-of-charge, commercially available mHealth platform that seeks to improve both ART (HIV specific) and other medication adherence (ie, diabetes, mental health, or blood pressure medications) among diverse PLWH with multiple health comorbidities.

Methods

Overview

The Florida mHealth Adherence Project for PLWH (FL-mAPP) is an innovative, interventional, clinical pilot study to determine the acceptability and uptake of a mobile phone mHealth intervention platform that incorporates biprogrammatic formats

(ie, smartphone and SMS messaging platforms) among PLWH in public health HIV care clinics. More specifically, the study aimed to identify the willingness of PLWH enrolled in public health HIV specialty care clinics to try an existing biprogrammatic mHealth platform called Care4Today [43]; to compare characteristics between self-selecting mHealth users and nonusers, including differences in demographic characteristics, mobile phone type, baseline ART adherence, HIV VL suppression, and attitudes and beliefs; and to identify PLWH preferences for different types of future mHealth interventions.

Study Design

This study was a cross-sectional analysis of baseline data from a longitudinal mHealth study that offered an ART adherence mHealth intervention and obtained data at baseline (day 0), interim (day 30), and final (day 90) follow-up from self-reported survey responses and queried mHealth app responses. This paper describes baseline and initial update data only, with interim and final data reported elsewhere [44].

Recruitment

A convenience sample of PLWH in Florida was recruited from three HIV longitudinal care clinics in the Florida Department of Health from 2015 to 2016. Persons eligible to participate in the study were current patients at one of the participating public health clinics that presented within a 4-week window of a scheduled HIV VL test per usual care. Participant inclusion criteria were as follows: confirmed HIV-positive status, on currently prescribed ART, age≥18 years, fluency in written and spoken English, and owning an individual smartphone (eg, iPhone or Android) or feature phone that was able to receive and send text messages. Participant exclusion criteria were as follows: sharing their phone with another person, unwilling or unable to afford any potential fees for receiving and replying to text messages, or visually impaired to the extent that precluded use of the mHealth platform.

Participant recruitment strategies at the three clinics included print flyers in the lobby and clinic waiting areas as well as targeted preclinic visit screening notices to providers for patients who qualified by chart review. Eligible participants were referred by the provider to research staff and then offered an opportunity to participate with signed informed consent.

Both the Institutional Review Boards of the Florida Department of Health and the University of Florida approved the study. Participants were provided a US $10 incentive at baseline and at each of two follow-up intervals for a maximum of US $30 over the study duration.

Data Collection

After enrollment, all participants completed an initial paper-based survey of 49 questions to capture the demographic, behavioral, clinical, and attitudinal characteristics of PLWH regarding mHealth interventions, informed by previous research on feasibility and acceptability of adopting technology [45,46]. Question items included those on baseline demographics, general items, substance use (ie, tobacco, alcohol, injection drug use, cocaine, heroin, and methamphetamine), and baseline Patient Health Questionnaire-2 screening (to assess comorbid mental health barriers to adherence, and current pill burden). The survey also queried current cellular phone use, current mHealth app use, and attitudes toward the perceived use and utility of mHealth apps for various health-related issues. Specifically, participants were asked to what extent one agreed about the general use of mHealth interventions to manage health and respond using a 5-point Likert scale. The response options of “agree” or “strongly agree” options were combined into one category “agree,” whereas the “neutral,” “disagree,” and “strongly disagree” options were combined into the category “disagree” for statistical facilitation to fit the multivariate model. Participants were also asked how often one would use a free phone app to track alcohol and drug use behavior; communicate with a doctor or clinic; remember to take medication; engage in social networking with other people who live with HIV; connect with family about medications; and track exercise, diet, and weight. Self-reported ART adherence at baseline, 30 days, and 90 days was measured by a follow-up 13-question paper survey item and compared to the corresponding patient self-recorded mobile app responses. ART adherence data available through the app were later presented to the medical provider at the 90-day mark to evaluate if they were consistent with the HIV VLs. Patients were considered adherent to ART if they reported missing less than 2 days of doses in the previous month.

After completion of the baseline survey, research assistants provided information about a specific, existing, commercially available mHealth platform designed to improve medication adherence for multiple health conditions including HIV (Care4Today Mobile Health Manager, Johnson & Johnson, New Brunswick, NJ) [43]. This mHealth interface, biprogrammatic with smartphone (iPhone or Android) and text messaging SMS interfaces, was previously developed commercially and catalogs preprogrammed visual, written, and photographed descriptions of nearly any available medication in the United States to be selected by the user. Once registered, the app cues the participant with visual and optional sound reminders at the selected time of day when the medication is due. The app also records patients’ self-entered dosage completion logs. Such logs are securely stored and available for future retrieval and review by both patients and providers with the patient's consent. The research team kept close logs of participants and was able to download reports directly from the app with patient consent. Participants could also choose to use a more limited mHealth SMS text intervention that would just send written reminders at the time that ART was due, to which the patient could reply with a text message stating “1” to indicate medication completion.

No additional monetary incentive was provided above baseline for participants who agreed to use or decline this mHealth platform. Participants self-selected one of three groups: no mHealth intervention, SMS text reminders, or smartphone app reminders. Research assistants helped participants create their accounts and download and configure the app (Figures 1 and 2).

Figure 1. Representative user-facing image for the mobile health app visual for antiretroviral medications as seen in the smartphone program (source: Care4Today Mobile Health Manager, Johnson & Johnson, New Brunswick, NJ).

Figure 2. User-facing mobile health app instructions for the antiretroviral app reminder system (source: Care4Today Mobile Health Manager, Johnson & Johnson, New Brunswick, NJ).

For those who agreed to try the mHealth intervention, the research team tracked whether the participants ever used (responded to text or entered adherence information) the mHealth intervention. For this analysis, “mHealth users” were defined as participants who had at least one recorded interaction with the mHealth platform. “ mHealth non-users” were defined as those who either declined to try the mHealth platform or agreed to try but never accessed the mHealth platform after enrollment.

Baseline HIV VL level and CD4+ T-cell count were recorded as the most recent value recorded within 30 days of enrollment and were logged at day 30 (short term) and day 90 (long term). HIV viral suppression was defined as <200 copies/mL, per the current US Centers for Disease Control and Prevention, Division of HIV/AIDS, epidemiological definition [2].

Statistical Analysis

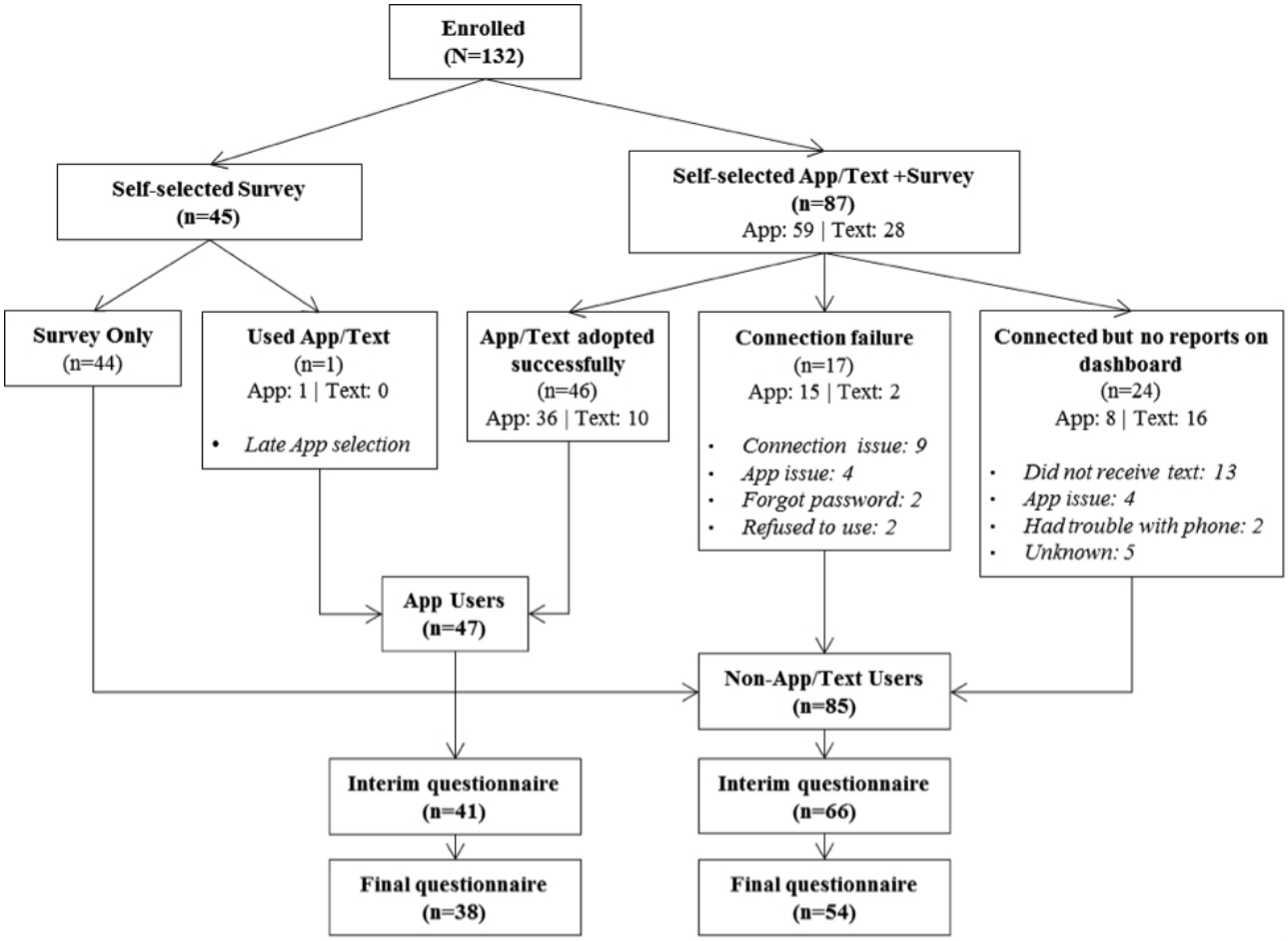
We analyzed baseline data on mHealth user demographics to understand attitudes, beliefs, and willingness to use a biprogrammatic mHealth tool among PLWH in a public health clinic setting. Sociodemographic and attitudinal variables among mHealth users and nonusers were compared using Chi-square tests, with statistical significance set at $P<.05$. A multivariable logistic regression analysis (ie, multivariate analysis) was conducted to identify independent factors associated with successful use of the mHealth platform, as the outcome was binary. Any variables associated with app use in the bivariate analysis with $P<.20$ was included in the multivariable model to maintain inclusivity of variables in a small sample size in a nonimputed model. Missing data were rare, as evidenced in the table format. Results of overall interest in mHealth and preferences for specific types of mobile apps are presented descriptively. All analyses were performed in SAS software, version 9.4 [47].

Results

Participants

Among the 132 PLWH enrolled, 66% (n=87) initially agreed to use the mHealth platform, of which 54% (n=47) successfully connected to the platform at least once (Figure 3). Nearly 34% of the sample (n=45) self-selected the survey only and did not state a desire to try the app. Unsuccessful attempts to use the app were due to either a reported connection failure (n=17, 20%) or inability or unwillingness to input personal data on adherence (n=24, 28%). Of the 87 PLWH agreeing to use the mHealth platform, we found an approximate 2:1 ratio of persons agreeing to try the smartphone app (n=59) versus the SMS text messages (n=28). Reanalysis of the data into three categories to identify participants who initially had agreed to use the app but who did not ultimately access the app showed no statistical difference in terms of demographics or other covariables: app users (n=45), nonusers (n=43), and those who initially agreed to use the app but ultimately did not use it (n=38). The refusal rate to participate in the study was estimated to be approximately 30% clinic wide and was thought to be mainly due to language barrier or anticipated difficulty with study requirements and not adverse feelings toward technology. However, interested participants who were ultimately referred for a face-to-face visit with the study team had a refusal rate of <5%, likely due to the positive dynamic and cultivated trust between providers, research staff, and clinic patients as well as the noninvasive nature of the study. One participant who had initially declined to use any mHealth option subsequently requested to use the mHealth platform and was reassigned to the mHealth user group, likely due to renewed interest in the app at a later date after the initial educational session.

Figure 3. Initial uptake and retention of mobile health users in the Florida mHealth Adherence Project for people living with HIV, 2015-2016 (N=132).



User Demographics

Baseline demographics of the sample size of 132 participants were characterized as follows: A majority were men (n=88, 66.7%), were of African American ethnicity (n=79, 60.3%), completed a high school education (n=55, 41.7%), were single/never married (n=88, 66.7%), and were ≥50 years of age (n=58, 46.0%). The average age was 45.8 years (range: 22-69 years). Gender identity, including transgendered identity, but not sexual orientation, was recorded, which is a limitation discussed below.

The majority of participants had a suppressed baseline HIV VL (n=91, 71.0%), with a CD4+ T-cell count > 500 cells/μL (n=69, 54.3%), although by survey, 44% of participants reported <95% ART adherence in the previous month and 28% had detectable HIV viremia at the last laboratory draw.

Importantly, mHealth users were significantly more likely than non-mHealth users to have higher than high school education (57.5% versus 32.9%, *P*=.02) and to already own a smartphone (87.2% versus 67.9%, *P*=.01). However, there were no significant differences in app users and nonusers in terms of age, gender, race, marital status, self-reported ART adherence, HIV viral suppression, and CD4+ T-cell count (Table 1).

Evaluation Outcomes: Attitudes and Beliefs

Attitudes toward mHealth app uptake at baseline were significantly correlated with the response “having the need to use the app” (*P*=.002), which was defined as the patient’s perception of having difficulty with medication adherence and needing additional support, and the perception of receiving assistance with app navigation (*P*=.04). Peer input or influence, receiving timely medication reminders, and the user-friendly aspect of the app were not significant at baseline for this study group (Table 2).

A multivariate analysis revealed four demographic factors that were significantly correlated with mHealth use: having higher than high school education (adjusted odds ratio [AOR] 2.65; *P*=.05), having confidence that a clinical staff member would assist with mHealth app use (AOR 2.92, *P*=.048), belief that PLWH would use such an mHealth app (AOR 2.89; *P*=.02), and ownership of a smart phone in contrast to a “flip-phone” model (AOR 2.80; *P*=.05; Table 3).

Table 1. Baseline characteristics of mobile health platform users and nonusers among people living with HIV/AIDS (PLWH) in the Florida mHealth Adherence Project for PLWH Study, 2015-2016.

Characteristics	Total[a] (N=132)	mHealth[b] users (n=47)	mHealth nonusers (n=85)	*P* value
Age (years), mean (SD)				.43
18-29	14 (11.1)	3 (6.7)	11 (13.6)	
30-39	24 (19.0)	11 (24.4)	13 (16.0)	
40-49	30 (23.8)	12 (26.7)	18 (22.2)	
≥50	58 (46.0)	19 (42.2)	39 (48.1)	
Gender at birth				.37
Male	88 (66.7)	29 (61.7)	59 (69.4)	
Female	44 (33.3)	18 (38.3)	26 (30.6)	
Race/ethnicity				.15
Hispanic	23 (17.6)	13 (27.7)	10 (11.9)	
White, non-Hispanic	23 (17.6)	8 (17.0)	15 (17.6)	
Black, non-Hispanic	79 (60.3)	24 (51.1)	55 (65.5)	
Other, non-Hispanic	6 (4.6)	2 (4.3)	4 (4.8)	
Education				.02[c]
Less than high school	41 (31.1)	11 (23.4)	30 (35.3)	
High school graduate or GED[d]	36 (27.3)	9 (19.1)	27 (31.8)	
Higher than high school	55 (41.7)	27 (57.5)	28 (32.9)	
Marital status				.11
Single/never married	88 (66.7)	26 (55.3)	62 (72.9)	
Divorced/widowed/separated	26 (19.7)	13 (27.7)	13 (15.3)	
Married/living with a long-term partner	18 (13.6)	8 (17.0)	10 (11.8)	
Adherence to antiretroviral therapy				.70
<95%	57 (44.5)	19 (42.2)	38 (45.8)	
≥95%	71 (55.5)	26 (57.8)	45 (54.2)	
HIV viral load suppression (≤200 copies/mL)				.15
Yes	91 (71.0)	37 (78.7)	54 (66.7)	
No	37 (28.9)	10 (21.3)	27 (33.3)	
CD4+ T-cell count (cells/µL)				.94
0-200	15 (11.8)	6 (13.0)	9 (11.1)	
201-500	43 (33.9)	15 (32.6)	28 (34.6)	
>500	69 (54.3)	25 (54.4)	44 (54.3)	
Ownership of a smart phone				.01[c]
Yes	98 (74.8)	41 (87.2)	57 (67.9)	
No	33 (25.2)	6 (12.8)	27 (32.1)	

[a]N does not always total to 132 due to missing data for some items.

[b]mHealth: mobile health.

[c]*P* values are significant (<.05).

[d]GED: General Educational Development.

Table 2. Participants' attitudes at baseline, regarding utility of a mobile health app for people living with HIV/AIDS (PLWH) in the Florida mHealth Adherence Project for PLWH Study, 2015-2016.

Attitudinal items	Total[a] (N=132)	mHealth[b] users (n=47)	mHealth nonusers (n=85)	*P* value
Mobile app could help me remember to take my medications				.15
Agree	112 (85.5)	43 (91.5)	69 (82.1)	
Not agree	19 (14.5)	4 (8.5)	15 (17.9)	
Too much effort to learn to use a new app				.17
Agree	25 (19.1)	6 (12.8)	19 (22.6)	
Not agree	106 (80.9)	41 (87.2)	65 (77.4)	
Most of my friends would agree that I should try a mobile app for medication reminders				.34
Agree	68 (51.9)	27 (57.4)	41 (48.8)	
Not agree	63 (48.1)	20 (42.6)	43 (51.2)	
Someone at the clinic will help to set up the app if I have difficulties				.04[c]
Agree	101 (77.1)	41 (87.2)	60 (71.4)	
Not agree	30 (22.9)	6 (12.8)	24 (28.6)	
The app must be fun to use				.52
Agree	69 (52.7)	23 (48.9)	46 (54.8)	
Not agree	62 (47.3)	24 (51.1)	38 (45.2)	
Will use app only if it is free of charge				.11
Agree	89 (67.9)	36 (76.6)	53 (63.1)	
Not agree	42 (32.1)	11 (23.4)	31 (36.9)	
I feel like I will need to use the app				.002[c]
Agree	76 (58.5)	36 (76.6)	40 (48.2)	
Not agree	54 (41.5)	11 (23.4)	43 (51.8)	

[a]N does not always total to 132 due to missing data for some items.

[b]mHealth: mobile health.

[c]*P* values are significant (<.05).

Table 3. Multivariate correlations between baseline characteristics and adoption of the mobile health platform to improve antiretroviral therapy adherence among people living with HIV/AIDS (PLWH) by multivariable analysis in the Florida mHealth Adherence Project for PLWH Study, 2015-2016 (N=132).

Characteristics	Unadjusted odds ratio (95% CI)	*P* value	Adjusted odds ratio (95% CI)	*P* value
Education (ref: less than high school)				
High school graduate or GED[a]	0.91 (0.33-2.53)	.86	0.85 (0.29-2.52)	.76
Higher than high school	2.63 (1.1-6.28)	.03	2.65 (1.02-6.86)	.045[b]
Ownership of a smart phone (ref: no)				
Yes	3.24 (1.23-8.55)	.02	2.80 (1.00-7.84)	.05[b]
Someone at the clinic will help to set up the app if I have difficulties (ref: disagree)				
Agree	2.73 (1.03-7.27)	.04	2.92 (1.01-8.41)	.048[b]
I feel like I will need to use the app (ref: disagree)				
Agree	3.52 (1.58-7.84)	.002	2.89 (1.23-6.81)	.02[b]

[a]GED: General Educational Development.

[b]*P* values are significant (<.05).

Interest in Future Mobile Health Tools

Use of an mHealth app for potentially tracking alcohol or drug use received support from 34.8% (n=16) of mHealth users reporting a theoretical "daily" interest and 68.2% (n=58) of non-mHealth users reporting no interest in such an app (*P*=.002). Overall, 18.3% (n=24) of the study sample expressed occasional interest (Table 4). Interestingly, 70.2% (n=92) reported daily interest in receiving medication adherence reminders via the app (80.4% versus 64.7%), although the value was not significantly different among the user groups (*P*=.06; Table 4).

Attitudes toward social networking with other PLWH were mixed, with overall responses indicating "never/rarely" for this function (n=53, 40.8%) and with nonusers decidedly against such an option (49.4% nonusers versus 24.4% users; *P*=.02).

Table 4. Baseline behavioral intent regarding use of a mobile health platform to enhance other forms of health promotion among people living with HIV/AIDS (PLWH) enrolled in the Florida mHealth Adherence Project for PLWH Study, 2015-2016 (N=132). The responses are to the question, "If available and free, how often would you use a phone app to help you?"

Intention item	Total[a] (N=132)	mHealth users (n=47)	mHealth nonusers (n=85)	*P* value
Track changes in mood and emotions				.45
Never/rarely	45 (34.6)	16 (35.6)	29 (34.2)	
Occasionally	36 (27.7)	15 (33.3)	21 (24.7)	
Daily	49 (37.7)	14 (31.1)	35 (41.2)	
Improve health by providing tips				.72
Never/rarely	22 (16.9)	7 (15.2)	15 (17.9)	
Occasionally	52 (40.0)	17 (37.0)	35 (41.7)	
Daily	56 (43.1)	22 (47.8)	34 (40.5)	
Track alcohol or drug use behavior				.002[b]
Never/rarely	75 (57.3)	17 (37.0)	58 (68.2)	
Occasionally	24 (18.3)	13 (28.3)	11 (12.9)	
Daily	32 (24.4)	16 (34.8)	16 (18.8)	
Communicate with doctor or clinic				.80
Never/rarely	35 (26.9)	13 (28.3)	22 (26.2)	
Occasionally	53 (40.8)	17 (37.0)	36 (42.9)	
Daily	42 (32.3)	16 (34.8)	26 (31.0)	
Remember to take medication				.06
Never/rarely	26 (19.8)	4 (8.7)	22 (25.9)	
Occasionally	13 (9.9)	5 (10.9)	8 (9.4)	
Daily	92 (70.2)	37 (80.4)	55 (64.7)	
Engage in social networking with other people who live with HIV				.02[b]
Never/rarely	53 (40.8)	11 (24.4)	42 (49.4)	
Occasionally	38 (29.2)	17 (37.8)	21 (24.7)	
Daily	39 (30.0)	17 (37.8)	22 (25.9)	
Connect with family about medications				.62
Never/rarely	83 (63.4)	27 (58.7)	56 (65.9)	
Occasionally	23 (17.6)	10 (21.7)	13 (15.3)	
Daily	25 (19.1)	9 (19.6)	16 (18.8)	
Track exercise, diet, or weight				.11
Never/rarely	35 (26.7)	8 (17.4)	27 (31.8)	
Occasionally	37 (28.2)	12 (26.1)	25 (29.4)	
Daily	59 (45.0)	26 (56.5)	33 (38.8)	

[a]N does not always total to 132 due to missing data for some items.

[b]*P* values are significant (<.05).

Interest in mHealth tools for tracking changes in mood/emotion, providing health tips, connecting with family, or tracking changes in exercise/diet were mixed and not significant between users and nonusers of the app (Table 4).

Discussion

Principal Results

In this study of Florida PLWH recruited from public health clinics, we found that approximately one-third of the persons who were counseled about the opportunity to try an existing mHealth app platform were successful baseline users. mHealth users were significantly more likely to have higher than high school education and own a smart phone. However, successful mHealth use was not significantly associated with age, sex at birth, ethnicity, marital status, baseline ART adherence, baseline HIV VL suppression status, or baseline CD4+ T-cell count, perhaps because these were similarly distributed at baseline.

PLWH baseline attitudes most strongly associated with mHealth use were related to the perceived need to use such an app and perceptions that someone in the clinic would assist them. This finding shows that self-motivation and clinical staff influence can encourage and maintain use of adherence reminders. Even with an older cohort than that described in the literature, age did not make a difference, as expected, probably because of the biprogrammatic interface that allowed for flip phone text use. This has important implications in future mHealth app development, as it highlights the importance of including technical advances for older adults. The biprogrammatic aspect of incorporating SMS/text messaging importantly captured additional participants; if this factor made any clinical impact, further analysis will be needed. In the context of previous studies, these findings are important and inclusive of a diverse cohort of PLWH by age, self-identification, and demographics, whereas previous literature has focused on app development and uptake among specific groups of persons (ie, MSM or youth) and often resulted in "home grown" apps that are not available on a wider or reproducible scale [25,27,28]. One inclusive and robust pharmacological app adherence study by Davies et al [48] was neither HIV specific nor US based. Further, a commercially available app has advantages with regard to sustainability, as it is widely available, consistent across users, and technologically supported for upgrades and security functions as long as privacy options are understood and maintained by both the user and administrator. These findings have important ramifications for implementation science in mHealth, as this successful state-wide pilot study is now ready for scale-up among demographically diverse PLWH [49,50].

Nearly 70.2% (n=92) of participants indicated interest in using an app daily to monitor their medication adherence, if one was available and free; this is promising for an integrative medication reminder model among more educated and mobile phone–savvy PLWH. However, more research is needed to maintain interest and trust among app users and to make apps relevant to care for both the patient and provider. Integrating positive feedback such as suppressed HIV VLs and other imported positive lab results into the app may increase both app and medication adherence over the long term.

A strength of this study is that it included a diverse group of PLWH across all demographics, ages, and risk factors; future studies should incorporate a wider geographical expanse of clinics using the idea of a biprogrammatic, free-of-charge, commercially available app to further refine an app that would be useful for the widest array of PLWH, across all health conditions, and appropriate to an aging PLWH population that often has the highest pill burden.

Limitations

This study had a few limitations that need to be addressed. First, participants were recruited only within public health clinics; however, this was designed to be a pilot study, and the results should be generalizable to PLWH who are seen in public health clinical settings. The participating public health clinics captured a wide variety of sociodemographic groups and can be considered representative of the Ryan White Funded HIV clinics in the state of Florida [51]. Although the exact income levels were not recorded, individuals receiving Ryan White support met certain income requirements. Second, the survey and app only included English-speaking individuals; more interventions should be considered for Spanish-speaking and Haitian Creole–speaking populations, especially in states such as Florida. Third, the current report only considers factors associated with baseline characteristics, general interest in mHealth tools, and initial use of the mHealth tool. Collection of information on the sexual orientation, and not just gender identity, would have been useful for this cohort of participants, given the extensive prior work among MSM youth in the literature, especially since mHealth pilot interventions for HIV have mainly focused on this risk group.

Comparison with Prior Work

Prior work on mHealth apps for PLWH has focused on the *de novo* development or iteration of an app or new technology in a subset of PLWH (ie, grouped by age or risk factor status). In contrast, this study focuses on the baseline and long-term usability of a ready-made, freely available, commercial app for ART adherence among a diverse population of PLWH in a biprogrammatic platform. This would be relevant and important in a larger, national scale-up for a translational technological link between the patient, app, and provider to synchronize medical adherence to virological suppression and thus to real-time clinical outcome success. This commercially available app is free of charge and updated regularly to ensure security and usability.

Conclusions

The FL-mAPP successfully demonstrated uptake of a widely available, free-of-charge, commercially available mHealth medication adherence app in a diverse population of PLWH. The results are promising, as they illustrate the usefulness of a biprogrammatic platform inclusive of diverse and aging PLWH users. For research on HIV implementation science focusing on mHealth, this successful statewide pilot study can be implemented on a larger scale.

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Conflicts of Interest

None declared.

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Abbreviations

AOR: adjusted odds ratio
ART: antiretroviral
FL-mAPP: Florida mHealth Adherence Project for PLWH
GED: General Educational Development
mHealth: mobile health
MSM: men who have sex with men
PLWH: people living with HIV
SMS: short message service
VL: viral load

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Original Paper

Patient Attitudes and Their Awareness Towards Skin Cancer–Related Apps: Cross-Sectional Survey

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Abstract

Background: In the emerging era of digitalization and electronic health, skin cancer–related apps represent useful tools to support dermatologic consultation and examination. Yet, little is known about how patients perceive the value of such apps.

Objective: The aim of this study was to investigate patient attitudes and their awareness toward skin cancer–related apps.

Methods: A cross-sectional study including 200 patients from the oncological outpatient unit was conducted at the University Hospital (LMU Munich, Germany) between September and December 2018. Patients were asked to complete a self-administered questionnaire on the popularity and usefulness of health-related and skin cancer–related apps. A descriptive analysis was performed with the expression of categorical variables as frequencies and percentages. For continuous variables, the median and range were indicated. Contingency tables and chi-square tests were performed to investigate associations between sociodemographic data and selected items of the questionnaire.

Results: A total of 98.9% (195/197) of patients had never used skin cancer–related apps or could not remember. In 49.7% (93/187) of cases, patients were unsure about the usefulness of skin cancer apps, whereas 42.6% (78/183) thought that skin cancer apps could supplement or support the professional skin examination performed by a physician. However, 47.9% (90/188) were interested in acquiring more information by their dermatologists about skin cancer apps. Young age (P=.002), male gender (P=.02), a previous history of melanoma (P=.004), and higher educational level (P=.002) were significantly associated with a positive attitude. Nevertheless, 55.9% (105/188) preferred a printed patient brochure on skin cancer to downloading and using an app.

Conclusions: The experience and knowledge of skin cancer–related apps was surprisingly low in this population, although there was a high general interest in more information about such apps. Printed patient brochures were the preferred information source.

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KEYWORDS

skin cancer; melanoma; mobile applications; telemedicine; awareness; patient education

Introduction

Nonmelanoma skin cancer (NMSC) is the most common malignancy in fair-skinned population groups. In Germany, the incidence was 221,800 new cases in 2014 [1]. About 77% of all NMSCs are basal cell carcinoma and 22% are squamous cell carcinoma [2]. Melanoma arises from the melanocytes of the skin and accounted for 21,220 new cases in Germany in 2014 [1]. It is the fifth most common malignancy among cancer patients. The incidence of melanoma has been steadily

increasing worldwide [3,4]. As a result of the increasing incidence of skin cancer [2,5] as well as the approval of new treatment regimens for advanced skin cancer, such as immune checkpoint blocking antibodies with unprecedented efficacy rates [6,7], the need for detailed patient information and education, for example, on potential adverse events under immunotherapy, is rising enormously. A survey among melanoma patients in German skin cancer centers including 67% patients with metastatic melanoma showed that more than half of the patients wished to receive advice on information resources that they can use outside the clinic to inform themselves [8]. Additionally, recent research suggests that the information-seeking behavior of melanoma patients and the resources they use have been changing with the accessibility of modern media [9-11]. Hence, in response to the increasing incidence and the growing demand on condition-related education, skin cancer–related and preventive smartphone apps have been launched successfully both for patients [12-14] and for health care professionals [15]. Most of the apps are easily accessible and address various topics, such as the detection of skin cancer via computer-based algorithms, self-examination or telemedicine, the tracking of skin changes, or the prevention of sunburns or skin cancer.

Physicians still serve as the primary information source for patients diagnosed with any cancer entity [16,17]. However, as physicians have limited time for comprehensive education [8,18], many patients tend to use further information sources to compensate for their informational deficits [19,20]. Skin cancer–related smartphone apps represent a useful supportive information tool to complement the physician's consultation. They have high potential to improve participatory decision making and informed consent. In this paper, we report the results of a cross-sectional study to investigate the dissemination of skin cancer–related smartphone apps among patients, patient attitudes toward the use of skin cancer–related smartphone apps, and the association between sociodemographic variables and the usage of such apps.

Methods

Study Design and Ethics Approval

A cross-sectional study that included patients from the oncological outpatient clinic of the Department of Dermatology and Allergy of the University Hospital of Munich was conducted between September and December 2018. This study was approved by the institutional review board of the University Hospital (LMU Munich) on May 4, 2018 (approval number 18-336 UE). We closely adhered to the Strengthening the Reporting of Observational Studies in Epidemiology statement for cross-sectional studies for the reporting of this study [21,22].

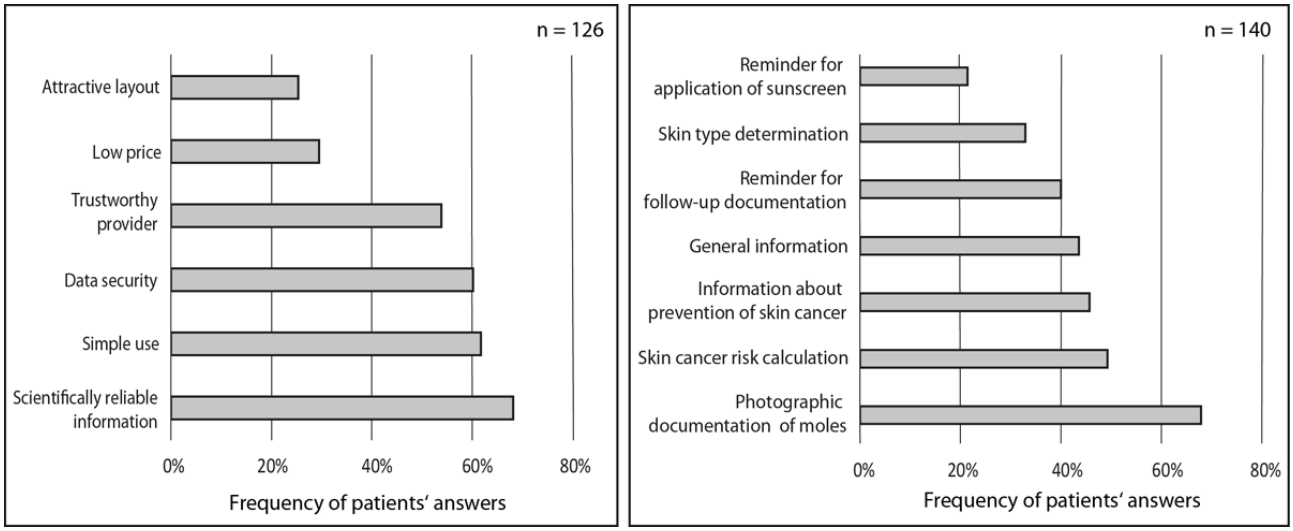
Setting and Participants

The oncological outpatient unit mainly focuses on the treatment and surveillance of patients with a previous diagnosis of any type of skin cancer undergoing follow-up care. Thus, the majority of the study population had been diagnosed with skin cancer before the assessment. All adult patients (aged 18 years or older) presenting at the unit were asked to complete a 2-page questionnaire either by a physician (SM) or a study nurse. Participation was voluntary, and all participants gave verbal informed consent before completing the questionnaire. Refusals were not documented, and no incentives were provided. Relatives or accompanying persons were excluded from the study. Each patient was allowed to participate only once in the survey (cross-sectional design).

Survey

As no validated survey tools existed for the objective of our study, the questionnaire was developed de-novo based on a literature review and dermato-oncological expert consulting, including questions on skin cancer–related smartphone apps and basic demographic information (age, gender, and highest level of education). In a multiple-choice question format, patients were asked about the reason of presenting to the unit at the day of the assessment and whether they had already been diagnosed with skin cancer before. Other questions addressed the patients' previous use of health-related apps and, specifically, skin cancer–related apps and their relevance for skin cancer detection as well as concerns regarding digital security. These questions were dichotomous; however, patients could also state that they were unsure. The questions are presented in Figure 1. The full questionnaire can be obtained from the Multimedia Appendix 1. The questionnaire was pretested by independent researchers (TJB and A-CN) and patients without skin cancer for clarity and comprehension. On the basis of their suggestions, the questionnaire was revised to the final form. Completed questionnaires were sequentially numbered for data entry purposes but were not linked to any identifying patient information to assure irreversible anonymity.

Figure 1. The frequencies of patients' specific answers regarding the preferred features in health-related apps in general (left) and skin cancer–related apps (right).



Data Analysis

We calculated an estimated sample size of n=197 required for this descriptive study with an alpha error of 5%, a power of 80%, a CI of 95% and a relevant effect strength of 20%. The calculation was based on the item "Do you find the use of skin cancer apps useful for patients?" as we hypothesized that this question would be the most appropriate and a global indicator for the patient attitude toward skin cancer apps. The effect strength of 20% was a conservative estimate based on a previous study which was performed in the Munich area where approximately 25% did not own a mobile device or had access to a personal computer only [23]. For statistical analysis, the categorical variables were expressed as frequencies and percentages and were compared using the chi-square tests. For continuous variables, the median and range were used. A 2-sided *P* value <.05 was considered statistically significant. Statistical analyses were conducted with SPSS (IBM SPSS Statistics version 25, IBM Corporation).

Results

Baseline Characteristics of the Study Population

A total of 200 patients were included, 34.4% (67/195) of whom had an appointment for skin cancer treatment; 49.7% (97/195) underwent skin cancer screening, and 20.0% (39/195) had a follow-up appointment; 6.2% (12/195) of the patients presented because of a suspicious mole (multiple answers possible, hence values do not sum up). The majority of patients had already been diagnosed with skin cancer (173/193), most of them with melanoma (131/186, 70.4%), followed by basal cell carcinoma (32/186, 17.2%). The median age was 66 (range 20-91) years, and 62.7% (121/193) were males (Table 1).

Table 1. Baseline characteristics of the study population.

Characteristics	Values
Sex (n=193), n (%)	
Female	72 (37.3)
Male	121 (62.7)
Age (years; n=190)	
Median (range)	66 (20-91)
Mean (standard deviation)	62.63 (15.56)
Education (n=183), n (%)	
High level of education	
University degree	41 (22.4)
General higher education entrance qualification	32 (17.5)
Middle to low level of education	
Secondary school leaving certificate	52 (28.4)
Lower secondary school leaving certificate	52 (28.4)
Other	
Other degree	4 (2.2)
No degree	2 (1.1)
Reason for appointment (n=195, multiple answers possible), n (%)	
Skin cancer screening	97 (49.7)
Skin cancer treatment	67 (34.4)
Follow-up visit	39 (20.0)
Suspicious mole	12 (6.2)
Previous diagnosis of skin cancer (n=193), n (%)	
No	20 (10.4)
Yes	173 (89.6)
Type of skin cancer (n=186, multiple answers possible), n (%)	
Melanoma	131 (70.4)
Basal cell carcinoma	32 (17.2)
Squamous cell carcinoma	17 (9.1)
Other (including actinic keratosis and Merkel cell carcinoma)	19 (10.2)

Previous Experience With Health Apps

A total of 66.7% (130/195) of patients were owners of a smartphone and 31.8% (62/195) of a tablet device. Additionally, 8.7% (17/195) reported to also use other devices such as wearables. When asked about previous experiences with health-related apps, 8.5% (17/199) stated that they had previously made use of such apps, whereas the overwhelming majority (180/199, 90.5%) denied or was unsure about it (2/199, 1.0%). Apps that had already been used by the patients were predominantly health-tracking apps offered by Apple and Android or the fitness-tracking app, Runtastic. Others included diet apps such as Weightwatchers and apps provided by health insurance companies (GesundheitsApp der Gothaer Krankenversicherung AG) and a skin cancer–related app (SkinVision).

Most patients (86/126, 68.3%) rated scientifically reliable information as the most important feature for health-related apps, followed by user convenience (76/126, 60.3%) and data security (76/126, 60.3%). For 54.0% (68/126) of patients, credibility of the app provider was important; 29.6% (37/125) and 25.4% (32/126) considered a low price and an attractive layout as critical, respectively (Figure 1).

Attitude Toward the Use of Skin Cancer–Related Apps

Only 1% (2/197) of the patients had already used skin cancer–related apps, namely the app, SkinVision. The majority of patients had never used skin cancer apps (189/197, 95.9%) or did not remember a previous usage (6/197, 3.0%).

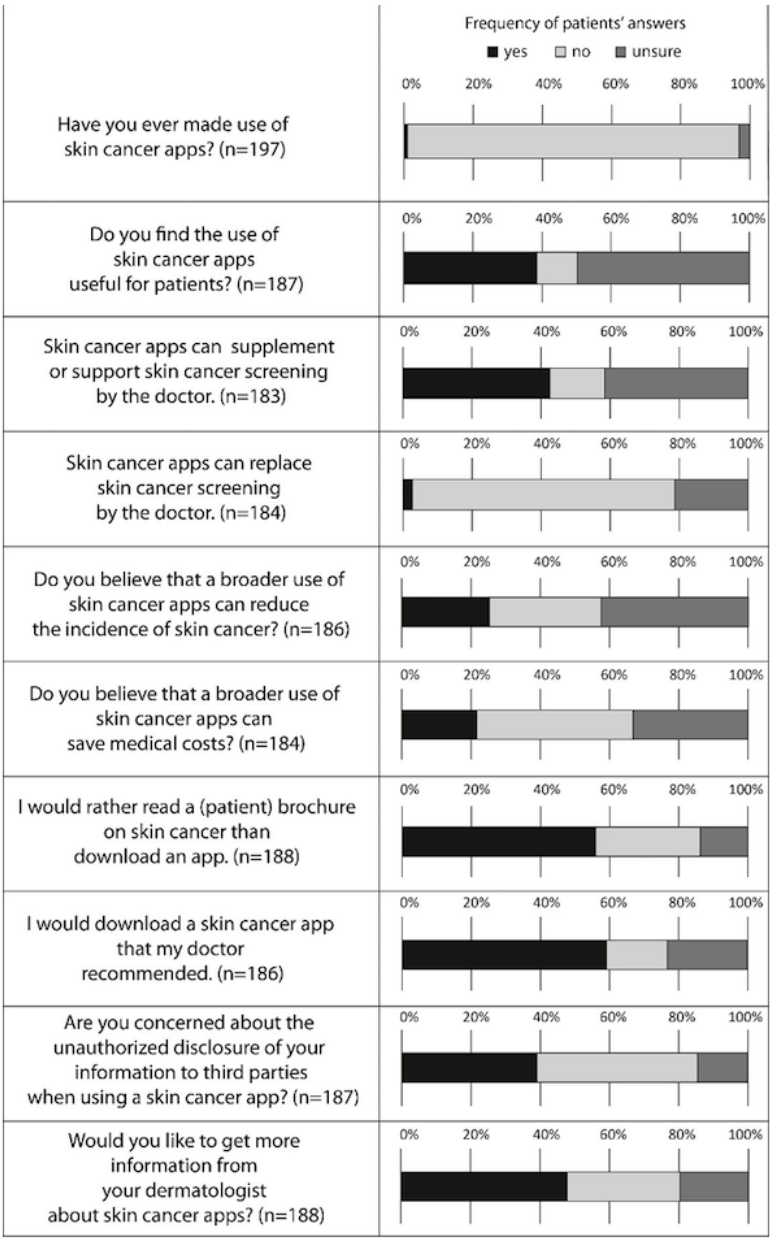
Half of the patients (93/187, 49.7%) were unsure about the usefulness of skin cancer apps for patients, whereas 38.5% (72/187) thought that such apps are useful for patients; 42.6%

(78/183) voted that skin cancer apps can supplement or support professional skin cancer screening by a physician, whereas 41.5% (76/183) were unsure. The majority figured that skin cancer apps cannot replace skin cancer screening performed by a physician (cannot be replaced: 76.1% [140/184] and unsure: 21.2% [39/184]). Less than half of the patients (83/184, 45.1%) thought that a broader usage of skin cancer apps can reduce medical costs (33.2% [61/184] were unsure) and did not agree with the statement that skin cancer apps can contribute to the reduction of the incidence of skin cancer (disagree: 32.3% [60/186] and unsure: 42.5% [79/186]). Nevertheless, nearly half of the patients (90/188, 47.9%) were interested in acquiring more information from their dermatologist about skin cancer apps (Figure 2).

Interestingly, 55.9% of patients (105/188) preferred a printed patient brochure on skin cancer to downloading and using an app; 39.0% (73/187) of patients had concerns about the unauthorized disclosure of information to third parties, 46.5% (87/187) did not have concerns, and 14.4% (27/187) were unsure. However, 59.1% of the patients (110/186) would download a skin cancer app recommended by their physician.

We also asked the patients which features they find important for skin cancer apps. The majority reported the documentation of moles with photos to be important (95/140, 67.9%), followed by individual skin cancer risk calculation (69/140, 49.3%), information on the prevention of skin cancer (64/140, 45.7%), general information on skin cancer (61/140, 43.6%), and reminders to take regular photos for a follow-up examination (56/140, 40.0%). One-third (46/140, 32.9%) found the individual determination of the skin type to be important, whereas 21.4% (30/140) favored reminders for the re-application of sunscreen (Figure 1).

Figure 2. The frequencies of patients' specific answers regarding their attitude toward skin cancer apps.



Association Between Sociodemographic Data and Attitude Toward Skin Cancer Apps

There was a statistically significant association between owners of a tablet and the previous use of a health-related app (P=.01), that is, patients who were owners of a tablet device were more likely to already have used health-related apps.

With regard to the preferred features of skin cancer apps, patients with a history of melanoma found the photographic documentation (P=.04), reminder function for follow-up documentation (P=.03), and the possibility for a risk calculation (P=.002) more important than those without a previous diagnosis of melanoma. Furthermore, melanoma patients were more interested in acquiring more information on skin cancer apps (P=.02), and they would also download an app that is recommended by their physician (P=.004). Men were generally more willing to download an app that has been recommended by their physician than women (P=.02).

Besides, patients aged >61 years rather did not think that skin cancer apps can replace the physician in comparison to those under the age of 61 years (P=.02). In contrast to this, older people were more likely to think that the usage of skin cancer apps can contribute to saving medical costs (P=.008). People aged over 61 years in our sample would rather read a printed brochure on skin cancer than download an app (P<.001). In contrast, patients under the age of 61 years would download an app that has been recommended by their physician (P=.002), and they were more interested in acquiring additional information on skin cancer apps (P=.01). People with low-middle level of education rather agreed that skin cancer apps can replace the physician (P=.008). They would also rather read a brochure than download an app (P=.003). Higher educated patients would rather agree in downloading an app that has been recommended by their physician (P=.002).

Patients agreeing with the statement that skin cancer apps are useful for patients also thought that skin cancer apps can supplement or support skin cancer screening by the physician (P<.001). However, they disagreed with the statement that apps can replace skin cancer screening by a physician (P=.001). Additionally, they were more likely to think that skin cancer apps can contribute to the reduction of the incidence of skin cancer (P<.001). Interestingly, they did not think that such apps can contribute to saving medical costs or were unsure about it (P<.001). Patients rating skin cancer–related apps as useful preferred downloading an app to reading a brochure (P=.002). They were also more likely to download an app that has been recommended by their physician (P<.001) in comparison to patients who do not think that the usage of apps is reasonable. Yet, those who thought that skin cancer apps are useful were interested in gaining more information related to this topic (P<.001).

Discussion

Principal Findings

This cross-sectional study was designed to characterize patient attitudes toward skin cancer–related apps. Surprisingly, we observed a substantial lack of patients' knowledge about the availability and usability of health-related apps in general. Our results contrast sharply with the recent perception of health-related apps among health care professionals in the emerging era of electronic health and digitalization [24,25]. Only a minority of study participants were aware of the existence of skin cancer apps to support their skin examination. As we surveyed a population in which most patients had been previously diagnosed with skin cancer, we assume that this lack of awareness is even higher in the general population and persons who have never faced a diagnosis of skin cancer. However, our survey also identified subgroups that seemed more amenable to the usage of apps. In particular, patients younger than 61 years and men were significantly more frequently interested in acquiring further information and indicated that they would download an app recommended by their physician. A similar trend was registered with regard to the level of education, as higher educated patients were more willing to use and download an app than those with lower to middle education. Interestingly, this association has also been detected in other studies [26,27]. However, analyzing a possible correlation between educational level and app usage was not reasonable for this study, as only 2 out of 197 study participants had ever used skin cancer–related apps.

Nevertheless, our results underline that the majority of patients and particularly those who were older than 61 years remain skeptical about the usage of skin cancer apps, which is in accordance with a survey conducted in cancer patients regarding general app-assisted cancer care [23]. Various reasons for this negative attitude are conceivable. Patients in our sample were more likely to think that skin cancer apps can contribute to saving medical costs on the one hand but cannot replace professional skin examination on the other hand. This ambivalence might reflect a general fear that the apps have mainly been developed to reduce costs by replacing physicians. This hypothesis would fit well with the results of a previous survey in which the wish for personal contact with the treating physician was among the most common obstacles for not using medical apps [23].

A further reason for the skepticism may be a lack of capable devices and general concerns regarding technical issues, in particular among the elderly. In comparison to the overall German population where 79% were estimated to own at least one smartphone in 2016 [28], only 66.7% (130/195) of our study population were smartphone owners. We deem this value representative for the regional population of the Munich area as it is in line with 69.6% of mobile device users in a cross-sectional study that was conducted at several oncological departments of the hospital of the Technical University of Munich [23]. The deviation from the German population might be explained by the fact that the patients in our sample were much older than the overall population in Germany (median age: 66 years vs 45.9 years) [29]. In this context, it still remains remarkable that only 2 patients had ever used a skin cancer–related app before, although more than two-thirds of all participants owned a smartphone and nearly one-third, a tablet. However, despite their lack of personal experience, almost 40% thought that these apps are generally helpful, which contrasts with the low level of awareness.

These results imply that there is an urgent need for more education and information of both skin cancer apps and the usage of electronic devices in general. Print media offer advantages as they are readable without any additional equipment. Indeed, most patients in our study preferred to read a printed patient brochure for education to downloading and using a skin cancer app. This is consistent with a previous report by Brütting et al who surveyed melanoma patients from 27 German skin cancer centers and found that the majority used the internet and booklets as their preferred source of information [30,31]. The probability of rating the internet as an important information source was 2.2 times higher in melanoma patients aged ≤55 years [30]. However, an evaluation of German booklets has shown that most of them are of medium quality and difficult to read owing to incomplete reporting and insufficient meta-information [32].

Melanoma patients preferred distinct features in skin cancer apps compared with nonmelanoma patients. The most important ones included photographic documentation, reminder for follow-up documentation, and the possibility for a risk calculation. We assume that this subgroup of patients is generally more aware of the importance of regular self-examination and a consequent follow-up of suspicious lesions because of their personal experience and medical history [33]. Photographic documentation of suspicious lesions and intelligent algorithms for data analysis can assist in the self-detection and follow-up of skin cancer. In combination with deep neural networks, algorithms were even reported to outperform dermatologists in the detection of benign lesions [34,35]. Additionally, melanoma patients were more interested in acquiring further information about skin cancer apps and eager to download an app that has been recommended by their physician. We hypothesized that the melanoma subgroup was younger and therefore more familiar with the use of new technologies. However, there was no significant association between these 2 variables.

Limitations

We are aware that this study has several limitations. The sample comprised 200 patients presenting to the oncological outpatient unit. First, the sample size of this study is relatively small and, second, it was not sampled in a random fashion but depending on the availability of patients. Thus, the results presented here may not be fully generalizable to the general population and are at risk for sampling bias.

Conclusions

Altogether, this cross-sectional study demonstrates that the awareness and popularity of skin cancer–related apps is still low. A high level of education, young age, male gender, and a history of melanoma were important factors for a positive attitude. To fully exploit the potential of those apps, physicians may encourage their use in these subgroups and propagate their use as a supplementary information source. However, patient brochures remain the preferred information source for skin cancer patients until now.

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Authors' Contributions

TS, MVH, A-CN, and CB designed the questionnaire and the study. SM, MVH, and TS contributed to the distribution and collection of the questionnaires. TS and AW were responsible for data analysis and statistical analysis. TS, AW, and MVH drafted the manuscript. A-CN, LEF, SM, TJB, and CB critically revised the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Questionnaire about patients' attitude toward skin cancer–related apps (in German language).

[PDF File (Adobe PDF File), 78KB - mhealth_v7i7e13844_app1.pdf]

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Abbreviations

NMSC: nonmelanoma skin cancer

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Original Paper

The Preferences of Patients With Cancer Regarding Apps to Help Meet Their Illness-Related Information Needs: Qualitative Interview Study

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Abstract

Background: The shift from inpatient to outpatient and community cancer care means that more patients with cancer need to manage their condition at home, without the direct supervision of their clinician. Subsequently, research has reported that many patients with cancer have unmet information needs during their illness. Mobile devices, such as mobile phones and tablet computers, provide an opportunity to deliver information to patients remotely. Before designing an app intervention to help patients with cancer to meet their information needs, in-depth qualitative research is required to gain an understanding of the views of the target users.

Objective: We aimed to develop an app intervention to help patients meet their illness-related information needs in noninpatient settings. This study explored the information needs of patients with cancer and their preferences for an app and desired app features. Specifically, the perceived acceptability of an app, desired app features, and the potential benefits and disadvantages of, and barriers to, an app were explored.

Methods: Qualitative, one-on-one semistructured interviews were conducted with patients with urological, colorectal, breast, or gynecological cancers (N=23) across two hospitals in South Wales. Interviews were audio-taped, transcribed, and analyzed using a thematic analysis.

Results: Findings indicated that barriers to information exchange and understanding in consultations, and identification of reliable information sources between consultations, appeared to contribute to patients' unmet information needs. Consequently, app feature suggestions included a question prompt list, a glossary of cancer terms, a resources feature, and a contacts feature. Anticipated benefits of this type of app included a more informed patient, improved quality of life, decreased anxiety, and increased confidence to participate in their care. The anticipated barriers to app use are likely to be temporary or can be minimized with regard to these findings during app development and implementation.

Conclusions: This study highlights the desire of patients with cancer for an app intervention to help them meet their information needs during and between consultations with their clinicians. This study also highlights the anticipated acceptability and benefits of this type of intervention; however, further research is warranted.

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KEYWORDS

education, medical; medical information exchange; smartphone; mobile apps

Introduction

Survival rates for patients with cancer in the United Kingdom have doubled in the past 40 years, so for many patients, cancer is a chronic condition that they live with for many years [1]. Consequently, there has been a shift from inpatient to outpatient and community cancer care, where patients manage their condition at home, with less regular supervision by clinicians. This requires patients to take a more active role in their treatment and survivorship. To do this and to cope with and manage these changes in daily life, patients require relevant information [2]. Consequently, government initiatives and National Health Service (NHS) plans, such as the national cancer strategy, have highlighted information provision as one of their key priorities for 2015 to 2020 [3].

Studies suggest that patients generally want information on the extent of the disease, prognosis, available treatments, side effects of treatment, self-care, and return to normal life [4-6]. Other, less urgent, information needs include the impact of the illness on social activities, family and friends, mental well-being, sexual activity, and the risk of others getting cancer [4-6]. In this paper, the term "illness-related information needs" includes information related to the disease itself, treatment, psychological support services, and practical support.

Although many people with cancer want as much information as possible about their condition [7], studies across the United States and Europe have reported high rates of unmet information needs [4,8]. Apart from limiting patients' ability to participate in their care, unmet information needs are associated with a lower quality of life, loss of control over one's life, increased anxiety and depression, and dissatisfaction with care [9-12].

The introduction of smart technology, including smartphones and tablet computers, has provided a new platform for delivering information-based interventions to patients. Surveys demonstrate the increasing popularity of digital information resources due to increased access to devices and availability of information websites and apps [13-16]. Cancer outpatients in France reported that half of them had used websites and a quarter of them had used apps to search for health information [14]. The acceptance of new information resources for patients is expanding as expected in line with generational trends and over time [15,16]. The UK government has encouraged the integration of interventions delivered by mobile technology into traditional health care services [17]. Furthermore, key reviews, such as the NHS Five Year Forward review [18] and the Wachter review [19], have highlighted the importance of, and urgent push for, digitization in the NHS to provide a high level of health care at an affordable cost.

A recent systematic review has identified that the current mobile interventions for patients with cancer are limited to mainly helping patients with their treatment or symptom-related information needs [20]. More comprehensive interventions are required for patients managing their condition in noninpatient settings.

This study is part of a series documenting the systematic development of an app to help patients with cancer to meet their illness-related information needs [20]. The primary aim of this study was to explore the potential value of an app for patients with cancer and to establish the type of app required. This included exploration of preferences for an app and its features and the potential benefits and disadvantages of, and barriers to, this type of intervention, as well as the types of patients and the time at which they might find an app most useful. This information will help anticipate the potential uptake of the intervention and its possible outcomes, including potential benefits and disadvantages. Ultimately, this process enables development of interventions that are more relevant and engaging for users and helps to circumvent or minimize common issues in digital intervention research, such as low uptake and adherence [21].

Methods

Overview

Semistructured interviews were conducted with patients with cancer in their homes between November 2014 and February 2015. NHS ethical approval and R&D approval was granted (14/WA/0066). Semistructured interviews were chosen as they enable a more personal and in-depth response from individuals compared with quantitative methods [22]. This method also allows participants the freedom to bring up other relevant issues [23].

Participants

Maximum variation sampling was used to enable divergent views to emerge [24]. Participants were recruited from colorectal, urological, breast, and gynecological cancer clinics within the University Hospital Wales and Velindre hospital in South Wales, United Kingdom. These 4 cancer types were chosen to have a variety of some of the most common cancers in the participant sample [25]. A decision was made to include a varied sample of patients, including the following:

1. Patients undergoing surgery, radiotherapy, chemotherapy, or hormone therapy for cancer
2. A range of cancer types: breast, gynecological, colorectal, and urological
3. Women and men
4. Patients aged older than 60 years and patients aged younger than 60 years

Patients' eligibility for the study was assessed by cancer nurse specialists (CNSs) at the clinics. The inclusion criteria were as follows: patients were male or female; aged 18 years or above; receiving neoadjuvant, adjuvant, radical, or palliative treatments; at least 2 weeks after diagnosis (to allow patients enough time to come to terms with their diagnosis); able to give informed consent. The exclusion criteria were as follows: patients who do not have an estimated life expectancy of at least 12 months; patients who the clinician deems to be unsuitable for the research (eg, in a current state of crisis or have their own significant health or social problems, unable to provide informed consent, or other reason for not being approached about the study).

Recruitment

A total of two CNSs assisted with recruitment by distributing information packs to eligible patients, containing an invitation letter, an information sheet, reply form, and prepaid envelope. The number of information packs distributed was recorded.

Procedure

Interested participants contacted the lead researcher, and interviews were arranged in their own homes. The interview was confidential, and only the research group had access to the anonymized data. Participants consented to participate at the time of interview and completed a demographic questionnaire. Interviews were audio-recorded and transcribed verbatim.

Interview Topic Guide

Relevant literature informed the development of a semistructured interview topic guide [20]. Topics included the following: information needs and information-seeking, communication with clinicians in consultations, experience with mobile technology, acceptability of an app intervention, desired app features, and the perceived benefits and disadvantages of, and barriers to, this type of intervention. All participants, regardless of characteristics such as cancer type and stages of disease, were asked the same questions. Participants who were unfamiliar with apps received a brief explanation by showing examples of existing apps on a smartphone (eg, notes app, social media apps, and email app). Additionally, features of the National Coalition for Cancer Survivorship "Pocket Cancer Care Guide" app were shown to provide these participants with examples of the types of features that could be used by patients with cancer. Participants who were familiar with apps were simply told that an app could help with a wide range of things, such as their information needs, communication with clinicians in consultations, adherence to medication, and social support. See Multimedia Appendix 1 for the topic guide.

Analysis

Patients were interviewed until the research team felt that data saturation was reached. Data saturation was considered to have occurred when no new themes were identified for at least 3 interviews. Data were managed using the qualitative analysis software package NVivo 10 (QSR International). Interview transcripts were analyzed using a thematic analysis as this helps to provide insights by moving from a broad reading of the data to reporting patterns and themes, followed by their interpretation [26]. The analysis was neither considered purely inductive nor deductive. Instead, it can be considered as a blend of both approaches. Inductive approaches are those that start from the data and search the data for patterns that suggest general laws, ultimately aiming for generation of theories. In contrast, deductive approaches start with hypotheses that are derived from a theory, which are then tested against a body of data that was gathered to test the hypotheses. However, in practice, all research incorporates elements of both inductive and deductive logic [27]. Each transcript was read several times for familiarity, actively searching for, and noting, meanings and patterns. Initial codes were generated from each data item, and mind maps were created to identify the links between codes and possible overarching themes. Codes were then organized into meaningful subthemes and main overarching themes. Themes were reviewed and refined by reviewing each data item within a theme to ensure coherence. A total of 5 transcripts were independently analyzed by a second author to reduce the potential bias of subjectivity associated with coding and facilitate the interpretation of findings. Discrepancies were resolved through discussion.

The author, RR, a research associate and health psychologist, conducted and analyzed the data. Coauthor, FW, a senior lecturer and medical sociologist, double-coded a subset of transcripts as described above. Both authors maintained an awareness of how their own personal characteristics and values may have influenced data collection or analysis. For example, neither RR nor FW has had a previous diagnosis of cancer and therefore may not fully understand participants' experiences or the psychosocial context. During interviews, some participants might have been wary of RR because of her profession as an academic researcher, and some participants may have assumed that she was in contact with their cancer clinician. RR was aware of how this might have influenced participants' trust and openness during the interviews and so made every effort to build a rapport and trust before the interview to make the participants feel comfortable and at ease. RR assured participants that the interviews were confidential and that their views and opinions would not be discussed with their clinicians or affect their care in any way.

Results

A total of 23 interviews were conducted between November 2014 and February 2015. The average length of the interviews was 43 min (range: 16-75 min).

Sample Characteristics

A total of 130 information packs were distributed to eligible patients (40 urological cancer patients, 30 colorectal cancer patients, 30 gynecological cancer patients, and 30 breast cancer patients). Of these, 33 patients returned a reply form indicating interest in participating, of which 23 participated and completed the study (overall response rate: 18%). Of the responding patients, 4 did not answer the telephone or respond to emails, 4 stated that they were not feeling well enough to participate, 1 patient was on holiday, and 1 patient declined. Sample characteristics are presented in Table 1. The most common age category was 56 to 65 years (35%, 8/23) and the most common cancer type was colorectal cancer (44%, 10/23). The response rate from each cancer type was 7% (3/40) for urological cancer, 13% (4/30) for breast cancer, 16% (5/30) for gynecological cancer, and 33% (10/30) for colorectal cancer. The most common time since diagnosis was 1 to 2 years (35%, 8/23). Nearly three-quarters of participants were educated to at least the secondary level (74%, 17/23), and over a quarter were educated to the degree level (26%, 6/23). All participants were white Caucasian. In total, 74% of participants (17/23) reported that they owned (or co-owned) a smart device (smartphone or tablet).

Table 1. Sample characteristics.

Identification number	Age (years)	Gender	Cancer type	Time since diagnosis	Education level
P[a]1	66-75	Male	Urological	2-4 years	GCSE[b]/O levels[c]
P2	18-25	Female	Gynecological	3-6 months	Diploma
P3	66-75	Male	Colorectal	1-2 years	No education
P4	66-75	Male	Colorectal	2-4 years	Degree
P5	56-65	Female	Breast	3-6 months	Postgraduate degree
P6	66-75	Male	Colorectal	3-6 months	No education
P7	56-65	Female	Colorectal	2-4 years	Degree
P8	56-65	Female	Gynecological	5 years +	Degree
P9	85+	Female	Colorectal	1-2 years	No education
P10	66-75	Female	Other	1-2 years	No education
P11	46-55	Female	Gynecological	2-4 years	GCSE/O levels
P12	46-55	Female	Breast	1-2 years	Missing data
P13	56-65	Female	Gynecological	2-4 years	Degree
P14	66-75	Male	Colorectal	1-2 years	Postgraduate degree
P15	76-85	Male	Urological	1-2 years	Diploma
P16	56-65	Male	Colorectal	6 months-1 year	No education
P17	46-55	Male	Colorectal	6 months-1 year	Degree
P18	56-65	Male	Colorectal	2-4 years	GCSE/O levels
P19	36-45	Female	Breast	1-2 years	NVQ[d]/HNC[e]/HND[f]
P20	56-65	Female	Gynecological	1-2 years	Degree
P21	66-75	Female	Breast	5 years +	GCSE/ O levels
P22	76-85	Male	Colorectal	2-4 years	No education
P23	56-65	Male	Urological	3-6 months	GCSE/O Levels

[a]P: patient.

[b]GCSE: General Certificate of Secondary Education.

[c]O level: General Certificate of Education Ordinary Level.

[d]NVQ: National Vocational Qualification.

[e]HNC: Higher National Certificate.

[f]HND: Higher National Diploma.

Interview Themes

From the interviews, 4 key themes were identified: (1) suggested app features, (2) anticipated benefits of app use, (3) potential disadvantages of app use, and (4) anticipated barriers to app use.

Theme 1: Suggested App Features

Most participants wanted informational features that would support self-management of their condition such as providing information on treatment-related side effects, cancer support services, lifestyle changes (eg, diet, exercise, and smoking), survival and recurrence rates, alternative therapies, managing finances, psychological support, and logistical issues:

> *Well the sort of information that I wanted was um symptoms, you've been told you've got colon cancer, like myself, um the sort of thing I wanted to find out was how curable is it? Um...treatments, I wanted to know what sort of treatment I was having.* [P11; 46-55 years, gynecological cancer]

Some participants suggested to include links to credible cancer information websites, as they reported that they found it difficult to navigate the internet and identify reliable information:

> *It [the app] could be used to direct them [patients] towards websites that contain that information, so you could use it as a roadmap, that I suspect could be useful.* [P14; 66-75 years, colorectal cancer]

Some participants suggested that a treatment-related symptom diary feature would be useful. Participants described how keeping a diary helped to predict how they would feel at certain times during their treatment and helped them to plan ahead to prevent or remedy symptoms and organize their diet and social calendar. Participants explained that they felt reassured by knowing when symptoms were likely to occur:

> *Uh like I told you when you start chemo, it's really good for you to have a report, a detailed report of symptoms, how you feel. So throughout the cycles, not only for yourself to prepare yourself for what's coming as well, for the nurses because they ask you, they ask you at every clinic, "How are you feeling?", "How did it go?". If you don't write it down I can tell you, you will forget. If the app has um a way so that you could personalize your own link and then you can actually have a diary.* [P19; 36-45 years, breast cancer]

Many participants also suggested app features that would facilitate information exchange in consultations, such as a question prompt list (QPL; a tailored list of questions to be asked). It was anticipated that a QPL would be the most useful feature for patients:

> *I think if the app does that, you know gives you a list of questions that would be useful for you to ask so you can write them down...I think it's extremely useful because at least you've got your mind set to ask the questions if you've got any...If I had any questions when I got home, I'd have to ring back and say, "Look I don't understand this," you know so I think if the app does that, that's really good.* [P19; 36-45 years, breast cancer]

Participants also suggested including a glossary that provided definitions of cancer terms, as they recalled not being able to understand the terminology used by clinicians or that in information resources such as leaflets:

> *I think that would be useful and explain what that means to them, because I think an awful lot of people would be to a degree, a little bit in awe of what the doctor is saying because they're not trained as uh doctors they wouldn't understand completely, and maybe there's a slight reluctance to say to the doctor, "Well explain that more fully, be more open with me" because of that if you like, power differential, between the patient and the doctor, so having the ability to go to an app afterwards, provided you remember what all the big words were.* [P14; 66-75 years, colorectal cancer]

Participants also suggested app features that would raise awareness of, and increase patients' access to, other types of support. Some participants suggested including links to local cancer support services, such as psychological support services, and help with managing finances and cancer charity websites. It was hoped that this would raise awareness of and increase access to some of the services that participants found helpful during their illness (eg, a financial benefits advisor for patients who were unable to work):

> *I think there's a lot of things the app could help to link up a bit. You know, there is a lot of stuff [cancer services] out there, putting it in one place would probably, I would've thought would be helpful, so that people haven't got...I kind of stumbled across things by accident, like I didn't realise that Macmillan did the complimentary therapy services thing, but there's also links to sort of art therapy and all sorts of things that are there, and they're there for families as well and I didn't know they were there initially.* [P8; 56-65 years, gynecological cancer]

Many participants recalled how they exchanged information with other patients with cancer, both face-to-face at hospitals and on the internet (eg, information on remedies for treatment side effects), which they described as invaluable. Therefore, some participants suggested including a social feature or links to existing social forums or media. Participants also suggested to include links to information on the internet or local support groups to meet other patients, as they found it difficult to locate information on these services:

> *Um, I think support side of it is very important, to give the information about support, um support groups, cos that's what I couldn't find, I couldn't find any support groups. It was only about last year I found a support group near home.* [P11; 46-55 years, gynecological cancer]

Theme 2: Anticipated Benefits of App Use

Participants identified the potential benefits of an app that would help patients meet their information needs. Owing to increased access to reliable and relevant information, participants anticipated that future patients would have a better understanding of their condition and the information provided in consultations. A more informed patient was expected to be able to identify the side effects of treatment and treat them accordingly, which may prevent complications and potentially improve their quality of life. For example, one patient reported that her lack of knowledge on the importance of monitoring her temperature during treatment almost led to her hospitalization:

> *On the Sunday night when I was feeling like death I took my temperature and it was 37.5 so I took it with another thermometer and it was 37.4, because 37.5 is the magic number [the threshold] I went to bed, in the morning I took my temperature and it was 37.9 ...but because I didn't want to go in, "Its 37.4, I don't want to go in". If I had understood the very important aspect of that, I would have gone in to hospital that night.* [P5; 56-65 years, breast cancer]

A more informed patient was also expected to have lower levels of anxiety throughout their illness owing to having a better understanding and more realistic expectations of their prognosis and treatment:

> *I think uh, give information on treatment, be specific about what's involved with chemotherapy because people are afraid of chemotherapy and if it was explained to them beforehand they might not be as afraid. Explain about what happens with radiotherapy, as again, people are afraid of it.* [P7; 56-65 years, colorectal cancer]

There was some evidence to suggest that an app could help patients increase their confidence in actively participating in their care and to communicate with their clinicians:

What benefits do you think there might be for patients using this type of app? [Interviewer]

Well it might help them, it might help them get some confidence, within the system, because if they, you know if it opens up questions and answers session when they go [to clinic] it's going to make them more confident next time isn't it? It's going to help encourage their relationship with their practitioners, so you know with their doctors, so... [P20; 56-65 years, gynecological cancer]

Participants also highlighted the benefits of smart technology. Accessing cancer-related information and resources via an app was expected to be less burdensome than searching through printed leaflets and booklets:

You have these pile of booklets off them and when you see all that you're like, "Oh have I really got to read all that?", so if you've got an app there it's easier then isn't it? It's like you haven't got to carry everything around, and say you're in an appointment, you can just pull the app up on your phone and just read up on it, rather than carrying all these massive books with you. [P2; 18-25 years, gynecological cancer]

Theme 3: Potential Disadvantages of App Use

Few participants were concerned that some patients might become anxious if they misinterpreted information or were misinformed by inaccurate information:

One point that might manifest itself would be Joe Bloggs getting the wrong end of the stick, when they've been diagnosed with a particular condition, their research may take them away from the condition to something else, and maybe anxiety could set in as a result of that, because they've over researched it perhaps and frighten themselves. [P14; 66-75 years, colorectal cancer]

Additionally, a small number of participants also worried that if patients actively used an app in a consultation, it might distract them from the conversation with the clinician:

In my case it [the app] would hinder communication...because you're looking at this [the app] and you're not looking at them [the clinician] and you're just reading a list. [P10; 66-75 years, other cancer]

Theme 4: Anticipated Barriers to App Use

Most participants reported that they did not foresee any barriers to the use of an app. The most commonly anticipated barrier was patients' age and experience with smart technology. Some participants anticipated that many older patients would lack the knowledge and experience to be able to use an app, in comparison with younger patients:

If you said to me there's this app called such and such then I'd just go and look at it and find it out for myself, like my dad bless him who's 82 and he plays around with his laptop um he wouldn't know like to look at the little words and to click on them and things and explore an app you know? ...When somebody of your generation finds it, oh that sounds patronizing but imagine that um you know, there are some people they still don't know what an app is. [P13; 56-65 years, gynecological cancer]

In support of these views, few participants anticipated that they would be unlikely to use an app as they preferred traditional methods to gather information, such as asking a nurse or friend. Some participants also anticipated that a minority of patients would favor an avoidant coping approach and only want minimal information to minimize their anxiety:

Do you think if you had a Smartphone or tablet that you would use, or try to learn to use the app? [Interviewer]

Probably not, I would probably still ring the nurses. [P10; 66-75 years, other cancer]

I can't have enough information, but I know from my experience people don't want a lot of information. [P5; 56-65 years, breast cancer]

Access to smart devices, in terms of cost or access to the internet, was also highlighted as a barrier by participants, though patients who did not own a smart device often had access to one via family or friends:

...The only barrier I can think of is that some people do not have any access to the Internet and I suppose that's something that you just have to accept, you know that's not a reason for not producing something, but that's the only barrier that I can see, in that people, there are people who don't have Internet access. [P13; 56-65 years, gynecological cancer]

Few participants were concerned about the accuracy of information sourced from an app; however, they suggested that future patients would be likely to trust an app if it was endorsed by their clinicians or affiliated with a reputable cancer charity. Similarly, some participants who were less familiar with smart technology were concerned about the confidentiality and security of personal information:

How reliable it is? For example, if you told me that the app had support or background from the cancer research, I would be more than happy to you know to look up anything that I would read, or that I would obtain from the app was accurate and that I could rely on, for me that would be "the" thing reliability, where it comes from, what's the basis, can I trust it personally? [P19; 36-45 years, breast cancer]

...As long as it keeps confidentiality, which is I think absolutely imperative, I mean certain things slip past the old uh marker at times, um, yeah I think that's generally that's the most important thing confidentiality is not in any way breached, you know. [P3; 66-75 years, colorectal cancer]

Discussion

Principal Findings

This is the first study, as far as we are aware, to explore the views of patients with cancer about an app that aims to help them meet their illness-related information needs in noninpatient settings. The primary aim of this study was to explore the value of an app for patients and to establish the type of app required and its potential outcomes. Suggestions for app features indicated the need for an app that supports patients to retrieve the information that they need from their short time in consultations, facilitates understanding, collates large amounts of information regarding available services, and helps patients to navigate through them. The potential benefits of this type of app included a more informed patient, improved quality of life, reduced anxiety, and increased confidence to participate in their care. The benefits appeared to outweigh the potential disadvantages, which were identified as increased anxiety and distraction in consultations. The anticipated barriers to app use included age and experience with smart technology, access to smart devices and the internet, an avoidant coping approach, and security and confidentiality of personal information.

Patients' desires for particular app features reflected their experiences of information gathering and understanding during and between consultations. First, participants suggested app features that would facilitate patients' self-management of their condition by providing detailed information on their condition. This type of information might also prevent hospitalizations [28]. Participants also suggested links to reliable websites to help them navigate the internet and source accurate information. As the internet is now a common health information resource, studies have highlighted the importance of guiding patients and educating them on how to filter accurate health information [29,30]. However, information needs vary throughout a patient's illness, as well as among patients with different types of cancers (eg, common vs rare cancers) and stages of a disease (eg, stage I vs stage IV). Although it would not be feasible to develop an app that includes all the possible information to fit all patients for all types and stages of cancer, the addition of a QPL, in which patients could add their own specific questions to ask their clinician during consultations, would enable an app to facilitate more personalized care that meets the individual needs of each patient.

Second, patients suggested app features to enable them to overcome barriers to communication in consultations. For example, a QPL might help patients to remember to ask important questions. Reviews of the use of paper-based QPLs for cancer consultations have suggested small but positive effects on communication, question asking, and information recall [31,32]. A glossary of cancer terms was also suggested in the hope of enabling patients to develop a better understanding of cancer-related information.

Finally, patients highlighted other negative consequences of a cancer diagnosis, such as financial and psychological issues, and suggested that an app could provide information on the available cancer services for patients to raise awareness of and signpost them to relevant support. Similarly, patients suggested to include a feature than enables contact with other patients for emotional support. This finding is consistent with previous studies on the benefits of social support during cancer [33].

The most commonly anticipated outcome of this type of intervention was a more informed patient, which, in turn, was expected to lead to a range of other benefits, such as increased quality of life, reduced anxiety, and increased confidence to participate in their care. Previous studies have provided evidence for these types of benefits because of improved communication with clinicians in consultations and increased access to information outside of consultations [34-36]. Suggestions that this type of app might increase users' knowledge of their condition, and participation in consultations, might indicate that this type of app has the potential to increase patients' levels of activation [37].

Some participants in this study expected that older patients would be less likely to use an app, and consistent with these expectations, few older patients in the study thought they would not use an app, and instead preferred more traditional methods of information gathering. In contrast to these expectations, studies show that many older patients are willing to learn to use new technology if they think that it will benefit them [38,39]. Other perceived barriers to app use included access to smart devices, the perceived reliability and security of information, and an avoidant coping approach. Access to smart devices is likely to be a temporary barrier, as ownership of smart devices is increasing rapidly in the United Kingdom across all demographic groups [40]. Furthermore, affiliation with a reputable organization and development of an app that does not require personal information will reduce concerns about reliability and security of information. A minority of participants appeared to have an avoidant coping style and therefore anticipated that they would not want to learn more about their illness. However, other features, such as links to information on psychological support, might still be of use for this group of patients.

Finally, two potential disadvantages of using this type of app were suggested including increased patient anxiety and distraction in consultations, potentially leading to poorer communication with clinicians. The risks of these potential consequences may be minimized by including only reputable information resources and avoiding active engagement with the app during communication in consultations (ie, use as a reference and not to type notes). Overall, the anticipated benefits of this type of intervention appeared to outweigh the potential disadvantages.

Implications

This study presented novel findings on the preferences of patients with cancer regarding the development of an app to help meet illness-related information needs, including the potential outcomes and benefits of this type of intervention. These findings can be used to develop intervention objectives and inform the selection of app features [21]. For example, based on patients' views reported in this study, the objectives of the intervention might be to facilitate the development of patients' understanding and self-management of their condition, and it is anticipated that this could be achieved by including the

following app features that enable patients to (1) gather, exchange, and understand information during consultations with their clinicians, (2) access and navigate reliable cancer information resources on the internet, and (3) identify and access patient services that will provide further information and support where needed (such as social support). This study also identified the potential disadvantages of, and barriers to, this type of an app, and these findings can be considered during app design to optimize its uptake, usability, and usefulness [21]. For example, patients suggested that lack of access to the internet might prohibit app use for some, and so a design objective could be to design an app that may be used offline, without an internet connection. Similarly, to circumvent some patients' worries about the security and confidentiality of the app, a further design objective could be to design an app that does not require the input of identifiable or personal information, such as names and addresses.

Limitations

The varied sample of patients is a strength of this study; however, there are several limitations to consider. The study had a low response rate, included high numbers of smart technology owners, and most participants had higher educational levels. Additionally, information on the key characteristics of those who declined to participate was not collected, and the different cancer sites had varying response rates. The lowest response rate was from patients with urological cancer. Owing to these limitations, the sample may have included those with more favorable perceptions of an app. Those who declined to participate may have not been familiar with smart technology or disliked the idea of an app for patients with cancer. Similarly, patients who do not own smart technology were likely to be less familiar with it and may therefore have had more negative perceptions about this technology. The low response rate from patients with urological cancer and a fairly low response rate from patients with breast and gynecological cancers might indicate differences in opinion between cancer sites. For example, patients with urological cancers are more likely to be older male patients, and studies have shown that this population group is less likely to engage in health information-seeking and other related Web-based activities [41].

A further limitation of this study is that all participants were white Caucasian. Although some studies suggest little evidence for a digital divide by race or ethnicity [41], some report that black and ethnic minority groups, such as African American and Chinese, may have different experiences of cancer and use different information sources, and may therefore have different needs and preferences regarding an app [42,43].

Providing examples of types of app features that could be used by patients with cancer before beginning the interview might have influenced some participants' responses owing to social desirability. The risk of this bias was minimized as the interviewer explained that all opinions were valued, both positive and negative, to develop an app that would be most useful for future patients.

Finally, participants were asked to reflect on a hypothetical scenario where an app could be available for them to use during their illness. Participants were also asked to anticipate *potential* benefits and disadvantages of, and barriers to, a hypothetical app. As a result, the data are not necessarily grounded in concrete experiences and therefore may not translate into engagement.

Conclusions

This study is the first to explore the preferences of patients with cancer regarding an app that aims to help them meet their illness-related information needs in noninpatient settings. Participants highlighted types of app features that they would find useful, specifically an app that would enable patients to develop an understanding of and subsequently self-manage their condition, including features to support information exchange and understanding in consultations and features to increase access to support for patients. The potential outcomes of this type of an intervention were highlighted, and the benefits of an app appeared to outweigh the few possible disadvantages and barriers to app use.

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Authors' Contributions

RR, PK, KB, JS, and FW were responsible for the concept, design, and conduct of the study. RR was responsible for data collection and analysis, as well as manuscript preparation. FW was responsible for double coding a subset of interview data. FW, PK, and KB reviewed the manuscript drafts. All authors approved the final version of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Topic guide.

[PDF File (Adobe PDF File), 80KB - mhealth_v7i7e14187_app1.pdf]

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Abbreviations

CNS: cancer nurse specialist
NHS: National Health Service
QPL: question prompt list

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Original Paper

Exploring the Impact of a Mobile Health Solution for Postpartum Pelvic Floor Muscle Training: Pilot Randomized Controlled Feasibility Study

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Abstract

Background: The postpartum period is a vulnerable time for the pelvic floor. Early implementation of pelvic floor muscle exercises, appropriately termed as pelvic floor muscle training (PFMT), in the postpartum period has been advocated because of its established effectiveness. The popularity of mobile health (mHealth) devices highlights their perceived utility. The effectiveness of various mHealth technologies with claims to support pelvic floor health and fitness is yet to be substantiated through systematic inquiry.

Objective: The aim of this study was to determine the acceptability, feasibility, and potential effect on outcomes of an mHealth device purposed to facilitate pelvic floor muscle training among postpartum women.

Methods: A 16-week mixed methods pilot study was conducted to evaluate outcomes and determine aspects of acceptability and feasibility of an mHealth device. All participants received standardized examination of their pelvic floor muscles and associated instruction on the correct performance of PFMT. Those randomized to the iBall intervention received instructions on its use. Schedules for utilization of the iBall and PFMT were not prescribed, but all participants were informed of the standard established recommendation of PFMT, which includes 3 sets of 10 exercises, 3 to 4 times a week, for the duration of the intervention period. Quantitative data included the measurement of pelvic floor muscle parameters (strength, endurance, and coordination) following the PERFECT assessment scheme: Incontinence Impact Questionnaire scores and the Urogenital Distress Inventory (UDI-6) scores. Aspects of acceptability and feasibility were collected through one-to-one interviews. Interview transcripts were analyzed using Thorne's interpretive description approach.

Results: A total of 23 women with a mean age of 32.2 years were randomized to an intervention group (n=13) or a control group (n=10). Both groups improved on all measures. The only statistically significant change was the UDI-6 score within both groups at 16 weeks compared with baseline. There was no statistically significant difference between the intervention group and control group on any outcomes. Most participants using the iBall (n=10, 77%) indicated value in the concept of the mHealth solution. Technical difficulties (n=10, 77%), a cumbersome initiation process (n=8, 61%), and discomfort from the device (n=8, 61%) were reasons impeding intervention acceptability. Most participants (n=17, 74%) indicated that the initial assessment and training was more useful than the mHealth solution, a tenet that was echoed by all control group participants.

Conclusions: Our pilot study demonstrated the potential for mHealth solution–enhanced PFMT in the early postpartum period. Usability issues in hardware and software hindered feasibility and acceptance by the participants. Our findings can inform the redesign of mHealth solutions that may be of value if acceptability and feasibility issues can be overcome.

Trial Registration: ClinicalTrials.gov NCT02865954; https://clinicaltrials.gov/ct2/show/NCT02865954

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KEYWORDS

postpartum; pelvic floor; mobile health; feasibility study; wireless technology; wearable technology; computer games; biofeedback

Introduction

The postpartum period is a vulnerable time for the pelvic floor [1]. Dysfunction of the pelvic floor musculature is associated with urinary and fecal incontinence, pelvic organ prolapse, and lumbopelvic pain [2-8]. Prevalence data vary; however, approximately 23% of postpartum women report either urinary or fecal incontinence [9].

Urinary incontinence represents the most prevalent issue and can be associated with reduced quality of life and mental health sequelae, such as depression and anxiety [10-14]. Stress urinary incontinence is defined as the involuntary loss of urine on effort or physical exertion, including coughing or sneezing [15]. It is associated with pregnancy, labor management, and birth and often manifests in the postpartum period [16-18].

Pelvic floor muscle training (PFMT) denotes individually tailored pelvic floor muscle rehabilitation programs aimed at restoring the fitness and function of the pelvic floor and associated deep core musculature. Early implementation of PFMT in the postpartum has been advocated based on 2 rigorously conducted reviews confirming prevention and correction of urinary incontinence through pelvic floor rehabilitation [19,20]. Research supports postpartum care to include basic evaluation of the pelvic floor musculature and associated education as well as feedback to ensure the correct performance of pelvic floor muscle exercises, namely PFMT [21,22]. PFMT can be effectively initiated with brief instruction through digital palpation of the pelvic floor muscles as associated feedback related to the muscle contraction completed [21]. It is established that, in the absence of providing adequate instruction and biofeedback, it is difficult for women to accurately perform pelvic floor muscle exercises [23,24]. Existing literature suggests that best practices for the prevention and management of pelvic floor dysfunction are not routinely implemented [25,26]. There is no universally accepted protocol for the initiation of PFMT in the postpartum period. This represents a research-practice gap in optimizing pelvic floor health in the postpartum period and beyond.

A proactive approach to pelvic health is needed as are strategies to overcome barriers contributing to this research-practice gap. Mobile health (mHealth) solutions may provide strategies to close the gap. mHealth solutions are defined by the World Health Organization [27] as the “medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants, and other wireless devices” [27]. The current market for mHealth technologies is growing, including applications marketed for pelvic floor rehabilitation and fitness [28-31]. These mHealth technologies may represent innovative modalities to support pelvic floor muscle fitness. Claims and proposed benefits of these mHealth solutions, compared with standard care, are based on concepts and have not been substantiated by scientific investigation. Overall, the body of evidence on the effectiveness of mHealth technology is, in general, weak [32].

This pilot randomized controlled study aimed to evaluate the feasibility and acceptability of an mHealth solution (iBall) as a rehabilitation tool to support PFMT efforts in the early postpartum period. The iBall is a device that, upon insertion into the vaginal canal, can detect the strength and muscular endurance of pelvic floor muscles. The results are displayed in the accompanying mobile app that incorporates various training routines and gaming options. It aims to encourage both adherence to and improvement of outcomes of PFMT. Specifically, we sought to assess the feasibility, acceptability, and effectiveness of outcomes of an mHealth device (iBall) compared with PFMT instruction alone in the early postpartum period.

Methods

Sample and Recruitment

Women in the third trimester of pregnancy, attending local midwifery practices, were invited to participate in the study. Posters were used to facilitate recruitment. All initial study procedures took place in the early postpartum period (within the fourth trimester, the first 13 weeks postpartum). Following initial screening and confirmation of eligibility, participants were prospectively randomized to an mHealth-assisted PFMT intervention or PFMT instruction only (Figure 1). The study was approved by the Hamilton Integrated Research and Ethics Board.

Intervention

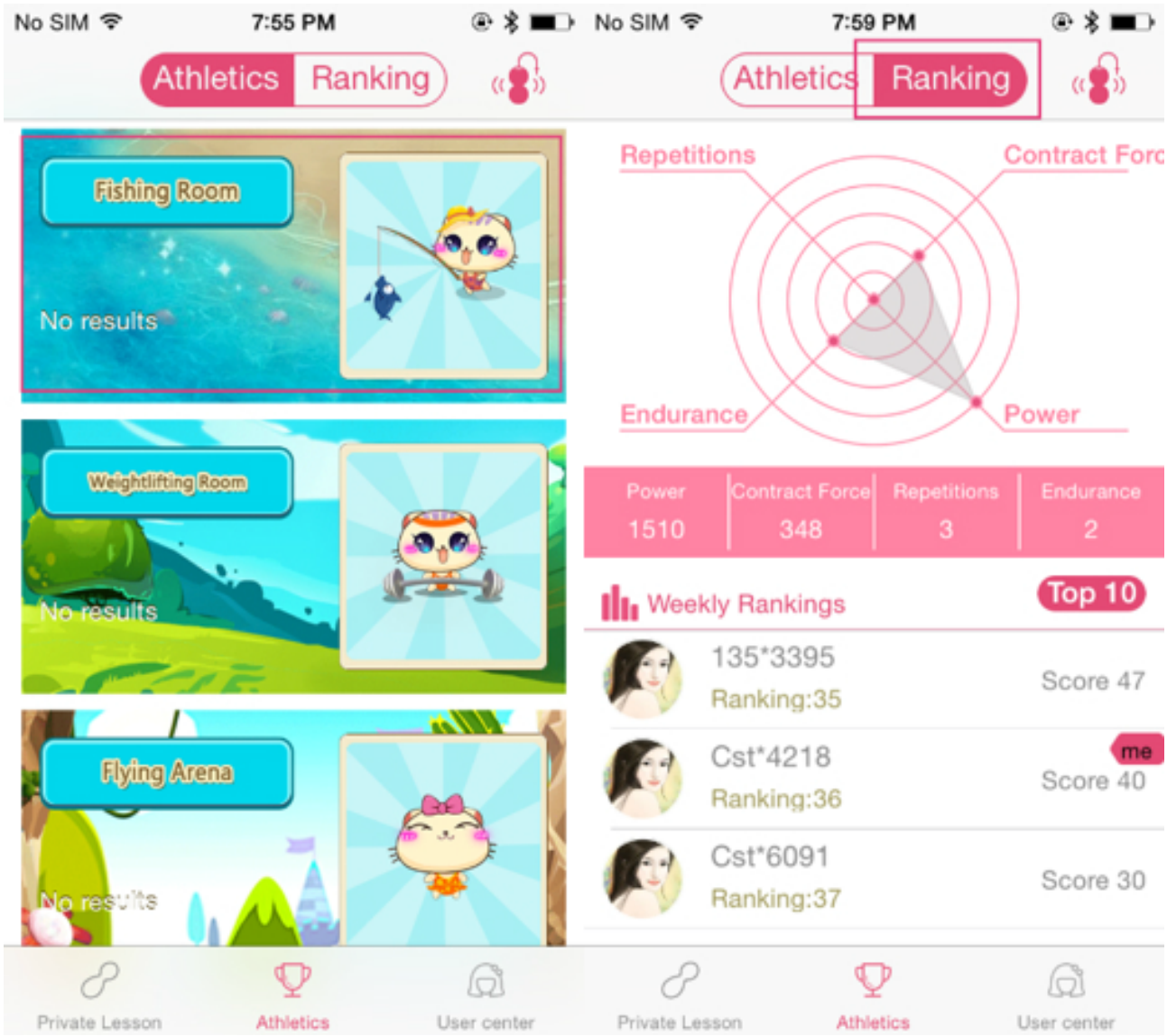
The iBall (ChunShuiTang Co Ltd) is an interactive mHealth device designed to facilitate PFMT. The iBall device is a US Federal Communications Commission–certified [33] and European Conformity–marked [34,35] device that, upon insertion into the vaginal canal, can detect the strength (power generation) and associated muscular endurance of pelvic floor muscles. Currently, iBall has been approved for consumer use in Europe and China. This information detected from the sensors within the device are transmitted via Bluetooth to a smartphone app that guides users in various exercise programs. The device is shown in Figure 1. It comprises 2 spherical compartments and a Bluetooth antenna for wireless communication with the smartphone. The whole device including the antenna is encapsulated in waterproof medical grade silicone casing. The battery and charging circuit are in the top spherical compartment with a waterproof charging port in the silicone encapsulation.

Figure 1. The mHealth iBall device. The iBall device consists of a Bluetooth antenna that sits outside of the body and 2 spherical compartments containing a battery and biofeedback sensor that sits within the vaginal canal.

The sensor and biofeedback motors are in the bottom compartment, which also contains a power button under the silicone casing. The user can press and hold the power button to turn on/off the device. The antenna also serves as a handle to push in and pull out the device from the vaginal canal. In this study, each participant in the intervention group will receive an iBall device along with an already paired smartphone (iPhone 5e) with the mobile app installed and tested with the device. Both the iBall device and the smartphone were originally fully charged, and power will last a few days depending on usage level. They both require periodic charging by the participants at home during the study period. Once inserted, the user has several interactive games or activities to choose from on the corresponding app on their smartphone (Figure 2). Their progress can also be tracked, both as a score in the game and as a measure of power, endurance, repetitions, and contracting force (Figure 2).

These quantitative results are saved with a time stamp in the mobile app. The data can also be automatically uploaded to an encrypted cloud storage server through an *opt in* option. In this study, the participants have consented to upload their usage data for the study with the uploading feature enabled. Each user's study smartphone app has already been configured with a unique randomly generated user account and log-in credential. Only the research team has a securely saved lookup table linking the user account and the identity of the participants. The cloud-stored data can be downloaded as structured data files (in American Standard Code for Information Interchange format) for further analysis. The original consumer product has a Web-based profile function allowing the users to access their data on the cloud server and interact (by users' choice) with other users in a Web-based community. This feature is only available in Chinese and was permanently disabled in the clinical study version of the smartphone app. As a result, although the device and app have the capability of Web access to their usage data and interacting with other users, such functionalities were disabled in devices used in this study. The iBall device is currently marked as a consumer electronics gaming device. Some quantitative results (eg, *power* or *contracting force*) are not calibrated for absolute pressure measurements. The results of metrics obtained from the devices are not included in this study.

Figure 2. The iBall App. Left: There are a number of activities that aid in engaging the pelvic floor. Right: The progress of the user can be tracked and monitored.



Research Design

This study was done in a 1:1 allocation ratio using random number assignments. Allocations were placed in sealed envelopes that were opened after the initial physical assessment at the time of randomization. Women having a vaginal or cesarean birth within 21 weeks of delivery were included. To maximize generalizability, the exclusions were made based on the individuals' inability to understand and read English and direction from their caregivers to not insert anything into their vagina.

An initial phone screening was conducted by a research assistant. Interested and eligible participants then met with a research assistant for further discussion and to obtain informed consent. The start time of the intervention took place in the early postpartum period, primarily during the fourth trimester (from week 6 postpartum to week 13 postpartum). The baseline characteristics of the participants have been provided in Table 1.

Subjects were then assessed by one of the expert assessors (SD and DF). The assessment included completion of 2 self-report outcome measures and a digital pelvic floor examination, inclusive of initiating PFMT by one of the 2 assessors. The 2 validated self-report measures that were administered were the Urogenital Distress Inventory (UDI-6) [36] and the Incontinence Impact Questionnaire (IIQ-7), which are shown in Table 2. The pelvic floor muscle examination followed the PERFECT scheme [8]. Clinically relevant changes in the PERFECT score was predetermined as an improvement of 20% based on previously published minimal clinical improvement thresholds (Table 3) [37].

Following assessment, subjects received their randomization allocation. Subjects randomized to the iBall group received additional instruction and training from the research assistant. Follow-up assessments were completed by the same assessors (SD and DF). A consistent process for assessment procedures including cueing during the pelvic floor muscle testing and instruction for the performance of pelvic floor exercises was established. All participants received instruction for the correct

performance of pelvic floor muscle exercises via digital palpation. Schedules for utilization of the iBall and PFMT were not prescribed, but all participants were informed of the standard established recommendation of PFMT, which includes 3 sets of 10 exercises, 3 to 4 times a week, for duration of the intervention period [38]. Neither assessor was at any time, during the conduct of the study, aware of which group a subject was allocated.

Participants randomized to the intervention group received additional instruction on how to use the mHealth solution (iBall) by a research assistant. Participants were shown how to use the device and were familiarized with the associated app on the associated smartphone. Maintenance was informed as per manufacturers recommendations, which involved washing the device with warm water and a natural soap and storing it in the case it came in. Participants then used the device according to their own schedule (eg, when to exercise, frequency, and how long). The PFMT with iBall occurs within the context of playing a variety of games. Participants in the intervention group received a *booster session*, midway through the intervention period. This booster session consisted of an email sent by a research assistant reminding participants of features of the *iBall* and benefits of postpartum pelvic floor muscle exercise as a means of self-management support. The use of booster sessions to facilitate self-management support has been shown to be a useful procedure in rehabilitation interventions [40]. Quantitative measures were obtained at baseline and following 16 weeks of treatment. The duration of treatment was chosen based on the existing literature using 12 or more weeks as a reasonable therapeutic window [41,42]. As this was a pilot study, a convenient sample size of 23 was selected. This size appeared reasonable, given other comparison studies of PFMT [43].

Table 1. Baseline characteristics and participant demographics.

Category	iBall, n (%)	Control, n (%)
Age (years)		
26-30	5 (21.7)	1 (4.3)
31-36	5 (21.7)	5 (21.7)
Unknown	3 (13.0)	4 (17.4)
Number of deliveries		
1	6 (26.1)	1 (4.3)
2	6 (26.1)	6 (26.1)
3	0	1 (4.3)
4	1 (4.3)	0
Unknown	0	2 (8.7)
Weeks postpartum		
<7	2 (8.7)	2 (8.7)
7-14	10 (43.5)	7 (30.4)
>14	1 (4.3)	0
PERFECT[a] score		
Power (<3/5)	2 (15.4)	4 (40)
Endurance (<6/10)	5 (38.5)	5 (50)
Repetition (<6/10)	7 (53.8)	7 (70)
Fast (<6/10)	6 (46.2)	6 (60)
Coordination (No)	6 (46.2)	6 (60)
Timing (No)	4 (30.8)	4 (40)

[a]PERFECT is an acronym where P is power or pressure, E is endurance, R is repetitions, F is fast contractions, and ECT is every contraction timed. The scheme was developed to simplify and clarify pelvic floor muscle assessment [8].

Table 2. Baseline characteristics and participant demographics: urogenital distress inventory and Incontinence Impact Questionnaire scores.

Category	iBall		Control	
	Mean	Range (SD)	Mean	Range (SD)
Age (years)	31	26-34 (2.7)	34	29-36 (2.2)
UDI[a]-6	18.9	0-47 (11.5)	25.4	0-54 (15.9)
IIQ[b]-7	8.1	0-50 (15.6)	7.4	0-28 (11.4)

[a]UDI: Urogenital Distress Inventory.

[b]IIQ: Incontinence Impact Questionnaire.

Table 3. Operational definitions and psychometric properties of outcome measures.

Assessment, references, and description of procedure	Interpretation	Reported psychometric properties
UDI[a]-6 [36]		
Designed to assess the degree to which symptoms associated with incontinence are troubling. The weight of accumulated evidence suggests that the both the UDI long and short forms are validated.	Symptoms scored according to self-rated severity.	Internal consistency=0.52; Correlation with long version=0.87
IIQ[b]-7 [36]		
Designed to assess the impact of urinary incontinence on activities and emotions. The weight of accumulated evidence suggests that both the UDI long and short forms are validated.	Symptoms scored according to self-rated severity.	Internal consistency=0.84; Correlation with long version=0.95
PERFECT score [8,39]		
P—power, using the Modified Oxford grading scale: 0-no contraction; 1-flicker; 2-weak squeeze, no lift; 3-fair squeeze, definite lift; 4-good squeeze with lift; 5-strong squeeze with a lift; Positive test: <4/5	Pelvic floor muscle strength	Kappa=0.48-0.77
E—endurance, the time (in seconds) that a maximum contraction can be sustained; Positive test: <10 seconds	Pelvic floor muscle endurance	Kappa=0.17-0.56
R—repetition, the number of repetitions of a maximum voluntary contraction; Positive test: <10 repetitions	Pelvic floor muscle endurance	Kappa=0.48-0.77
F—fast contractions, the number of fast (1 second) maximum contractions; Positive test: <10 repetitions	Pelvic floor muscle responsiveness	Kappa=0.29-0.65
ECT—timing-sustained voluntary contraction of the pelvic floor muscles with a cough; Positive test: no contraction of pelvic floor muscles before cough [35]	Pelvic floor muscle coordination	Kappa=0.14-0.53

[a]UDI: Urogenital Distress Inventory.

[b]IIQ: Incontinence Impact Questionnaire.

All quantitative data were inputted into an Excel spreadsheet (version 2017) for analysis. Data were cleaned and checked for out-of-range values, skip pattern problems, and duplicates. Tests of normality were completed to determine appropriateness of statistical methods. Analyses were performed using an intention-to-treat basis. All statistical tests used 2-sided tests at the .05 level of significance. Descriptive analyses of participants' characteristics and feasibility of the intervention were expressed as a mean (standard deviation) or median (minimum-maximum) for continuous variables and count (percent) for categorical variables. Changes in outcomes over time were examined using paired *t* tests for continuous variables and Fischer exact test for categorical variables.

In addition to repeating all baseline assessments, the postintervention assessments required additional data collection from both groups to determine the implementation outcomes of acceptability and feasibility of the intervention (Table 4).

The PFMT instruction only (control) group answered 3 self-administered questions.

1. Are you having any problems that you attribute to your pelvic floor needing rehabilitation (urinary or fecal incontinence, pelvic or lower back pain, painful intercourse, or pelvic pressure)?
2. Consider the last few months since your baseline assessment, is there anything that you think might have been useful to enhance your physical postpartum recovery?
3. If you had the opportunity to use a mobile health app designed to assist with PFMT (eg, iBall), would you want to try it?

Aspects of acceptability and feasibility were collected through one-to-one interviews. Interviews were conducted by one of the 2 study assessors (SD and SD); transcripts were analyzed using Thorne's interpretive description approach [44]. The larger purpose of this study was to seek an in-depth understanding of

the mHealth solution studied, such as to inform clinical practice. This included assessment of the interventions' perceived effects, barriers, and facilitators to implementation and strategies to implementing this approach to care. Participants in the intervention group were asked the following questions:

1. Tell me about your experiences using the iBall device?
2. What aspects of iBall were the most useful or helpful?
3. Which aspects of iBall were least useful or helpful?
4. Are there any changes you would make to the iBall device or app?
5. If you had to explain iBall to a friend, what would you say?
6. Would you recommend it to a friend? Why or why not?
7. Do you plan on continuing to use iBall at this time? Why or why not?
8. Would you consider using iBall again in the future?

Table 4. Description of implementation outcomes.

Outcome	Measures	Mode of analysis
Acceptability: A willingness to receive the offered intervention	Enrollment rate; attrition/retention rate; engagement/adherence rate	Research log: enrollment, follow-up and engagement tracking; analytics data; qualitative data
Feasibility: The capability to carry out intervention activities	Training of the interventionists; delivery of the program; outcome capture; perceptions of barriers and facilitators	Research log: enrollment, follow-up and engagement tracking; analytics data; qualitative data

Content analysis, following interpretive qualitative description, of participants' responses was used to analyze the qualitative data. The investigators systematically reviewed all transcripts and inductively generated a list of codes by hand. The codes were grouped into categories and then collapsed further into broader themes [44].

Results

A total of 23 participants were enrolled in the study. Of them, 13 were randomized to the iBall intervention group and 10 to the PFMT instruction group. Baseline characteristics were similar for both groups (Table 1).

Regarding implementation outcomes, which is the primary focus of this study, we found that, in its current form, the mHealth solution was not found to be superior to basic PFMT instruction alone (Table 5). A number of technical and logistical factors were found to hinder both the acceptability and feasibility of the mHealth intervention studied. A total of 15 categories emerged out of the qualitative analysis (Table 5), which were collapsed into 3 broader themes: (1) iBall represents an acceptable concept to support PFMT; (2) the steps involved in using iBall hinder the acceptability; (3) technology issues of this iBall are many but can be overcome.

There was no statistically significant difference between the groups for change scores (ie, 16-week score minus baseline score) for any measure (Table 6). The predetermined clinically relevant difference in PERFECT score of 20% was not achieved. Both the intervention and the standard care groups showed improvement on all outcome measures: PERFECT criteria, UDI-6, and the IIQ-7 at 16 weeks compared with baseline (Table 5). The UDI-6 score was the only outcome that achieved statistical significance in both groups.

Table 5. Pre- and postintervention measurements within group results.

Measurements	iBall (n=13)				Control (n=10)			
	Pre (SD)	Post (SD)	*P* value	95% CI	Pre (SD)	Post (SD)	*P* value	95% CI
UDI-6[a,b]	18.9 (11.5)	7.3 (5.9)	.009	—[c]	25.4 (15.9)	4.6 (6.0)	.004	—
IIQ-7[b,d]	8.1 (15.6)	3.7 (5.6)	1.00	—	7.4 (11.4)	3.2 (8.4)	.36	—
PERFECT score[e]								
Power <3/5	2 (1.3)	0 (1.5)	.27	0.03-5.25	2 (0.7)	1 (0.7)	.24	0.02-4.91
Endurance <6/10	2 (2.7)	0 (1.9)	.27	0.03-5.25	0 (0.7)	0 (1.4)	>.99	0.05-20.83
Repetitions <6/10	7 (3.1)	2 (3.7)	.07	0.01-1.32	3 (2.8)	3 (2.3)	.49	2.32-6.08
Fast <6/10	5 (2.7)	7 (2.9)	.051	0.02-6.35	3 (4.0)	2 (2.0)	.53	0.04-5.58
Coordination: Yes	6	6	.33	0.05-2.77	1	4	.06	0.04-1.52
Timing: Yes	6	6	1.00	0.17-6.00	1	4	.20	0.01-2.82

[a]UDI: Urogenital Distress Inventory.

[b]*P* value calculated through the Mann-Whitney *U* test.

[c]Not applicable.

[d]IIQ: Incontinence Impact Questionnaire.

[e]iBall and control PERFECT scores are mean difference values. *P* values are calculated through Fisher exact test.

Table 6. Postintervention measurements results between the iBall and the control groups.

Measurements	iBall (n=13), mean (SD)	Control (n=10), mean (SD)	*P* value	95% CI
UDI-6[a,b]	7.3 (5.9)	4.6 (6.0)	.28	−8.29 to 2.89
IIQ-7[b,c]	3.7 (5.6)	3.2 (8.4)	.50	−7.21 to 6.21
PERFECT score[d]				
Power>1	2 (0.7)	4 (1.3)	.09	0.06 to 3.17
Endurance>2	6 (0.7)	6 (2.7)	.60	1.41 to 4.53
Repetitions>2	5 (2.8)	3 (3.1)	>.99	0.32 to 11.8
Fast>2	7 (4.0)	4 (2.7)	>.99	0.45 to 15.3
Coordination: Yes	3	2	>.99	1.95 to 11.5
Timing: Yes	1	2	.24	0.03 to 5.88

[a]UDI: Urogenital Distress Inventory.

[b]*P* value calculated through the Mann-Whitney *U* test.

[c]IIQ: Incontinence Impact Questionnaire.

[d]iBall and control PERFECT scores are mean difference values. *P* values are calculated through Fisher exact test.

Discussion

Principal Findings

The results of this randomized controlled pilot study do not support the use of the studied mHealth device in its current form when compared with PFMT instruction alone using the chosen quantitative measures. Although most participants indicated that the concept of the mHealth solution has potential, technical difficulties and a cumbersome setup were the primary themes that emerged impeding the intervention's acceptability. Only 2 of the 11 participants would recommend the mHealth solution to a friend, although 7 would consider recommending with modifications. Only 2 participants would consider using it again in the future (Table 7). Analytics data combined with interview data highlighted the lack of adherence to the intervention protocol. Technical issues related to the mHealth solution function hampered use. Consequently, we were unable to demonstrate increased motivation and adherence when using this mHealth solution.

Although there was improvement in both groups, there was no statistically significant difference between groups. The development of pelvic floor dysfunction involves a complex process involving a multifactorial etiology manifesting in the perinatal period [45]. We found that both groups achieved satisfactory pelvic floor health at the end of the 16-week intervention period. Level 1a evidence recommends the commencement of proper pelvic floor exercises in the early postpartum period, confirmed through a digital vaginal examination [21]. We implemented this recommendation across both control and intervention groups and both groups appeared to benefit.

The lack of implementation and adherence to PFMT protocols in the early postpartum period translates to a large proportion of women (92%) continuing to have urinary incontinence 5 years postpartum if their incontinence was not resolved by 12 months postpartum [46]. Furthermore, 44.6% of women have been found to have incontinence 5 to 7 years postpartum [47]. These statistics are problematic considering that only a small proportion of women seek medical care for incontinence [48]. Our study results highlight the potential opportunity for enhanced pelvic floor muscle restoration and fitness development through more consistent implementation of postpartum PFMT.

Although the efficacy of PFMT is clearly established, the effect of adjunctive approaches is yet to demonstrate additional benefit. The International Consultation on Urinary Incontinence, a rigorous international committee-led review and analysis of the most up-to-date literature concluded that adjunctive pelvic floor muscle therapies such as biofeedback and electrical stimulation were not superior to supervised PFMT [49]. Many mHealth devices are available for use, and although they are designed to overcome some of the barriers inherent in traditional PFMT adjunctive technologies, few have been appropriately studied. A recent randomized controlled pilot study conducted to compare the Vibrance Kegel Device with a standard PFMT program suggested an added benefit to this mHealth solution [50].

The growing appeal of mobile solutions for health promotion and health care delivery can be attributed to the accessibility of the technology and the level of personalization that the technology enables [51]. Studies have shown that mHealth interventions have the potential to support successful management of chronic health conditions and associated health behavior change through (1) improving patient self-monitoring and management [52,53], (2) informing health care professionals of patients' health status [54,55], and (3) tailoring care and education to patient needs [56-58].

Table 7. Qualitative findings.

Perspective	Agreement, n (%)	Supporting quotes
The concept of a device to help rehabilitation of your pelvic floor through biofeedback is good	10 (73)	"As a busy mom I find I am too busy to be going to appointments, so this allowed me to get the help I needed without going to appointments" (1001); "The concept is really good, it's just that with a baby and a toddler time was my barrier" (1015); "I mean the premise of having a game to strengthen the pelvic floor made it intriguing" (1005)
The biofeedback was helpful	4 (31)	"When it was working it was helpful to have the feedback; I liked knowing how the pelvic floor was working" (1023); "I liked how on the strengthening aspect graded the strength of the contraction, that was cool visual feedback" (1005)
The biofeedback was not helpful (inconsistent/inaccurate)	8 (61)	"It didn't' reliably work so that really did not justify the effort in using it. It is not motivating using a device that is unreliable" (1002); "I was trying to squeeze as hard as I could and it just was not registering (1017)
Tracking my progress was a helpful feature	2 (15)	"Seeing your score and being able to keep track of your score so that you were working towards something was motivating. The other part was being able to see other peoples scores, that helped to give you a sense of where you ranked in comparison to other people. That was motivating too or at least made it more enticing to want to play more" (1013)
Tracking my progress was not helpful (inconsistent/inaccurate)	7 (54)	"I found it really difficult to use it properly, some of the time it would say it was connected but then none of my resulted recorded" (1023); "I did find out that the results were not getting sent in for whatever reason so this was off putting and really made me not want to use it" (1011)
Instructions were easy to follow and the purpose, clear	3 (23)	"it was pretty self-explanatory and I felt like the instructions I was given here at the beginning of the study were really clear and straight forward" (1001)
Instructions were not straight forward and the purpose, unclear	7 (54)	"It was a confusing because with the games there were no instructions, it took me multiple attempts to try to figure out what I was doing" (1005); "The instructions on the game could have been more clear, I never knew what the goal was or how long I should be playing for" (1017).
The device and app motivated me to do pelvic floor exercises (facilitator)	4 (31)	"In particular, I found the strength game really motivating" (1011); "I tried different games; the games were interesting they were like video games" (1010)
The device and app made it more difficult to do pelvic floor exercises (barrier)	8 (62)	"The other thing I realized though is that when you have a baby it is a lot harder to use a device than it is to just do the kegels that were taught to you on your own" (1002); "The hassle of using the whole device was an issue, it was not as easy as just doing the [pelvic floor] exercises (1008); "The main barriers to using it was finding time to use it; needing privacy; and the cumbersome process to set it up" (1013)
Technical difficulties with the mHealth solution were an issue	6 (69)	"When I was trying to play the games I couldn't get any type of a score and it was frustrating because I didn't know if it was just a problem with the app or device or if I really was not getting any engagement of my pelvic floor" (1002); "The accuracy of how the device communicates with the definitely needs improvement" (1023)
The setup of the device and app was cumbersome (not *new mom* friendly)	8 (62)	"The fact that you have to set it up and lie down, get lubricant in order to use it – so set up and clean up doesn't mix well with the life of a busy mom who if constantly interrupted" (1015); "I was excited about it at first, but because it was too much work, a real hassle to get it set up, I didn't use it much" (1010)
The device was comfortable	5 (38)	"It was really easy to insert which was nice" (1011); "I found it comfortable and relatively user-friendly' (1015)
The device was uncomfortable	8 (62)	"I really haven't been using it – because it is big and frankly the idea of inserting it is not appealing, it took me 10 minutes to insert it" (1012); "I would make it [the device] more compact – it is big and not comfortable" (1008)
Optional positioning of the device was an issue	5 (38)	"but knowing the position of it – sometimes I wasn't sure if it was inserted too deep or too superficial" (1005); "Also, I did find slightly changing the position of the [device] really changed what the feedback indicated" (1023)
The mHealth solution was helpful when combined with a pelvic floor examination	4 (32)	"It is not useful to have this without having the assessment and some discussion with an expert' (1017); "I don't think a device like this would have much values at all if you didn't also at least have some type of follow up in person" (1013)
Instruction from the practitioner was more helpful than feedback from the device and app	9 (69)	"When I did the initial exam I found that really helpful here because I was never assessed like that before but I think I would have benefited from another appointment rather than just using the device" (1010); "I feel like I need proper pelvic floor physiotherapy as I feel like everything is too tight. so, I think that is really what I need, not a device like this" (1012)

The iBall is a dynamic and interactive mHealth solution that has the capacity to enhance PFMT. With the capacity to provide biofeedback, record data, and track progress, iBall has the potential to increase motivation and adherence. Furthermore, the iBall device and smartphone app have the capability of remote storage of usage data for record keeping and additional analysis. The Web-based data feature is designed for further gamification apps. Owing to research ethics app constrains (Hamilton integrated Research Ethics Board has concerns regarding data access), the Web-based interaction features were disabled in this study. Nonetheless, based on experiences from gamification of wearable fitness devices [59], we foresee that such an interactive design feature will generally improve user motivation and adherence.

Our study has highlighted several aspects that are important for mHealth solutions to be acceptable and feasible for pelvic floor rehabilitation in the early postpartum period. Convenience, user friendliness, reliable technology, accurate biofeedback, and user progress tracking were identified as being important features (Table 7). Effective mHealth solutions require consideration of the understanding and capabilities of end users (patients and practitioners) to use the technology [60].

End user engagement throughout the design and development processes help ensure that mHealth solutions are acceptable and feasible by fitting within the end user's context [61]. Our study results emphasize the need of end user input in the design of mHealth solutions for pelvic floor muscle function/dysfunction. Acceptability and feasibility need to be established before testing the efficacy of potential pelvic floor rehabilitation mHealth solutions in fully powered randomized controlled trials (RCTs).

A significant limitation of this study is the small sample size. We had challenges with both recruitment and follow-up. Both contributed to poor feasibility. The small sample size confers caution to interpreting the statistical findings. As we did not conduct a priori sample size calculations, the results should be considered exploratory. We acknowledge possible ceiling effects related to the outcome measures. The low burden of pelvic floor dysfunction at baseline and limitations related to the UDI-6 and IIQ-7 in the postpartum period resulted in poor discriminatory powers of the measurements. The UDI-6 and IIQ-7 are well-established psychometrically sound self-report questionnaires that were developed for symptomatic patients and not healthy women in the early postpartum period. A recent review of 33 urogynecology questionnaires confirmed that none target postpartum women and that tools specific to this population are needed [62].

This pilot trial was designed to establish feasibility and identify issues for such mHealth technologies to be used in future clinical applications. Our results have led to the identification of several issues in the current device technologies that prevent it from being used in a large-scale trial and potential future clinical use. We also identified potential solutions that were mostly related to redesigning the device for clinical therapeutic use rather than recreational applications. Such changes are easy to implement with little technological barriers. For a future clinical trial, we expect a minor redesigning of the hardware, a major revision of the software (ie, the iBall app), and adjustments to the intervention protocol to reduce loss to follow-up and potentially improve adherence.

Conclusions

This pilot study has demonstrated that an mHealth solution may be useful in supporting PFMT. The concept of the mHealth solution was acceptable. However, several usability issues in hardware and software hindered its feasibility and acceptance as a rehabilitation tool by the participants. The results from this study affirm the potential for mHealth solutions to support PFMT in the early postpartum period, particularly with redesigning that allows for enhanced technical literacy and accurate biofeedback. We also affirmed the benefit of recommended PFMT alone, which recommends instruction of correct pelvic floor exercises through digital palpation early postpartum. Established acceptability and feasibility parameters are needed before testing potential pelvic floor rehabilitation mHealth solutions in future in fully powered RCTs to determine efficacy of this modality.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

CONSORT - EHEALTH checklist (V 1.6.2).

[PDF File (Adobe PDF File), 112KB - mhealth_v7i7e12587_app1.pdf]

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Abbreviations

IIQ: Incontinence Impact Questionnaire
mHealth: mobile health
PFMT: pelvic floor muscle training
RCT: randomized controlled trial

UDI: Urogenital Distress Inventory

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Original Paper

A Combination of Indoor Localization and Wearable Sensor–Based Physical Activity Recognition to Assess Older Patients Undergoing Subacute Rehabilitation: Baseline Study Results

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Abstract

Background: Health care, in recent years, has made great leaps in integrating wireless technology into traditional models of care. The availability of ubiquitous devices such as wearable sensors has enabled researchers to collect voluminous datasets and harness them in a wide range of health care topics. One of the goals of using on-body wearable sensors has been to study and analyze human activity and functional patterns, thereby predicting harmful outcomes such as falls. It can also be used to track precise individual movements to form personalized behavioral patterns, to standardize the concept of frailty, well-being/independence, etc. Most wearable devices such as activity trackers and smartwatches are equipped with low-cost embedded sensors that can provide users with health statistics. In addition to wearable devices, Bluetooth low-energy sensors known as BLE beacons have gained traction among researchers in ambient intelligence domain. The low cost and durability of newer versions have made BLE beacons feasible gadgets to yield indoor localization data, an adjunct feature in human activity recognition. In the studies by Moatamed et al and the patent application by Ramezani et al, we introduced a generic framework (Sensing At-Risk Population) that draws on the classification of human movements using a 3-axial accelerometer and extracting indoor localization using BLE beacons, in concert.

Objective: The study aimed to examine the ability of combination of physical activity and indoor location features, extracted at baseline, on a cohort of 154 rehabilitation-dwelling patients to discriminate between subacute care patients who are re-admitted to the hospital versus the patients who are able to stay in a community setting.

Methods: We analyzed physical activity sensor features to assess activity time and intensity. We also analyzed activities with regard to indoor localization. Chi-square and Kruskal-Wallis tests were used to compare demographic variables and sensor feature variables in outcome groups. Random forests were used to build predictive models based on the most significant features.

Results: Standing time percentage (P<.001, d=1.51), laying down time percentage (P<.001, d=1.35), resident room energy intensity (P<.001, d=1.25), resident bed energy intensity (P<.001, d=1.23), and energy percentage of active state (P=.001, d=1.24) are the 5 most statistically significant features in distinguishing outcome groups at baseline. The energy intensity of the resident

room (P<.001, d=1.25) was achieved by capturing indoor localization information. Random forests revealed that the energy intensity of the resident room, as a standalone attribute, is the most sensitive parameter in the identification of outcome groups (area under the curve=0.84).

Conclusions: This study demonstrates that a combination of indoor localization and physical activity tracking produces a series of features at baseline, a subset of which can better distinguish between at-risk patients that can gain independence versus the patients that are rehospitalized.

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KEYWORDS

rehabilitation; frailty; remote sensing technology; wearable electronic devices; fitness trackers; monitoring ambulatory; smartwatches; bluetooth low energy beacons

Introduction

Background

According to the most recent census statistics, by 2050, the population aged 65 years and older is projected to double in size to 83.7 million in the United States [1]. With the increase of this geriatric population, health care utilization will increase dramatically, with a concomitant demand for rehabilitation and in-home care after hospitalization [2]. Finding the best way to support patients during rehabilitation, both at facilities and in home, without compromising patient safety is considered to be a significant challenge. The importance of patient safety and rehabilitation has highlighted the need for constant vigilance and fostered methodologies by which patients can be remotely monitored [2-8].

Numerous studies have investigated the effectiveness of remote patient health monitoring, some suggesting the potential for such technologies to reduce the overall re-admission cost [9]. With the advent of wearable devices in recent years, remote health monitoring has evolved and drawn attention, mainly by utilizing physical activity trackers. It is widely assumed that a physical activity regimen implies behavioral patterns that can affect health outcomes. Hence, tracking these patterns and leveraging them may allow the prediction of harmful outcomes, such as falls, in a timely manner. Moreover, tracking individuals' personalized behavioral patterns may allow for the creation of actionable messages to patients and caregivers to improve patient health and outcomes [10]. The purpose of this study was to investigate the physical activity and indoor localization features obtained from our remote patient monitoring system, Sensing At-Risk Population (SARP) [2,11-14]. This study reports on SARP sensor–based markers for rehabilitation screening within a geriatric population, exploring if SARP can be used to prospectively distinguish between at-risk patients in a subacute rehabilitation environment.

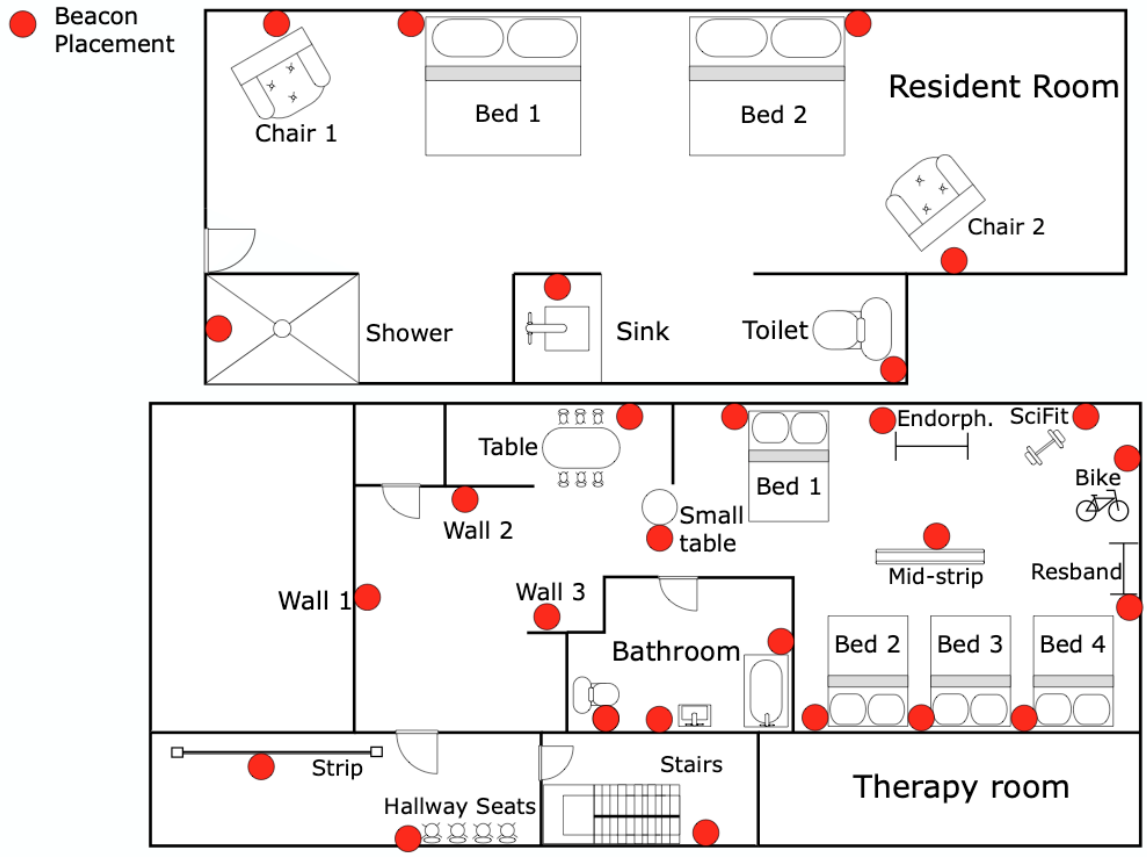
Sensing At-Risk Population System Overview

Details of the system architecture with proximity-based sensors (beacons) and a Bluetooth-enabled smartwatch as its main components can be found in the study by Moatamed et al [2] and the patent application by Ramezani et al [14]. Building models for physical activity tracking and indoor localization was based on data collected using (1) commercially available Sony SmartWatch 3 with built-in EM7180 ± 2 g triaxial accelerometer, 420 mA battery, and BCM43340 Bluetooth module and (2) proximity beacons (MCU ARM Cortex-M4 32-bit processor with floating-point unit). To build the activity tracking and indoor localization models of SARP system, patients were consented on admission to a subacute care rehabilitation center in Los Angeles.

Bluetooth Low Energy Beacons and Indoor Localization

Beacons broadcast their presence to Bluetooth-enabled devices. Utilizing the beacons' Received Signal Strength Indicator (RSSI) values using smartwatches, the SARP system calculates the proximity of the watch to each beacon, thereby inferring the indoor location of the patient wearing that watch. BLE beacons (bluetooth low-energy sensors) have become popular in gathering contextual awareness because of durability and low cost. When used in health care, however, validating reliability and accuracy of their location information is paramount. Beacons are highly susceptible to diffraction, multipath propagation, angle-of-arrival, lack of line-of-sight, and absorption by the human body. In this project, because locations of interest were within close proximity, we considered RSSI values ranged between −50 dBm to −100 dBm. The average RSSI within the line-of-sight, measured by the watch at 1 feet distance, was −66 dBm. To achieve the best accuracy with respect to locations of interest, shown in Figure 1, considering beacons hardware specification was crucial. Beacon's antenna configuration and the proximity of locations heavily influence the accuracy of indoor localization. Hence, to achieve a high indoor localization accuracy, it was essential to refine beacon placements iteratively. Moreover, in the rehabilitation facility shown in Figure 1, we empirically learned to set the transmission power to −12 dBm and the transmission interval to 250 ms. In studies by Bouchard et al [11-13], we proposed a few methods and considerations that can help enhance the indoor localization accuracies. A summary of the ground truth testing executed at the rehabilitation facility shown in Figure 1, with an overall accuracy >80%, can be found in a study by Moatamed et al [2].

Figure 1. Subacute rehabilitation facility map: resident room on top and therapy room at the bottom with locations of mounted beacons shown in red.



Accelerometer Data Processing and Physical Activity Parameters

To infer physical activity of patients in this study, 3-axis raw acceleration signal sampled at 16 Hz was extracted, and the signal magnitude (SM) was initially calculated according to Figure 2, equation 1, where *acc* indicates acceleration force around each axis in g units including gravity (1 g=9.81 m/s^2). The range of the acquired signal is ± 2g. Batches of 160 samples (window size of 10 seconds) were fed to a fifth order Butterworth band-pass filter with cut-off frequencies of 0.5 and 8 Hz. The filtering limited the signal to highlight the frequencies that are most representative of human motion while eliminating the direct current component. Various window sizes ranging from 4 to 12.8 seconds with different overlapping implementations have been used in different studies [15]. These characteristics are normally chosen empirically based on feature extraction, activity labeling, and other annotation factors. In this study, a window size of 10 seconds was used with a 1-second overlap [2]. After preprocessing the accelerometer data, the next step was to infer human activity (positioning) and to later translate the positioning into a quantifiable metric. However, quantifying the physical activity can be deemed challenging and will be discussed after a brief description of physical activity classification.

A decade has passed since the advent of commercially available low-cost, light-weight accelerometers. The enthusiasm about their potential in extracting physical patterns to usually, but not exclusively, improve health outcomes has led researchers to master the techniques of activity recognition [15,16]. Some researchers have even tried to infer activity intensities and predict energy consumption by comparing accelerometer patterns with measured metabolic equivalents [17-19]. Despite significant and impressive outcomes, the triumph is mostly based on analyzing small cohorts, or often a homogeneous group of people, with similar age or health conditions. Training and testing datasets in most studies are normally collated from people following a certain protocol, whereas in real life, human movements are intertwined, that is, the sequence of movements does not always form a same pattern. As such, the performance of various activity recognition algorithms/approaches applied to real-world scenarios should be taken with a grain of salt [15,16,18-20]. The following factors are influential in any human activity tracking algorithm: (1) diversity of human movement habits; (2) variety of human disabilities needing different assistive devices, yielding distinct movement patterns; (3) deficiencies of machine learning algorithms in building one-size-fits-all model; and (4) limitations to distinguish particular motions due to accelerometer placement, for instance, classifying sitting still and laying down with sensor on wrist versus waist [15,20]. To reduce the negative effect of the mentioned factors, this study uses a combination of classifications in 3 steps according to algorithm shown in Figure 3. Time and frequency domain characteristics of the signal (main, median, variance, skewness, kurtosis, peak frequency, and peak power) were used as features. SARP initially categorizes activities broadly into walking and stationary.

Figure 2. Equations. MAD: mean absolute deviation.

Number	Equation	Summary
(1)	$SM = \sqrt{acc_x^2 + acc_y^2 + acc_z^2}$	Signal Magnitude
(2)	$MAD = \frac{1}{N}\sum_{i=1}^{N=160} \lvert x_i - x_{ave} \rvert$	MAD of accelerometer magnitude signal
(3)	$d = v_0 t + \frac{1}{2} at^2 = \frac{1}{2}\ 0.02\ (10^2) = 1$	Hand displacement in 10 seconds when threshold on MAD = 0.02 m/s^2
(4)	$Time_{spent}(T\%)$	Time spent in *walking, sitting, standing, laying,* or in *locations of interest* (Table 3) divided by *uptime*
(5)	$energy_{intesity}(E)$	Energy spent in *walking, sitting, standing, laying,* or in *locations of interest* divided by their corresponding *time spent*. In addition to energy intensity spent at each location, we calculated the total energy intensity in *resident* room and *therapy* room. Energy intensity in resident room, (loc_{res_E}) is $\frac{\sum_i loc_{i_E}}{total\_time\_in\_res}$, where $loc_i \in$ resident room. Energy intensity for therapy room was similarly calculated
(6)	$energy_{percentage}(E\%)$	Total energy spent in *walking, sitting, standing, laying* or in *locations of interest* divided by *total energy* spent in that day.

Figure 3. Hierarchical Activity Recognition Pseudo Code.

```
input: Features extracted from 10s Filtered Accelerometer Signal
       (acc_x, acc_y, acc_z, SM)
1  begin
2      Classify Stationary/Walking
3      if Walking then
4          Classify: Assistive/Non-Assistive Devices
5      else
           /* Stationary case                          */
6          Determine: Active / Non-Active
7          if Active then
8              Classify:
9              Sitting/Standing/Laying Down
10         else
11             Classify:
12             Sitting/Standing/Laying Down
```

Walking embodies active status, and when stationary, the classifier separates brisk (active) and idle (nonactive) movements and later classifies postures into sedentary, standing, and laying down. Both Tables 1 and 2 depict the summary of physical activity (positioning) classifiers' 10-fold cross-validation results built on 50 patients over approximately 22 hours of collated data at subacute care rehabilitation center in Los Angeles. The algorithms were later validated and refined over the course of 6 months of ground truth testing at the same skilled nursing facility.

Step Counts Versus Raw Accelerometer Assessment

The next stage was to find a way to quantify the difference between different activity status. Step counting is a common way that has long been used to quantify the ambulatory physical activity. However, similar to activity recognition approaches explained earlier, the accuracy of step counters is often the subject of debate among researchers. Comprehensive studies with contradictory results on the accuracy of pedometers and wearable accelerometers can be found in the studies by Crouter et al [21], Mammen et al [22], and Case et al [23]. What is rather clear in using step counters/pedometers is their efficacy in quantifying *ambulatory* activities and not *stationary*. For step counters to be more accurate, a user is required to satisfy a minimum walking speed that is often mentioned in the literature as 67 m/min or even higher [24-26]. Therefore, step counters are less likely to produce accurate assessment for less mobile geriatric population. Besides, they are deemed even less effective in quantifying activities in stationary positions. Most studies assess the accuracy of step counters by asking users to walk on a treadmill, which neglects scenarios in which users are stationary, yet pedometers accumulate step counts because of movements in hand. To account for any movements (stationary and ambulatory), this study calculates mean absolute deviation (MAD) of accelerometer magnitude signal using equation 2, Figure 2. MAD calculates the statistical dispersion of acceleration from the mean and its unit is meter per second squared,

where x_i is the SM in each 10-second window, and the x_{ave} is the average of accelerometer magnitude for 160 samples (10-second epoch×16 Hz). MAD of accelerometer magnitude represents the average magnitude of acceleration within an interval (in this case, 10 seconds) and is proportionate to force applied to the watch by patient since f=ma. This value multiplied into displacement will produce relative work and energy. Take into account that calculating displacement from acceleration, however, is not very accurate because it is the result of accelerometer's double integration, that is, any acceleration jitter accumulates and yields big drifts in displacement. Calculating force, however, is accurate and proportionate to energy; hence, the term *energy* has been used in this study to quantify human activity movements.

Another way of quantifying activity is to integrate each acceleration channel to produce kinetic energy using $e=1/2m.v^2$. This way, however, requires more calculations compared with MAD; for the actual speed, each channel should be considered separately so that the direction of acceleration and deceleration that are removed in SM will be taken into account.

It is worth highlighting that by using a smartwatch accelerometer, it is only possible to calculate the force, proportionate to energy, that is spent *on the watch*. Hence, if a patient is carrying a weight on the watch-worn hand, the energy expenditure of the patient will not change with regard to the watch.

Active/nonactive is determined in this study using an empirical threshold of 0.02 m/s^2 (2 cm/s^2) over the MAD value. As explained earlier, calculating displacement from the accelerometer is not highly reliable. However, for illustrative purposes, assume the initial speed of hand movement in each window of 10 seconds is zero. Using equation 3 shown in Figure 2, the value 0.02 indicates that a patient's hand displacement has been 1 m in 10 seconds. In case of equal or greater shifts, the patient is considered active, otherwise, idle (nonactive).

Figure 4 shows 10-second examples of acceleration SM of a person. It illustrates the difference in walking, active and nonactive stationary positions.

Table 1. Online watch classifier.

Class	TP[a] rate	FP[b] rate	Precision	Recall	F-measure	ROC[c] area
Stationary	0.992	0.015	0.977	0.992	0.984	0.954
Walking	0.985	0.008	0.995	0.985	0.990	0.992
Weighted average	0.988	0.011	0.988	0.988	0.974	0.929

[a]TP: true positive.

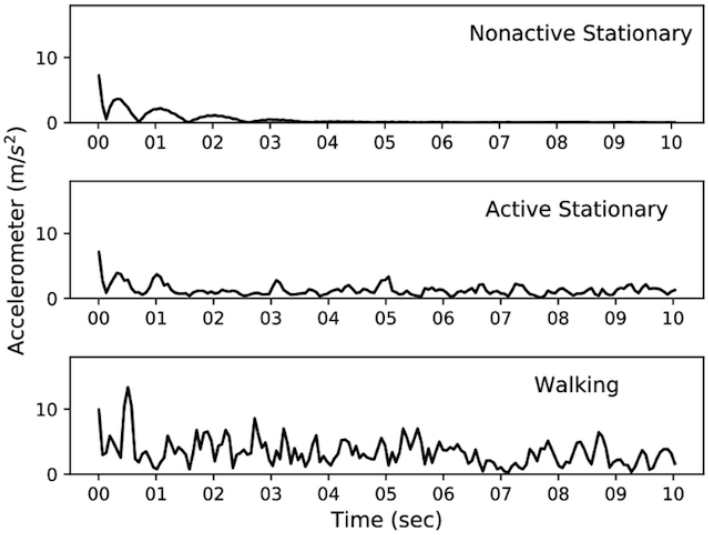
[b]FP: false positive.

[c]ROC: receiver operating characteristic.

Table 2. Activity recognition: positioning.

Position	Accuracy	Precision	Recall	F-measure
Stand	91	0.94	0.91	0.92
Sit	93.7	0.87	0.93	0.90
Lay	90.8	0.97	0.90	0.94
Walk	95.1	0.92	0.95	0.94

Figure 4. Magnitude of accelerometer signal after filtering (direct current component removed before filtering).



Methods

Overview

From June 2016 to November 2017, we recruited patients after admission to a subacute rehabilitation center in Los Angeles. We performed a cross-sectional baseline study of this cohort to better understand data features collected by the SARP system. We investigated the prevalence of physical activity tracking features and indoor localization features at baseline for both outcome groups (hospital vs long-term care). Moreover, we assessed their efficacy in determining the outcome (hospital vs long-term care).

Participants

Participants aged older than 60 years were recruited from a subacute rehabilitation facility in Los Angeles. The study cohort contains patients who had been admitted to a subacute rehabilitation center for 21 days. After this period, patients were either re-admitted to hospital (H) or stayed in community (C; either at home or long-term care). The inclusion criteria were broad, allowing any patient to participate as long as they were aged older than 60 years, English speaking, and able to consent with the exclusion criteria including movement disorders or paralysis of the upper or lower extremity. The diversity of cohort included patients who were a postsurgical, poststroke, and postclinical decompensation because of medical illnesses. Eligible participants signed a consent form approved by the University of California, Los Angeles, Institutional Review Board.

Study Design

Patients were given a smartwatch by a clinical coordinator every morning at 9 am. Patients were asked to wear their watches at all times until the coordinator collected the watch at around 6 pm every day. Watch batteries were expected to last longer than the protocol period (>9 hours). Patients normally stayed in the *resident room* (bedroom) and were scheduled for an hour of daily exercise and activity in the *therapy* room. Beacons were mounted at *locations of interest* (Table 3), shown with color dots in Figure 1 within bedroom and therapy room. Take into account that despite imposing an identical protocol for all patients, daily collected data from each individual may differ. This is primarily because of patients not complying with the protocol at all times, losing interest during the day, feeling uncomfortable, and getting concerned about their privacy. Therefore, to provide a situation in which a fair comparison among patients can be enforced, we determined *analysis inclusion criteria*.

Table 3. Locations of interest. For sensor-based feature assessment throughout the paper, shower, toilet, and sink are considered as bathroom; walls 1, 2, and 3 as wall; beds 1 to 4 inside the therapy room and beds 1 and 2 inside the resident room as beds.

Location	Sublocations
Resident room	Bed, chair, shower, toilet
Therapy room	Bed, resband, bike, endorphine, strip, table, small table, hallway, seats, wall, hallway doors, sink, bath

Analysis Inclusion Criteria

For this baseline analysis, we included study participants who satisfied the following constraints: (1) patients with 4 hours or more of watch wear time data in at least 1 day within the first 3 days of admission (*defined as baseline*); and (2) having 15 min or more of therapy room wear time in that particular *baseline* day. In case both inclusion criteria were satisfied on more than 1 day, the earliest day was selected as *baseline*. The reason for choosing 4 hours or more wear time was to set a standard minimum; given the health of this population whom mostly recently discharged from the hospital, we anticipated variability in watch usage. To have a minimum standard, we agreed that patients needed to wear the watch more than 50% of the available hours per day (in this study, 8 hours).

The hours when the watch was not worn were excluded from the study; therefore, baseline hours may not be *consecutive*.

Measures

Demographic and Clinical Characteristics

We collected the demographic characteristics of patients such as age, race, gender, and ethnicity. We also translated the clinical coordinator's assessments including usage of assistive devices and their type, measures of activity of daily living (ADL), pain (yes/no), and number of active diagnosis (more or less than 10). We investigated the significance of such characteristics in distinguishing the outcome (community vs hospital).

Sensor-Based Parameters

Sensor-based features are combination of 3 groups of parameters that are achieved by harnessing smartwatch and BLE beacons. The features are based on (1) activity recognition such as sitting time and standing time; (2) indoor localization, for example, time in bed, time in bathroom, or therapy room; and (3) row acceleration quantification, MAD (energy; see section Sensing At-Risk Population System Overview). By combining these attributes, we achieved features such as sitting time in bed or energy spent in walking or in bed.

To perform a fair comparison among patients with different watch wear time, we *normalized* features: time spent (minutes) in a certain physical activity or location was divided by *uptime* (the total watch wear time in a day in minutes) to yield normalized time features. Uptime is an essential factor in providing fair comparison

We investigated the significance of sensor-based features with respect to the outcomes: hospital versus community. All measurements are at baseline, that is, the day that satisfies inclusion criteria from 9 am to 6 pm. We calculated "time spent in percentage," "energy intensity (E)," and "energy spent in percentages," as shown in equations 4, 5, and 6 in Figure 2.

To recap, for each individual, *time-related* features such as *sitting time* were divided by *uptime*. Energy-related features such as *walking* were divided by: (1) the uptime, yielding energy intensity and (2) their total daily value, producing the energy percentage.

Statistical Analysis

We explored the capability of baseline sensor-based and demographic features to distinguish between subacute rehabilitation patients based on their outcomes (ie, re-admitted to hospital (H) vs staying in the community (C) either long-term care or home). Chi-squared tests were used to compare categorical demographic variables between outcome groups. We compared quantitative demographic variables and sensor-based metrics (physical activity derived from watch accelerometer and indoor localization inferred from BLE beacons RSSI) between groups using the Kruskal-Wallis test. Cohen *d* was used to summarize the effect size and illustrate the discriminatory power of each feature. Commonly, 0.2, 0.5, and 0.8 are Cohen *d* cut-off values indicating small, medium, and large effect size, respectively. Spearman rho was used to measure correlations between physical activity and location-based features.

Predictive Models of Outcome

We investigated the capability of features at baseline to triage and predict patients who were re-admitted to the hospital or who stayed in community. We built random forest models (maximum depth=2, random state=40, and class_weight=balanced), with hospital patients as positive group. We used single or combination of features with highest statistical significance in distinguishing outcomes according to Kruskal-Wallis tests. Model generation and evaluating performance characteristics (3-fold cross-validation) including sensitivity, specificity, accuracy, and area under the curve (AUC) estimation were performed using Python Programming Language libraries Pandas (version 0.21.0) and Numpy (version 1.14.5), Scipy (version 1.0.0), and Scikit-learn (version 0.19.1) [27-30].

Results

Demographic and Clinical Characteristics

From 184 consented subjects, 30 were excluded because of not satisfying the analysis inclusion criteria. A total of 154 patients were included in this study in which 145 (94.2%) of subjects discharged home/community (C), and 9 (5.8%) re-admitted to hospital (H) at the end of their rehabilitation process. Table 4 presents detailed sociodemographic and clinical characteristics of this cohort, such as age, gender, race-ethnicity, presence of pain, number of active diagnoses, usage of assistive devices, and ADL. Table 4 indicates the mean (SD) and number of patients included for every particular parameter. Among the clinical assessments, Table 4 shows that ADL Toilet is significant in determining the outcome (P=.007) with 65% of the cohort in need of extensive assistance and 35% limited assistance.

Table 4. Sociodemographic and clinical characteristics of the cohort of 154 patients.

Parameter	Community	Hospital	Community vs hospital (*P* value)
Subjects, n (%)	145 (94.2)	9 (5.8)	__[a]
Age (years), mean (SD)	82.16 (9.55)	84.22 (13.87)	.24
Gender, n (%)			.56
Female	104 (71.7)	4 (44.4)	
Male	41 (28.3)	5 (55.6)	
Race/ethnicity, n (%)			>.99
Asian	5 (3.4)	0 (0.0)	
Black/African American	14 (9.7)	0 (0.0)	
Hispanic/Latino	4 (2.7)	0 (0.0)	
Native/Hawaiian Pacific Islander	3 (2.1)	0 (0.0)	
White	119 (82.1)	9 (100)	
Pain present, n (%)			.92
No	44 (31.7)	1 (14.3)	
Yes	95 (68.3)	6 (85.7)	
Active diagnoses, n (%)			>.99
<10	22 (15.2)	1 (11.1)	
≥10	123 (84.8)	8 (88.9)	
ADL[b] transfer , n (%)			.77
Limited assistance	65 (45.1)	2 (22.2)	
Extensive assistance	79 (54.9)	7 (77.8)	
ADL dress, n (%)			.96
Limited assistance	32 (22.2)	1 (11.1)	
Extensive assistance	112 (77.8)	8 (88.9)	
ADL eat, n (%)			.91
Independent	128 (88.9)	7 (77.8)	
Supervision	4 (2.8)	0 (0.0)	
Limited assistance	9 (6.2)	1 (11.1)	
Extensive assistance	3 (2.1)	1 (11.1)	
ADL toilet, n (%)[c]			.007
Limited assistance	50 (34.7)	1 (11.1)	
Extensive assistance	94 (65.3)	7 (77.8)	
Total dependence	0 (0.0)	1 (11.1)	
ADL walk room , n (%)			.73
Limited assistance	73 (50.7)	2 (22.2)	
Extensive assistance	59 (41.0)	5 (55.6)	
Activity did not occur	12 (8.3)	2 (22.2)	
ADL walk hall, n (%)			.88
Limited assistance	73 (50.7)	2 (22.2)	
Extensive assistance	64 (44.4)	6 (66.7)	
Activity occurred only once or twice	2 (1.4)	0 (0.0)	
Activity did not occur	5 (3.5)	1 (11.1)	

Parameter	Community	Hospital	Community vs hospital (*P* value)
ADL walk on unit, n (%)			.85
Supervision	1 (0.7)	0 (0.0)	
Limited assistance	71 (49.3)	2 (22.2)	
Extensive assistance	72 (50.0)	7 (77.8)	
ADL hygiene, n (%)			.84
Supervision	2 (1.4)	0 (0.0)	
Limited assistance	71 (49.3)	2 (22.2)	
Extensive assistance	71 (49.3)	7 (77.8)	
ADL bed, n (%)			.61
Supervision	1 (0.7)	0 (0.0)	
Limited assistance	83 (57.6)	2 (22.2)	
Extensive assistance	60 (41.7)	7 (77.8)	
Urinary continence, n (%)			.09
Always continent	117 (81.2)	4 (44.4)	
Occasionally incontinent	4 (2.8)	0 (0.0)	
Frequently incontinent	8 (5.6)	2 (22.2)	
Always incontinent	7 (4.8)	3 (33.3)	
Not rated	8 (5.6)	0 (0.0)	
Bowel continence, n (%)			.08
Always continent	128 (88.9)	5 (55.6)	
Occasionally incontinent	3 (2.1)	0 (0.0)	
Frequently incontinent	7 (4.8)	1 (11.1)	
Always incontinent	6 (4.2)	3 (33.3)	
Assistive devices, n (%)			.97
Walker	1 (0.7)	0 (0.0)	
Wheelchair	5 (4.0)	1 (14.3)	
Walker and wheelchair	123 (94.6)	6 (85.7)	
Cane and wheelchair	1 (0.7)	0 (0.0)	

[a]Not applicable.

[b]ADL: activity daily living.

[c]Parameters with $P<.05$.

Energy Intensity Features Assessment

Amongst sensory-based features shown in Figure 2, equations (4-6), energy intensity features are the ratio of the total energy spent in a particular activity or location to their corresponding time spent. Taking into account, indoor localization capability of SARP system enabled us to calculate the energy spent at each location of interest, sum of which was broadly categorized into (1) energy intensity in resident room and (2) energy intensity in therapy room. According to Table 5, energy features that best discriminated community and hospital patients were energy intensity in resident room ($P<.001$, $d=1.21$), resident_bed ($P<.001$, $d=1.23$), resident_bath ($P=.004$, $d=1.18$), and total energy intensity ($P=.003$, $d=0.87$). Features such as energy intensity of laying down ($P=.02$), and therapy_bathroom ($P=.02$), despite statistical significance, have low effect sizes ($d=0.418$ and $d=0.17$, respectively). Moreover, with $P<.001$ and $d=1.25$, energy intensity in resident room has high discriminatory power with respect to outcome.

Table 5. Sensor-based (activity and indoor localization) features: assessment according to outcomes.

Feature	Community, mean (SD)	Hospital, mean (SD)	*P* value	Effect size[a]	Frequency (n)	
					Community	Hospital
Energy % parameters						
Active[b]	2.37 (3.84)	1.00 (1.29)	.001	1.24	145	9
Walking	2.37 (3.84)	1.00 (1.29)	.08	0.50	145	9
Standing[b]	59.70 (8.70)	57.92 (6.39)	.002	1.24	145	9
Sitting[b]	17.83 (9.69)	13.33 (8.90)	.02	0.86	145	9
Laying down[b]	20.10 (6.43)	27.73 (9.94)	.04	0.54	145	9
Energy intensity parameters						
Total energy[b]	52.61 (18.23)	35.85 (16.53)	.003	0.87	145	9
Active	11.94 (18.27)	6.05 (8.02)	.30	0.42	145	9
Walking	450.47 (253.08)	366.45 (218.66)	.44	0.34	145	9
Standing	85.93 (26.92)	82.27 (36.12)	.32	0.11	145	9
Sitting	184.33 (97.58)	156.19 (104.74)	.31	0.28	145	9
Laying down[b]	26.23 (8.68)	19.54 (7.35)	.02	0.418	145	9
Energy intensity—therapy room						
Energy therapy room	70.75 (43.11)	68.49 (63.56)	.36	0.04	145	9
Bathroom[b]	74.84 (49.02)	62.35 (83.54)	.02	0.17	114	8
Strip	57.84 (42.33)	13.03 (8.30)	.06	1.43	88	2
Bed	60.22 (40.27)	39.09 (7.15)	.27	0.72	97	4
Resband	61.06 (43.10)	75.73 (85.49)	.57	0.20	100	6
Bike	91.80 (76.82)	120.58 (38.41)	.31	0.43	36	2
Scifit	98.39 (55.04)	0.0 (0.0)	__[c]	—	14	0
Endor	41.38 (6.74)	0.0 (0.0)	—	—	3	0
Midstrip	56.46 (48.92)	65.46 (24.53)	.38	0.22	45	3
Small table	61.07 (40.37)	148.47 (138.78)	.53	0.71	57	3
Table	93.49 (66.75)	0.0 (0.0)	—	—	56	0
Hallway seats	42.58 (43.13)	32.52 (7.89)	.87	0.32	43	3
Stairs	133.48 (128.07)	0.0 (0.0)	—	—	8	0
Wall	57.07 (28.49)	25.61 (0.0)	.17	—	73	1
Energy intensity—resident room						
Energy resident room[b]	43.32 (17.44)	26.99 (6.05)	<.001	1.25	145	9
Bed[b]	43.93 (19.01)	25.76 (4.37)	<.001	1.23	144	9
Bathroom[b]	55.89 (27.95)	32.50 (9.30)	.004	1.18	141	9
Chair	42.45 (20.61)	0.0 (0.0)	—	—	5	0
Time % parameters						
Active[b]	12.92 (6.52)	6.94 (4.01)	.001	1.10	145	9
Walking	0.35 (0.51)	0.15 (0.27)	.09	0.44	145	9
Standing[b]	44.22 (7.94)	32.68 (7.30)	<.001	1.51	145	9
Sitting[b]	8.60 (8.36)	6.16 (7.36)	.04	0.31	145	9

Feature	Community, mean (SD)	Hospital, mean (SD)	*P* value	Effect size[a]	Frequency (n)	
					Community	Hospital
Laying down[b]	46.83 (9.83)	60.99 (11.11)	<.001	1.35	145	9
Time spent %—therapy room						
Bathroom	0.03 (0.04)	0.06 (0.08)	.16	0.27	114	8
Strip	0.01 (0.03)	0.005 (0.002)	.62	0.48	88	2
Bed	0.62 (0.19)	0.55 (0.23)	.64	0.43	97	4
Resband[b]	0.02 (0.02)	0.05 (0.03)	.03	0.74	100	6
Bike	0.03 (0.03)	0.01 (0.002)	.51	0.80	36	2
Scifit	0.03 (0.02)	0.0 (0.0)	—	—	14	0
Endor	0.009 (0.01)	0.0 (0.0)	—	—	3	0
Midstrip	0.02 (0.02)	0.02 (0.02)	.31	0.49	45	3
Small table[b]	0.02 (0.03)	0.04 (0.02)	.04	0.50	57	3
Table	0.06 (0.05)	0.0 (0.0)	—	—	56	0
Hallway seats	0.006 (0.004)	0.01 (0.16)	.64	0.78	43	3
Stairs	0.02 (0.04)	0.0 (0.0)	—	—	8	0
Wall	0.01 (0.02)	0.01 (0.0)	.98	—	73	1
Time spent %—resident room						
Bed	0.62 (0.19)	0.55 (0.23)	.16	0.12	144	9
Bathroom	0.21 (0.17)	0.25 (0.20)	.92	0.52	141	9
Chair	0.007 (0.03)	0.0 (0.0)	—	—	5	0

[a]Effect sizes have been calculated as Cohen *d*.

[b]Parameters with *P*<.05.

[c]Not applicable (the *P* value or effect size cannot be calculated).

Figure 5 depicts the energy intensity distributions between 2 groups in resident and therapy rooms. It shows that energy intensity in therapy room in both groups has similar mean value (line within the box); therefore, a clear distinction cannot be made within 2 groups based on that feature. However, the mean value of community group in resident room is clearly higher than in hospital patients.

Kernel density estimation (KDE) distributions are shown in Figure 6 (subplots A and D). The figure attests to the distinction of energy intensity in resident room among community and hospital patients (subplot A). However, the KDE of energy intensity in therapy room (subplot D) does not indicate the same discriminatory power. Figure 6 (subplot B) indicates that energy intensity of most patients in therapy room is higher compared with resident room for both outcome groups because most patients fall below the identity line. Points shown on the identity line represent patients with same therapy and resident intensities.

According to subplot (C), the center core of the contour plot (representing most patients) in community group is almost circular contrary to hospital patients. This indicates that the ratio of resident to therapy intensity is closer to one (ie, same activity intensities). On the contrary, more oval shape of the contour core in hospital group can imply that most patients are persistently more active during therapy sessions while being less active in their resident room. The increase in energy levels can be seen clearly in Figure 7. The figure depicts the ratio of energy intensity in therapy room to resident room. Most patients in hospital outcome group, demarcated by red line, fall around number 2. In other words, therapy room energy intensity is twice the resident room for most patients in hospital group. However, 50 patients in community group (blue histogram) have the ratio close to 1, that is, the same intensity in both therapy and resident room. A more detailed scenario of both groups within the therapy room can be found in Figure 8 and Table 6.

Figure 5. Energy intensity distribution.

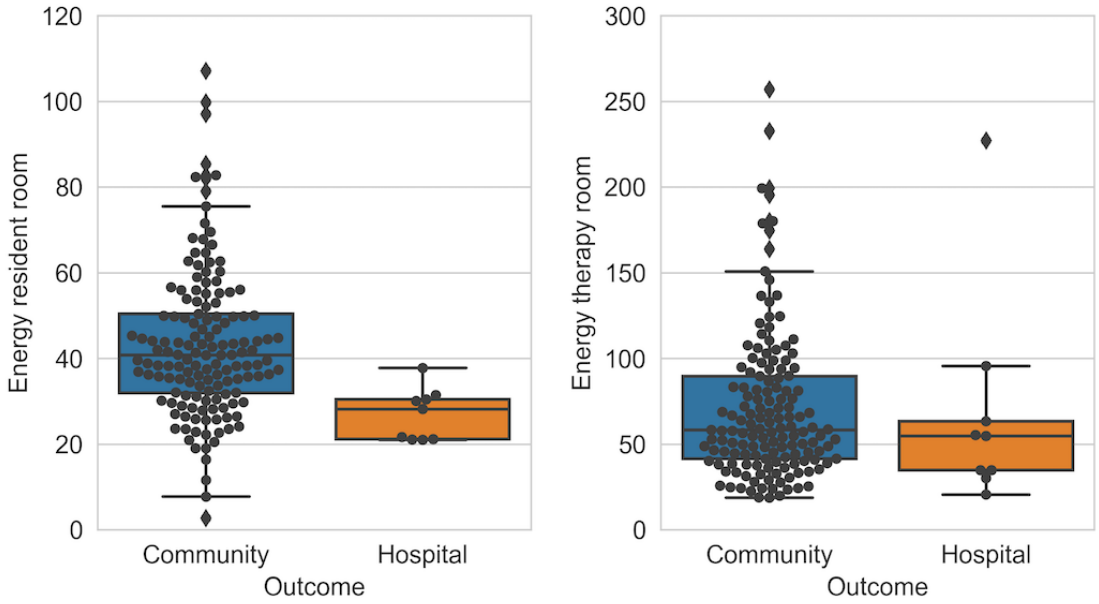


Figure 6. Gauging energy intensity in community versus hospital.

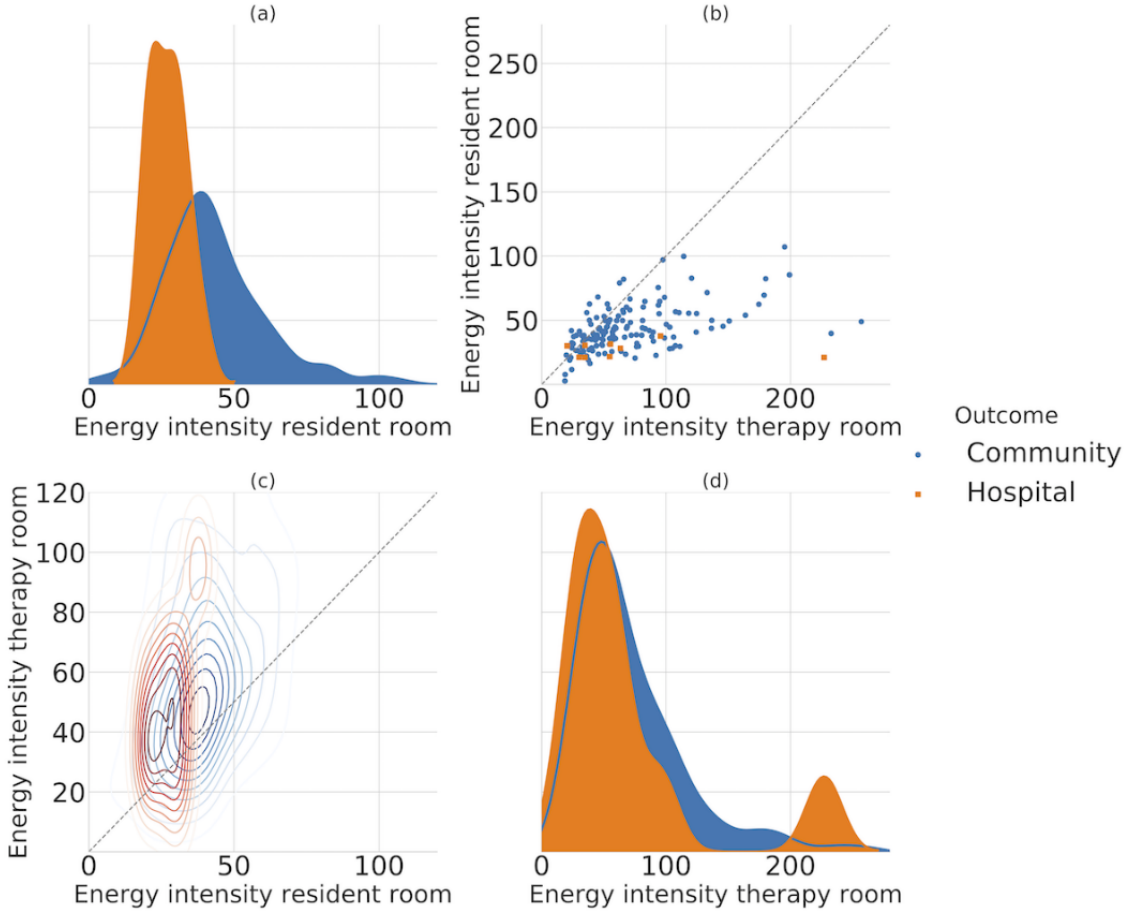


Figure 7. Distribution of patients spending energy in therapy room compared with resident room. X-axis indicates the ratio of energy in therapy to resident room.

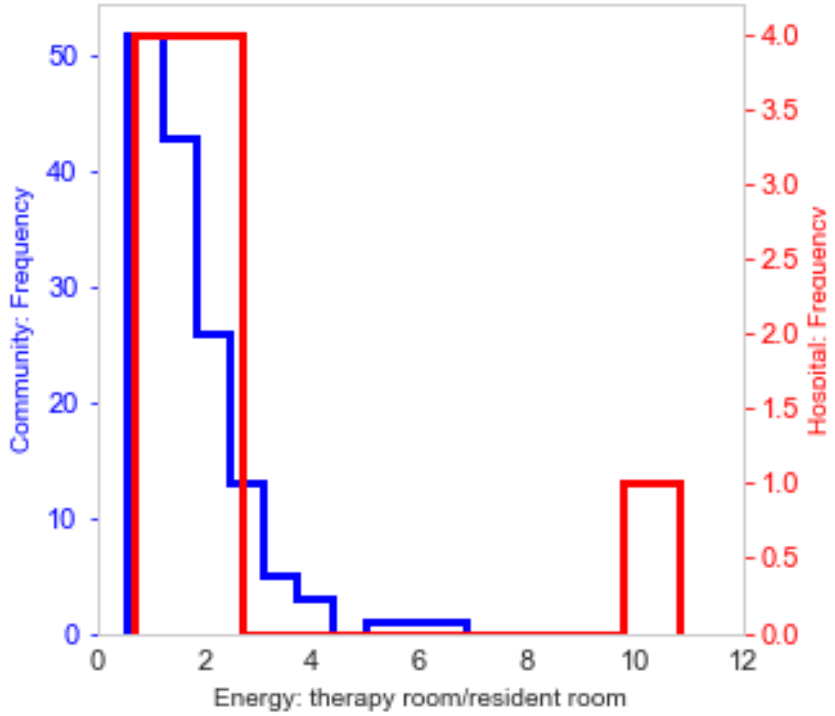
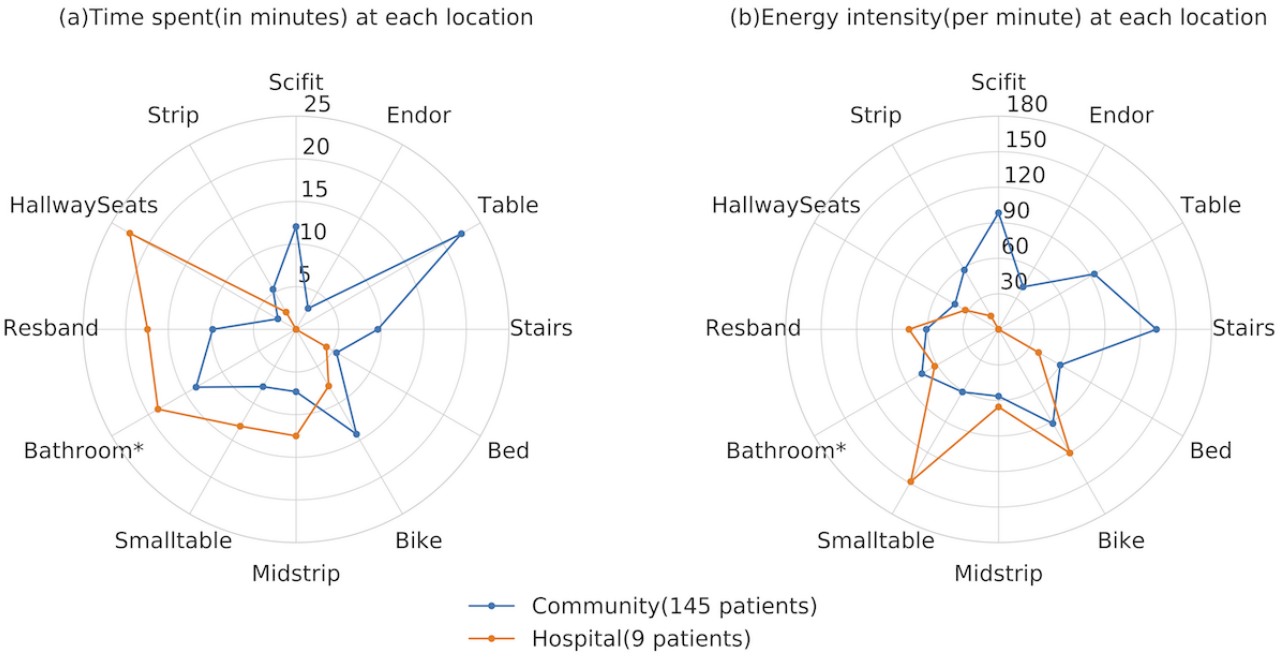


Figure 8. Time and energy intensity details of therapy room.



Average time spent and energy intensity at each therapy location stratified by groups are shown in Figure 8. It is clear that hospital group spent *no time* at stairs, scifit, table, and endorphine. The 5 most intensive activities were small table, *stairs, scifit, table, and bike*. Small table and table are places where patient normally carried out hand pedaling exercises. Table 6 further highlights the details of therapy room location/facility usage in each group. More than 70% of participants from both groups had used *bed* and *bathroom* in therapy room, with *bathroom* 's $P<.05$ (Table 5). However, it is worth mentioning that the effect size of *bathroom* energy intensity is small: 0.17 (cut-off regions: 0.2 small, 0.5 medium, and 0.8 large). Furthermore, Figure 8 reveals that both groups' intensities at bed and bathroom were less than 60 per min. In a study by Razjouyan et al [8], a cutoff point of 90 is suggested to differentiate between light and moderate-to-vigorous activities.

Table 6. Frequency of therapy room location/facility usage by group.

Location/facility	Frequency of facility usage	
	Community, n (%)	Hospital, n (%)
Scifit	14 (9.6)	0 (0.0)
Endor	3 (2.1)	0 (0.0)
Table	56 (38.6)	0 (0.0)
Stairs	8 (5.5)	0 (0.0)
Bed	118 (81.4)	7 (77.8)
Bike	36 (24.8)	2 (22.2)
Midstrip	45 (31.0)	3 (33.3)
Small table	57 (39.3)	3 (33.3)
Bathroom[a]	114 (78.6)	9 (100.0)
Resband	100 (69.0)	7 (77.8)
Hallway seat	43 (29.7)	3 (33.3)
Strip	88 (60.7)	3 (33.3)

[a]Parameters with $P<.05$.

Figure 9 illustrates Spearman correlations among features. According to annotations explained in the Features section, E indicates energy intensity, E% denotes energy percentage, and T% shows the percentage of time spent. Circles, contrary to ovals, correspond to low correlation, whereas lines imply the highest correlation. Darker spectrum on either side (red or blue) represents higher correlation; red implies positive, whereas blue is indicative of negative correlation. It is clear from the figure that laying down is negatively correlated with the rest of the features. Bath and bed in resident room are understandably correlated strongly with energy spent in resident room because almost all activities happened in those 2 locations, and patients hardly used the chair. Bed, bath, resband, small table, bike, and scifit are strongly correlated with energy spent in therapy room. It is clear that being active is highly correlated with overall energy intensity. Resident room energy intensity is strongly correlated with overall energy intensity.

Energy Percentage Features Assessment

Energy percentage feature, as mentioned in Figure 2, is the percentage of energy spent in *walking*, *sitting*, *standing*, *laying*, or energy spent in *locations of interest* divided by *total energy* spent in that day. According to Table 5, community patients are more active ($P=.001$, $d=1.24$) than patients re-admitted to the hospital. Meanwhile, energy percentage of standing ($P=.002$, $d=1.24$) and sitting ($P=.02$, $d=0.86$) of the community group is higher than those in hospital group. Other than walking, all energy percentage parameters were shown significant in distinguishing between both groups. Walking is not significant in distinguishing the outcome: Energy (%) in walking ($P=.08$, $d=0.50$) and energy intensity during walking ($P=.44$, $d=0.34$).

Time Features Assessment

According to Table 5, standing time (%) has the strongest discriminatory power ($P<.001$, $d=1.51$) among all watch-derived parameters. Community group has higher time percentage in laying down ($P<.001$, $d=1.35$) and active state ($P=.001$, $d=1.24$) compared with hospital group. Despite statistical significance of sitting time (%), its effect size is between small and medium ($P=.04$, $d=0.31$). Walking time was quite negligible (<1% of time for both groups with $P=.09$, $d=0.44$), whereas overall active state, which captures walking and stationary active periods, was highly significant ($P=.001$, $d=1.10$). As shown in the table, none of the time (%) parameters in resident room have the ability to discriminate between the 2 outcome groups.

Performance of Predictive Models at Baseline

Random forest models were built based on the most statistically significant features. In reviewing Table 4, the top 3 most influential features in distinguishing the outcomes were % standing time ($P<.001$, $d=1.51$), % laying down time ($P<.001$, $d=1.35$), *and resident room energy intensity* ($P<.001$, $d=1.25$). Results of 3-fold cross-validation models with their corresponding AUC score are presented in Table 7. Take into account that the sensitivity (recall) presented in the table is not the weighted average and reflects only recall of minority (H) group. Specificity indicates the true negative rate when negative group is comprised most patients returning to community setting (C) after the rehabilitation period.

Figure 9. Correlations among sensor-based features. Asterisk indicates parameters with $P<.05$.

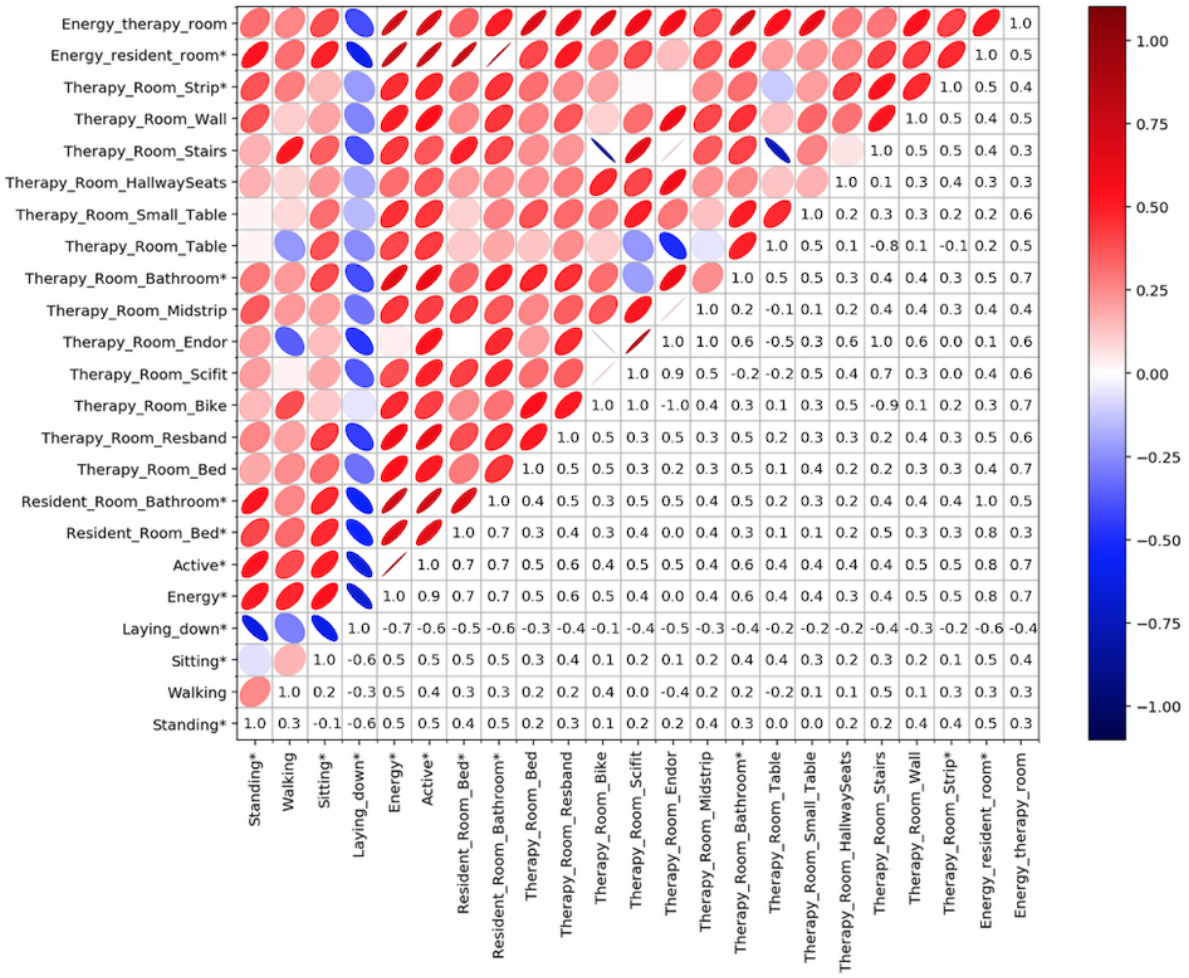


Table 7. Predictive models: 3-fold cross-validation (community, n=48; hospital, n=3).

Features	Sensitivity, mean (SD)[a]	Specificity, mean (SD)[a]	Accuracy, mean (SD)[a]	AUC[b], mean (SD)
Standing time (%)	22.2 (31.4)	74.4 (15.3)	71.4 (12.9)	0.62 (0.06)
Standing time (%), laying down time (%)	11.1 (15.7)	91.0 (0.9)	86.4 (1.5)	0.70 (0.10)
Standing time (%), laying down time (%), resident room energy intensity (%)	44.4 (41.6)	87.6 (4.3)	85.1 (5.5)	0.85 (0.09)
Resident room energy intensity	77.7 (15.7)	74.5 (8.5)	74.7 (7.3)	0.84 (0.10)

[a]Mean (SD) reported for the validation datasets based on a 3-fold cross-validation. Mean and SD are calculated across all 3 folds.

[b]AUC: area under the curve.

Discussion

To our knowledge, this is the first study that has combined indoor localization and accelerometer-based physical activity recognition to assess older patients. A subset of indoor location and physical activity features were found to be highly correlated with the outcomes (community vs hospital re-admission) at baseline. In this section, we discuss the significant highlights of the result.

Steps Versus Raw Acceleration Signal

Interestingly, walking, a known distinctive parameter in assessing physical functional performance in certain older populations [8], did not yield significance in this study. In populations that are frail, similar to that in subacute rehabilitation, only a negligible amount of time is spent walking (<1% of daily activity). This suggests that in these populations, steps counters may not necessarily be the best way to quantify active state [24,25]. It would be best to prepare for the stark reality that geriatric population may not be active enough to assess their well-being or infer their independence only based on step counts or by monitoring their walking. A combination of activity features that includes both wearable sensor and stationary beacons that provide corresponding indoor localizations could be a stronger indicator of their general well-being and/or frailty. Moreover, the use of raw acceleration signals to quantify energy intensity allows us to capture even small movements, the movements that may not trigger step

counters but still indicate some level of activity. Let us consider an example in which we considered energy spent rather than steps: compared with community, hospital patients show higher percentage of energy while laying down (P=.39, d=0.54). They also spent more overall time (%) in that position (60.99) compared with 46.83 for community patients. However, energy intensity of community patients is higher than hospital patients (26.23 vs 19.54). This indicates that community patients have been more active while lying down. Being more active while lying down may be the result of turning in bed; hence, this feature may denote higher ability to move in community patients. In this scenario, as discussed earlier, step counters will not produce reliable results to quantify patients' activity levels.

Activity With Therapist Versus Resident Time Alone

One interesting aspect of this study was to investigate the activity while a patient is with a physical therapist versus activity during the other hours of the day. It did not appear that a clear distinction could be made between different outcome groups based on therapy room energy intensity. This could be because all patients during therapy sessions are engaged by the therapist in similar physical activities following set protocols. However, the energy intensity of resident room was distinctive within outcome groups.

Value of Indoor Localization Data

To assess the value of indoor localization in activity tracking, it would be best to highlight some of the scenarios: according to Table 4, among clinical characteristic assessment, ADL toilet (P=.007) was the most significant feature in determining the outcome. This feature corresponds to the watch-derived feature energy intensity in resident bathroom. With P=.004 and effect size of d=1.18, energy intensity in *resident room* (achieved from indoor localization) hence confirms the clinical finding and can be considered in the absence of ADL evaluations. In other words, ADL variant, a highly significant clinical feature, can be replicated using combination of indoor localization and activity/energy derivations.

Both group energy intensities at bed and bath were less than 60 per min. In the study by Razjouyan et al [8], authors use a cutoff point of 90 to differentiate between light and moderate-to-vigorous activities. On the basis of that, given the intensity in both bathroom and bed for either of the groups, we can conclude that patients performed light activities in those locations.

None of the patients in hospital outcome group used therapy room toilet/bathroom. It is likely that those patients were not capable enough to perform such exercises or even not advised by clinicians/nurses to do so to prevent injury. Either way, the lack of performing an activity, in this case, information extracted from indoor localization data, could be an early indication of which group a patient belongs to; it could also potentially be used to identify adverse outcomes and proactively address to prevent a negative outcome.

Predictive Analysis: Statistically Significant Features

P value as statistical significance or strength of evidence index has long been a subject of debate [31,32]. It is very crucial to know that the P value is not a definite test; increasing more attributes significantly correlated with the outcome variable in a predictive model does not necessarily yield higher predictability. Although statistical significance index and its effect size provide a standard exploratory data analysis and perhaps a good informal heuristic for choosing attributes of a prediction model, machine learning practice has more freedom from model assumptions. This study shows that the addition of significant variants did not increase predictive power and the model with only energy intensity in resident room produced the highest recall of minority class (hospital outcome) and overall AUC (0.84).

Considering only the prediction results, we can infer that location data add value to our system. It is apparent that energy intensity in resident room is the most decisive feature in predicting the outcome.

Limitations and Future Research

Activity classification can best be obtained using a series of motion sensors placed on various parts of the body. Thus, a wide range of activities can be captured as most body motions are detected. However, to simplify the activity detection, using single motion sensors is quite popular. Placing an accelerometer on the hip has been one of the most popular methods because it captures almost all human motions; however, it underestimates the arm ergometry, as it cannot fully extract the arm movements [33]. Wrist-worn accelerometers are popular because of their ease of use, water resistance in most brands, and capturing a comprehensive set of activities. However, interpreting their data for certain sedentary activities such as sitting, standing, and laying is rather challenging, in that, hand movements are very similar in those scenarios. Although ambulation detection is evident in most cases, error rates of classification increase when using assistive devices, walking in very low speed, carrying a weight with the hand that is not wearing the watch, or doing activities involving hand and feet movement together such as sweeping [15,33,34].

Patients' compliance with wearing a smartwatch was the main challenge of this study, and we expect it to be a generic obstacle in similar studies that aim to harness wearable technology for patients. Moreover, if the target population is less familiar with new forms of technology such as wearable devices, the compliance issue might become even more crucial. In this study, we recruited 184 patients, of which 30 patients were excluded for not satisfying the analysis inclusion criteria (watch wear time constraint). Our baseline analyses revealed that 50% of patients removed their watches before the study coordinator collects them at the end of the 8 hours.

Dealing with medical datasets is rather challenging in that the datasets predominantly consist of normal cases in addition to minority abnormal instances that deem to be more interesting [35]. Many attempts have been made to overcome the obstacle of the normal and abnormal samples known as imbalanced datasets. There exist approaches to improve the performance of predictive models by oversampling and/or undersampling the dominant and abnormal instances [36-38]. In our study cohort, the 2 outcome categories are not equally represented, making the dataset imbalanced. In the future, we aim to further

investigate the use of oversampling and undersampling of our dataset as methods that perhaps are not very conventional in the medical field but can possibly improve the predictability of our models.

Next step would be the longitudinal analysis on the same study cohort over the 21-day period they were admitted to the same rehabilitation center. This will allow us to track the trends in sensor feature values and investigate if their changes mimic the daily assessment change performed by clinicians. The result can allow development of models of early frailty detection or producing intervention alerts.

Conclusions

Despite the evolution of eHealth and mobile health (mHealth) and the emerging role of wearable and mobile technology in new platforms of health care, there are anecdotal claims that wearable technology may not precisely quantify patients' health [39]. In this study, we showed that wearable technology, equipped with refined physical activity tracking algorithms, in our case, tailored for geriatrics, can result in a better understanding of patients and hopefully pave the way in developing intervention alerts and approaches. We discussed how SARP features provide a clearer storyline of daily activity patterns by merging indoor localization with physical activities. The SARP system can be incorporated into mHealth technology platforms and can provide a more objective assessment of the frail population.

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Conflicts of Interest

The SARP system is protected by a patent (US Patent Application 15/736,744) [14] owned by the University of California, Los Angeles, in which RR, AN, and MS are listed as co-inventors. RR and AN are co-founders of InvistaHealth LLC. Other authors have declared no potential conflict of interest with regard to the publication of this paper.

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Abbreviations

ADL: activity of daily living
AUC: area under the curve
BLE beacon: bluetooth low-energy sensors
C: community
H: hospital
KDE: kernel density estimation
MAD: mean absolute deviation
mHealth: mobile health
RSSI: Received Signal Strength Indicator
SARP: Sensing At-Risk Population
SM: signal magnitude

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Original Paper

Behavior Change Techniques Incorporated in Fitness Trackers: Content Analysis

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Abstract

Background: The use of fitness trackers as tools of self-management to promote physical activity is increasing. However, the content of fitness trackers remains unexplored.

Objective: The aim of this study was to use the Behavior Change Technique Taxonomy v1 (BCTTv1) to examine if swim-proof fitness trackers below Aus $150 (US$ 105) incorporate behavior change techniques (BCTs) that relate to self-management strategies to increase physical activity and reduce sedentary behavior and to determine if content of the fitness trackers correspond to physical activity guidelines.

Methods: A total of two raters used the BCTTv1 to code 6 fitness trackers that met the inclusion criteria. The inclusion criteria were the ability to track activity, be swim proof, be compatible with Android and Apple operating systems, and cost below Aus $150.

Results: All fitness trackers contained BCTs known to promote physical activity, with the most frequently used BCTs overlapping with self-management strategies, including goal setting, self-monitoring, and feedback on behavior. Fitbit Flex 2 (Fitbit Inc) contained the most BCTs at 20. Huawei Band 2 Pro (Huawei Technologies) and Misfit Shine 2 (Fossil Group) contained the least BCTs at 11.

Conclusions: Fitness trackers contain evidence-based BCTs that overlap with self-management strategies, which have been shown to increase physical activity and reduce sedentary behavior. Fitness trackers offer the prospect for physical activity interventions that are cost-effective and easily accessed by a wide population.

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KEYWORDS

behavioral medicine; self-management; fitness tracker; physical activity; sedentary behavior

Introduction

Regular physical activity has many health benefits, but many individuals are still not meeting the minimum guidelines for physical activity recommended by the World Health Organization and various public health organizations [1]. The inadequate level of physical activity to meet present physical activity guidelines has been referred to as physical inactivity [2-4], and it is increasingly being recognized as a major problem in global health [5,6]. Physical inactivity is considered to be the fourth leading risk factor for mortality, with an estimated contribution of 3.2 million deaths worldwide [4]. Sedentary behavior is also recognized as a contributing factor to global health issues [7], and it is defined as "any waking behavior characterized by an energy expenditure ≤1.5 metabolic equivalent tasks (METs) while in a sitting or reclining posture" [8]. Research indicates that prolonged sedentary behavior is linked to endothelial dysfunction [9], associated with increased risk of type 2 diabetes [10,11] and mortality because of cardiovascular disease [12,13]. Although being sedentary can contribute to higher levels of inactivity, it is not synonymous with physical inactivity. It is also not the inverse of physical

activity. For example, individuals who run for 40 min in the morning and then spend the rest of their day sitting are considered to be physically active (having met the minimum guidelines for physical activity) and sedentary, whereas those who spend their day standing and do not engage in other physical activity are considered to be physically inactive but not sedentary. Health organizations have recognized the need to address physical activity and sedentary behavior as separate constructs, and they have included sedentary behavior recommendations along with physical activity guidelines [14-16].

Interventions to decrease both physical inactivity and sedentary behavior are much needed. They should be affordable and accessible across population groups, which is particularly pertinent, given the higher prevalence of physical inactivity and sedentary behavior documented in those with less education and lower socioeconomic status [17,18]. Behavioral interventions that include self-management strategies to promote physical activity are emerging. Systematic reviews and meta-analyses have found that behavioral change techniques related to self-management strategies were effective in increasing physical activity in young and middle-age adults [19-22], older adults [23], and overweight and obese adults [24,25]. Furthermore, techniques related to self-management were found to be linked to maintenance of physical activity behavior [19], and these were also effective in reducing sedentary behavior [26]. The use of wearable fitness trackers as tools for self-management in physical activity interventions [27-30] is growing. These fitness trackers are typically worn on the body and are able to monitor and track statistics, such as distance walked or ran, number of steps taken, and calorie expenditure. Some fitness trackers are able to offer coaching and feedback during activities and provide prompts to engage in activity. Studies that examined the use of fitness trackers have shown them to be effective in increasing physical activity with adults who are inactive [31], sedentary [32], overweight and obese [33,34], patients with chronic illness, such as cancer [35-38], and older adults [39-42]. Behavior change techniques (BCTs) are observable, replicable, and irreducible components of interventions that can bring about behavioral change [43,44], including increased physical activity [19,45,46]. Taxonomies to identify BCTs have been developed and refined over the years, with the latest being the Behavior Change Technique Taxonomy v1 (BCTTv1). The BCTTv1 contains 93 distinct BCTs, and it can be used across behaviors and disciplines [47]. As individual BCTs are seldom applied in isolation, the combination of BCTs has been a topic of focus in recent studies. In terms of interventions to promote physical activity, it was found that the effectiveness of such interventions was enhanced when a self-monitoring BCT was combined with other self-management–related BCTs, such as goal setting, feedback on performance, and review of behavioral goals [20,48]. This combination of self-management–related BCTs has also been posited to contribute to maintenance of behavior change [49,50]. Another combination of BCTs that supports maintenance of change in physical activity includes BCTs that address capability, such as instruction or demonstration of behavior, and provide information about the significance of behavior change [25]. Furthermore, a meta-analysis that examined the effects of physical activity interventions found that a combination of at least 3 BCT clusters out of the 16 specific BCT clusters from the BCTTv1 was required within physical activity interventions to yield significant effects [51]. With the increasing use of fitness trackers as self-management tools to promote physical activity and reduce sedentary behavior, the lack of studies investigating their use of evidence-based techniques for behavioral change is surprising. Findings from the few studies that have investigated the use of BCTs in fitness trackers have shown that fitness trackers contained evidenced-based BCTs that supported users to increase physical activity [52-55]. Most of these BCTs were based around self-management strategies, mostly targeting physical activity rather than sedentary behavior [54]. Some aspects not addressed by these previous studies were the affordability of activity trackers and whether they corresponded to physical activity guidelines. Affordable and accessible interventions are much needed, particularly for individuals from low socioeconomic backgrounds who have been reported to be more inactive and sedentary [17,18]. This study assessed fitness trackers below Aus $150 (US$ 105) that are suitable for both land and water activities (henceforth swim proof), as identified on their official product websites, to address affordability and accessibility in terms of a wider coverage of activity types. The objective of this study was to examine if swim-proof fitness trackers below Aus $150 (1) incorporate BCTs that relate to self-management strategies, such as stimulus control, self-monitoring, and self-delivery of consequences, which have been linked to increased physical activity and reduced sedentary behavior, and the objective of this study was to (2) determine if they correspond to physical activity guidelines, particularly the accumulation of at least 150 min of moderate-to-vigorous physical activity per week and the reduction of sedentary behavior by minimizing the amount of prolonged sitting.

Methods

Search Strategy

Various brands of fitness trackers were identified on the basis of listings from 4 websites (CNET, TechRadar, Wareable, and AllThingsWaterproof). A list of their corresponding webpages about fitness trackers was created on January 9, 2018. The official product websites for each brand of fitness trackers were reviewed to identify the various models of fitness trackers pertaining to each brand. Each identified fitness tracker was assessed for the following inclusion and exclusion criteria through reviewing the specifications of each fitness tracker on its official product website.

Inclusion Criteria

Inclusion criteria for the fitness trackers were the following: (1) be able to track or monitor activity (eg, number of steps taken, minutes spent in swimming), (2) be swim proof, (3) be compatible with both Android and Apple operating systems, and (4) cost below Aus $150.

Coding Procedure

A total of two raters, the first author (GC) and an independent researcher (PP), wore each of the fitness trackers for a week

and downloaded and used companion apps of each fitness tracker on a smartphone. The fitness trackers and their companion apps were coded using the BCTTv1 coding manual, which contains labels, descriptions, and examples of each BCT. The raters also read the manual of each fitness tracker to ensure that no functions of the fitness tracker were left unnoticed and unassessed. Each BCT was coded using a dichotomous score of either 0 (not present) or 1 (present). Any coding disagreements were discussed between the two raters until an agreement was reached. To support study objectives, BCTs were only coded when they were applied to target behaviors of increasing physical activity or reducing sedentary behavior. BCTs that targeted other behaviors (eg, diet or sleep) were not coded. Before assessing the fitness trackers and their companion apps, the main author completed the Web-based BCTTv1 training through the official website and trained the other rater to use the BCTTv1 taxonomy. After this, a test for calibration was conducted, where the mobile app Runkeeper was coded using the BCTTv1 taxonomy. This app was chosen as it was found to contain the highest number of BCTs in a review of apps to promote physical activity in adults [56]. Furthermore, by using an app, the two raters were able to access the app and conduct the calibration process concurrently. Any ambiguous descriptors or definitions from the BCTTv1 taxonomy were discussed between the two raters until an agreement was reached during the calibration process.

Materials

The 6 fitness trackers that were included in this study were the Fitbit Flex 2 (Fitbit Inc), Huawei Band 2 Pro (Huawei Technologies), Misfit Shine 2 (Fossil Group), Moov Now (Moov Inc), Nokia Go (Withings), and Polar A300 (Polar Electro). The companion app of each fitness tracker was downloaded to an Apple iPhone 8 and a Samsung J5 Pro smartphone. Record forms were used to document the results from the data analysis of each fitness tracker. Each form included a table containing labels, definitions, and examples of each BCT from the BCTTv1 coding manual, as well as a 0 and 1 against each BCT for the raters to mark the absence or presence of the BCT.

Data Analysis

Descriptive statistics were used to summarize the BCTTv1 ratings of the fitness trackers. Interrater reliability was calculated by dividing the number of agreements plus disagreements and multiplying by a hundred. To assess the relationship between the cost of fitness trackers and the number of BCTs incorporated, a Pearson correlation coefficient was computed via SPSS Version 26 (IBM), using an alpha of .05 to determine statistical significance.

Results

Fitness Tracker Selection

A total of 39 fitness trackers were identified across 14 brands as shown in Figure 1. These 39 fitness trackers were assessed by reviewing their specifications on their official product website, and 12 of them were considered eligible for inclusion. Of the eligible 12 fitness trackers, 6 fitness trackers were variants of others from similar brands. As such, only the latest model of each brand of fitness tracker was retained, leaving a total of 6 fitness trackers for BCT analysis.

Presence of Behavior Change Techniques

The definition of each BCT is provided in Multimedia Appendix 1. The number and type of BCTs included in each fitness tracker were evaluated, and these are summarized in Tables 1 and 2. The interrater reliability for evaluating the presence of BCTs measured by percent of agreement was 100%. Disagreements were resolved through discussion. The cost, number of BCT clusters as identified by the BCTTv1 classification, and the number of self-management and nonself-management BCTs incorporated in each fitness tracker are outlined in Table 1.

The average number of BCT clusters included in each fitness tracker was 12, ranging from 6 to 9. The Fitbit Flex 2 and Nokia Go had the highest number of BCT clusters (n=9), followed by Huawei Band 2 Pro (n=8). Misfit Shine 2 had the lowest number of BCT clusters (n=6). The most common BCT cluster incorporated across all fitness trackers was *goals and planning* (mean BCTs incorporated=25%), followed by *feedback and monitoring* (mean BCTs incorporated=15.5%), *antecedents* (mean BCTs incorporated=14.3%), and *reward and threat* (mean BCTs incorporated=13.1%), as shown in Figure 2. The average number of BCTs per fitness tracker was 14, ranging from 11 to 20. The Fitbit Flex 2 had the highest number of BCTs (n=20), followed closely by Nokia Go (n=19). The Huawei Band 2 Pro and Misfit Shine 2 had the lowest number of BCTs (n=11). The Fitbit Flex 2 incorporated the most number of BCTs related to self-management strategies (n=14), followed by Nokia Go (n=12). Huawei Band 2 Pro and Polar A300 contained the least number of BCTs related to self-management strategies (n=9).

The names and types of BCTs incorporated in each fitness tracker are outlined in Table 2.

A total of 6 BCTs out of the total 93 were present in every fitness tracker. These 6 BCTs were *discrepancies between current behavior and goal*, *feedback on behavior*, *self-monitoring of behavior*, *feedback on outcomes of behavior*,*adding objects to the environment*, and *body changes*. A total of 8 BCTs were present in 50% or more of the fitness trackers. These were *goal setting of behavior* (n=5), *goal setting of outcomes* (n=3), *self-monitoring of outcomes of behavior* (n=3), *information about health consequences* (n=4), *social comparison* (n=5), *prompts and cues* (n=5), *social reward* (n=4), and *social incentive* (n=3). The BCTs that were present in fewer than 50% of the fitness trackers were *action planning* (n=1), *social support unspecified* (n=1), *instruction on how to perform behavior* (n=2), *monitoring of emotional consequences* (n=1), *information about emotional consequences* (n=2), *demonstration of behavior* (n=2), *behavioral practice and rehearsal* (n=1), *habit formation* (n=1), *graded tasks* (n=1), *credible source* (n=2), *incentive outcome* (n=1), and *reward outcome* (n=2). A Pearson correlation coefficient was computed to assess the relationship between the cost of fitness trackers and the number of BCTs incorporated. There was a nonsignificant correlation (r=0.21, n=6, *P*=.69) between cost of fitness trackers and the number of BCTs incorporated.

Figure 1. Flow diagram describing the fitness tracker search and selection process.

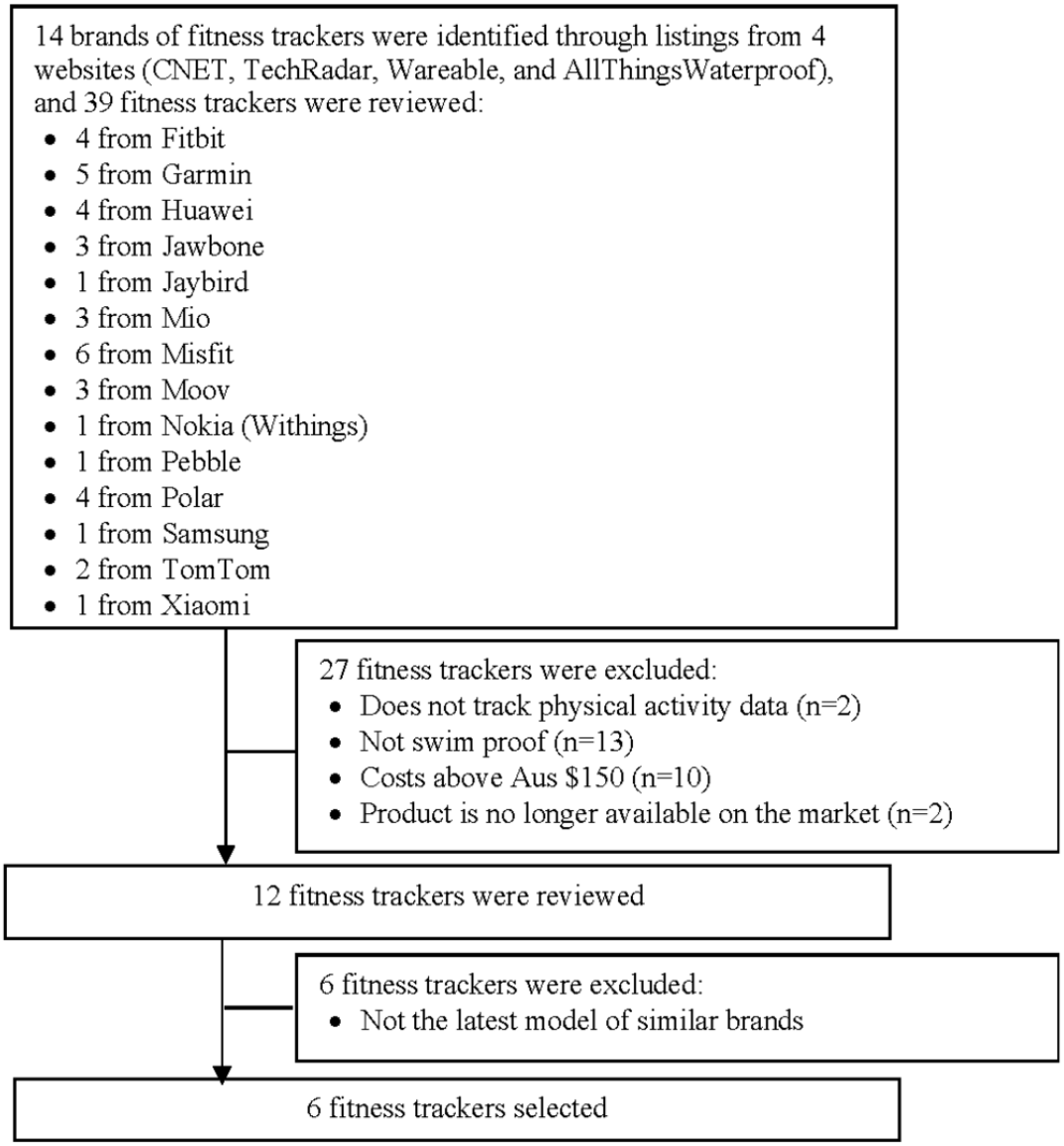


Table 1. Cost and the number of behavior change techniques incorporated in each fitness tracker.

Fitness tracker	Recommended retail price (Aus $)	BCT[a] clusters included (% of total 16 clusters), n (%)	BCTs included (% of total 93 BCTs), n (%)	BCTs related to self-management strategies, n	BCTs not related to self-management strategies, n
Fibit Flex 2	149.95	9 (56)	20 (21)	14	6
Polar A300	149	7 (44)	12 (13)	9	3
Misfit Sine 2	107.77	6 (38)	11 (12.8)	10	1
Huawei Band 2 Pro	98	8 (50)	11 (12.8)	9	2
Nokia Go	89.95	9 (56)	19 (20)	12	7
Moov Now	78.26	7 (44)	13 (14)	10	3

[a]BCT: behavior change technique.

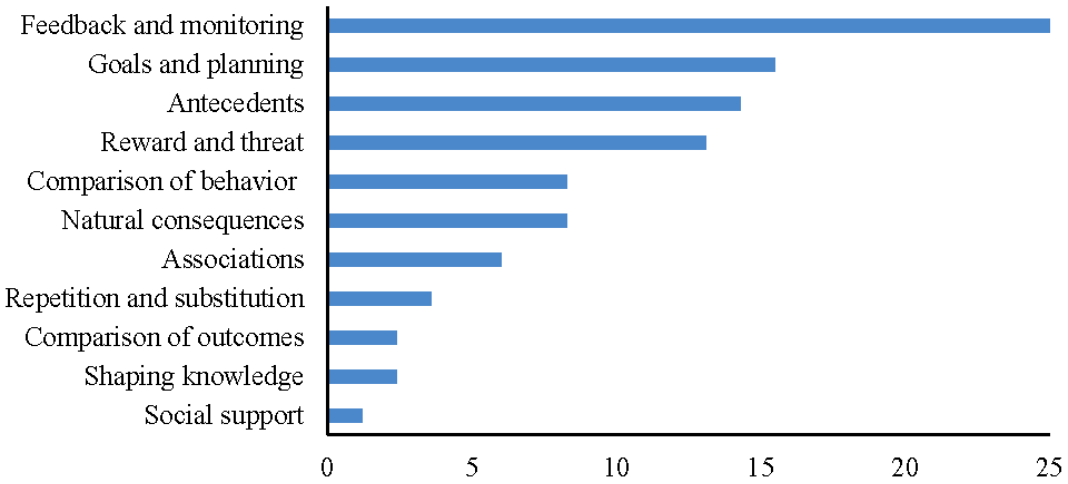
Table 2. Behavior change techniques' effect in increasing physical activity included in each fitness tracker.

Behavior change techniques	Fitbit Flex 2	Huawei Band 2 Pro	Misfit Shine 2	Moov Now	Nokia Go	Polar A300
Behavior change techniques related to self-management strategies						
Antecedents						
Adding objects to the environment	✓[a]	✓	✓	✓	✓	✓
Body changes	✓	✓	✓	✓	✓	✓
Prompts/ or cues	✓	✓	✓	—[b]	✓	✓
Goal setting (behavior)	✓	✓	—	✓	✓	✓
Goal setting (outcome)	✓	—	✓	—	✓	—
Graded tasks	—	—	—	✓	—	—
Self-monitoring and self-evaluation						
Self-monitoring of behavior	✓	✓	✓	✓	✓	✓
Self-monitoring of outcome(s) of behavior	✓	—	✓	—	✓	—
Feedback on behavior	✓	✓	✓	✓	✓	✓
Feedback on outcome(s) of behavior	✓	✓	✓	✓	✓	✓
Discrepancy between current behavior and goal	✓	✓	✓	✓	✓	✓
Self-delivery of consequences						
Social reward	✓	✓	—	✓	✓	✓
Social incentive	✓	—	—	✓	✓	—
Reward (outcome)	✓	—	✓	—	—	—
Incentive (outcome)	✓	—	—	—	—	—
Behavior change techniques not related to self-management strategies						
Information about health consequences	✓	✓	—	—	✓	✓
Information about emotional consequences	✓	—	—	—	✓	—
Instruction on how to perform a behavior	✓	—	—	✓	—	—
Demonstration of the behavior	✓	—	—	✓	—	—
Behavior practice and rehearsal	—	—	—	—	✓	—
Action Planning	—	—	—	—	✓	—
Habit Formation	—	—	—	—	✓	—
Credible Source	✓	✓	—	—	—	—
Social Comparison	✓	—	✓	✓	✓	✓
Social Support	—	—	—	—	✓	—
Monitoring of emotional consequences	—	—	—	—	—	✓
Total	20	11	11	13	19	12

[a]Indicates behavior change technique found in the fitness tracker.

[b]Indicates behavior change technique not found in the fitness tracker.

Figure 2. Mean percentage of behavior change technique clusters incorporated across all fitness trackers.



Presence of Behavior Change Techniques Related to Self-management Strategies

All fitness trackers incorporated components of self-management strategies to target participation in physical activity. These self-management components included goal setting, self-monitoring, and self-evaluation of activity in relation to goals, providing feedback of progress toward goals, and providing rewards on meeting goals.

Antecedents

Antecedent-based self-management strategies involve the manipulation stimuli, such as the environment or motivating operations, to increase the desired behavior [57]. All fitness trackers incorporated antecedent-based BCTs. Each fitness tracker device was a stimulus that was added to the environment, and 5 fitness trackers (Fitbit Flex 2, Huawei Band 2 Pro, Misfit Shine 2, Nokia Go and, Polar A300) provided prompts as reminders to be physically active. Prompts were inactivity alerts through vibration and flashing lights on the fitness tracker device, as well as push notifications on the app to go for planned activities or to hit target goals. All fitness trackers incorporated BCTs of goal setting to increase physical activity. Goal setting was achieved using the companion apps of the fitness trackers. A total of 5 fitness trackers (Fitbit Flex 2, Huawei Band 2 Pro, Moov Now, Nokia Go, and Polar A300) incorporated *goal setting of behavior*, such as setting the number of steps taken per day or distance covered. A total of 3 fitness trackers (Fitbit Flex 2, Misfit Shine 2, and Nokia Go) incorporated *goal setting of outcomes*, which allowed users to set a target weight. Only Moov Now incorporated *graded tasks*, in which a new goal of increased steps was suggested on the app when the previous goal had been achieved.

Self-Monitoring and Self-Evaluation

Self-monitoring related BCTs were incorporated in all fitness trackers. All fitness tracker apps automatically tracked the number of steps taken and allowed users to manually record other nonstep physical activities, such as swimming, cycling, and weight training. A total of 3 fitness trackers (Fitbit Flex 2, Misfit Shine 2, and Nokia Go) provided the functionality for users to record their weight using the companion apps.

Feedback on current behavior, such as duration of physical activity, number of steps taken, and distance covered, as well as number of calories burned, were presented on all fitness tracker apps. All fitness trackers also supported self-evaluation by presenting discrepancies between goals and results of current behavior through the use of visual indicators, such as bar charts, progress bars, and doughnut charts. These charts were often shaded or color coded to indicate proximity to goals, and these charts were presented on all fitness tracker apps, but they were presented only on 3 of the 6 fitness tracker devices (Huawei Band 2 Pro, Nokia Go, and Polar A300).

Self-Delivery of Consequences

All fitness trackers provided rewards to strengthen the target behavior of increasing physical activity. A total of 5 fitness trackers (Fitbit Flex 2, Huawei Band 2 Pro, Moov Now, Nokia Go, and Polar A300) incorporated *social reward*, which comprised congratulatory notifications and badges presented through the app when behavioral goals (eg, number of steps) were met. A total of 3 fitness trackers (Fitbit Flex 2, Moov Now, and Nokia Go) incorporated *social incentive*, which comprised presenting badges that users can unlock or earn on the apps. A total of 2 fitness trackers (Fitbit Flex 2 and Misfit Shine 2) incorporated *reward outcome*, which comprised congratulatory messages through the app, as well as vibration and animating lights on the device when outcomes of goals (eg, points earned through physical activity, calories burned) were met. Only the Fitbit Flex 2 incorporated *incentive outcome*, which comprised using text to inform users that they will receive celebratory messages when their goal outcomes (eg, calories burned) were met. Notably, self-management components found in Fitbit Flex 2, Huawei Band 2 Pro, Misfit Shine 2, and Polar A300 also targeted inactivity. This was achieved through setting a reminder to move after an hour of inactivity, which can also be considered as a form of goal setting and prompting. The devices vibrated and provided visual prompts as indicators of inactivity. The Fitbit Flex 2 and Polar A300 also provided feedback through visual charts of inactivity on the app, identifying the specific hour in the day where inactivity occurred.

Presence of Other Behavior Change Technique to Increase Physical Activity

A total of 11 BCTs that were not related to self-management strategies were found to be incorporated across the fitness trackers. A total of 4 fitness trackers (Fibit Flex 2, Huawei Band 2 Pro, Nokia Go, and Polar A300) provided *information about health consequences* through textual information on the app (eg, "put on your running shoes…work up a sweat…it can improve cardiovascular and respiratory health"). A total of 2 fitness trackers (Fitbit Flex 2 and Nokia Go) incorporated *information about emotional consequences*, presented as textual information on the app (eg, "…boost self-esteem and emotional state"). A total of 2 fitness trackers (Fitbit Flex 2 and Moov Now) incorporated the BCT *instruction on how to perform behavior* and *demonstration of behavior*, which were presented through videos on the app showing movements and describing the steps to undertake the physical activity. A total of 2 fitness trackers (Fitbit Flex 2 and Huawei Band 2 Pro) incorporated *credible source*, presented as textual information on the app (eg, "the American heart association recommends…"). All fitness trackers, except the Huawei Band 2 Pro, incorporated social comparison, using leaderboards of steps accumulated. Only the Nokia Go incorporated the BCTs *behavioral practice and rehearsal*, *action planning*, *habit formation*, and *social support* by setting alerts as prompts for action. Only the Polar A300 incorporated *monitoring of emotional consequences* through rating of emotions using emoticons on the app.

Correspondence to Physical Activity Guidelines

All 6 fitness trackers incorporated BCTs to increase physical activity, but only 2 fitness trackers (Fitbit Flex 2 and Moov Now) aligned with public health physical activity guidelines by including active minutes as a physical activity goal. The Huawei Band 2 Pro, Misfit shine 2, Nokia Go, and Polar A300 centered on the number of steps achieved daily as physical activity goals. A total of 2 fitness trackers (Fitbit Flex 2 and Polar A300) incorporated BCTs to reduce sedentary behavior, which was implemented through the BCT *information about health consequences* (eg, "sitting for long periods is bad for your blood circulation, especially in your legs" and "moving regularly breaks up sedentary time and can improve your well-being"). The Huawei Band 2 Pro, Misfit shine 2, Moov Now, and Nokia Go did not specifically target sedentary behavior.

Discussion

Principal Findings

This study aimed to evaluate the use of BCTs in fitness trackers that are swim proof and cost less than Aus $150 (US$ 105). Overall, all fitness trackers incorporated more than 3 BCT clusters, which has been shown to produce significant effects in physical activity interventions [51]. The Fitbit Flex 2 and Nokia Go incorporated the most BCT clusters. There was a nonsignificant correlation between the cost of fitness trackers and the number of BCTs incorporated. The Fitbit Flex 2, which costs Aus $149.95 (US$ 105, had the most BCTs (coded at 20), followed by the Nokia Go, at a cost of Aus $89.95 (US$ 63) with 19 BCTs. In comparison, the Misfit Shine 2 Pro, which costs Aus $107.77 (US$ 75), incorporated the least number of BCT clusters and BCTs, at 6 and 11, respectively. The findings indicated that the cost of fitness trackers does not necessarily reflect or is associated with the number of BCTs incorporated in them. The BCTs that were frequently incorporated across the 6 fitness trackers were mostly related to self-management strategies, such as goal setting, self-monitoring, self-evaluation (eg, feedback, provision of discrepancies between current behavior and goal), prompts and cues, and rewards (eg, social reward) [57]. This finding is similar to those from previous studies of fitness trackers [52-54] and apps [56,58] targeting physical activity, and they also overlap with reviews of BCTs that were rated as important by users of fitness trackers [55]. Notably, all 6 fitness trackers in this study incorporated a combination of 9 or more BCTs that were related to self-management. However, similar to the study by Lyons et al [52], this study also found that other effective BCTs were rarely incorporated in fitness trackers. Only Nokia Go contained the BCTs *behavior practice and rehearsal* and *social support*, through the use of prompts, that have been found to be effective in increasing physical activity for adults with obesity [24] and cardiovascular disease [45]. This indicates that certain fitness trackers may be more effective for particular population groups because of the types of BCTs incorporated in them. The combinations of informational and instructional BCTs that have been found to support maintenance of change in physical activity were only observed in the Fitbit Flex 2 fitness tracker. The Fitbit Flex 2 companion app provided links to a separate app called Fitbit Coach that contained a library of videos to instruct and model the way to perform various workouts. The Fitbit Flex 2 companion app also provided textual information about health and emotional benefits of physical activity and sedentary behavior. It seems that manufacturers of fitness trackers are more focused on functional features (eg, recording data, providing prompts) compared with informational and instructional features. It could be that certain BCTs, such as features that support self-management through recording behavioral data, evaluating and providing feedback about behavior and providing prompts, are better suited to delivery via wearable technology. There is some support for this contention in this study in the finding that informational and instructional BCTs were often presented on the companion apps instead of the device. A recent study also found that providing instructions was one of the most frequently implemented BCTs (17 of 25 apps) in mobile apps that aimed to improve physical activity and reduce sedentary behavior [59]. These findings are not surprising, as longer information and instructions might be more suited to technologies with larger reading screens or audio outputs, such as computers, tablets, and smartphones. Taken together, these findings highlight the importance of delivering BCTs through appropriate technological channels and leveraging and integrating different technologies to create a more holistic intervention for promoting physical activity.

Given that the purpose of fitness trackers is to promote physical activity, it is remarkable that not all fitness trackers assessed in this study aligned with public health physical activity guidelines. Physical activity guidelines for adults include engagement of at least 150 min of moderate-intensity physical activity per week, performed in bouts of at least 10 min duration [4,14,60]. Only the Fitbit Flex 2 and Moov Now aligned with public health

physical activity guidelines by including active minutes as a physical activity goal. Active minutes were calculated only if activities above 3 METs were detected continuously for 10 min at a time. Other fitness trackers focused on the number of steps achieved daily. The tracking of steps is a prominent part of data collection for most of the fitness trackers in this study. This was expected, as steps are a fundamental part of daily living, which might be more easily measured. However, the sole use of steps to measure physical activity may be insufficient. The tracking of step counts does not provide information about the intensity of the activity, which has been indicated to be more beneficial to health than number of steps taken [61]. Moreover, there has been a change in the fitness culture over the past decade, in which the trend for physical activity has been moving away from step-based activities to spinning (indoor cycling), dance workouts (eg, Zumba), and body weight training [62-64], as well as water sports, such as stand-up paddle boarding and kitesurfing. Although most fitness trackers allow for self-monitoring of physical activity that is not based on steps, these data have not been directly incorporated into physical activity goals. Given the findings from previous studies that goal setting is an effective BCT to increase physical activity [25,48] and reduce sedentary behavior [65], it would be optimal to integrate non-step-based activities into physical activity goals, as has been achieved by Fitbit Flex 2 and Moov Now, through the inclusion of active minutes as a goal. Regarding guidelines to minimize sedentary behavior by minimizing the amount of prolonged sitting [14-16], only the Fitbit Flex 2 and Polar A300 provided BCTs that directly targeted sedentary behavior in the form of providing *information about health consequences*. The Fitbit Flex 2, Huawei Band 2 Pro, Misfit Shine 2, and Polar A300 provided prompts to move after detecting inactivity over 1- or 2-hour periods. However, these prompts were based on a lack of steps detected within that period, instead of detecting sedentary behavior that has been defined as engaging in a sitting or reclining posture, with an energy expenditure less than or equal to 1.5 METs [8]. The authors of a previous study have coded the prompts of inactivity as targeting a reduction of sedentary behavior [54]. However, this study adhered to the definition of sedentary behavior by the Sedentary Behaviour Research Network [8] and took into account the distinction between physical inactivity and sedentary behavior in the coding of BCTs. Furthermore, studies have noted that interventions, which promote physical activity, do not necessarily have an effect on reducing sedentary behavior, and techniques that primarily aimed to change sedentary behavior were more effective in reducing sedentary behavior [65]. Despite literature showing that both physical activity and sedentary behavior are important to good health, it seemed that most developers of fitness trackers assessed in this study have focused on achieving sufficient amount of physical activity, but they have placed less emphasis on directly reducing sedentary behavior. It could be that the technology required to detect sitting and reclining postures is too costly to be incorporated into fitness trackers within the price range of Aus $150 and below and that a more cost-effective workaround to target sedentary behavior is to frequently prompt users to take more steps. Overall, the findings from this study show that fitness trackers below Aus $150 contain evidence-based BCTs known to promote physical activity and reduce sedentary behavior. The majority of BCTs implemented targeted physical activity, and the most frequently used BCTs overlapped with self-management strategies. This suggests that fitness trackers offer the prospect for physical activity interventions that are cost effective and easily accessed by a wide population. Opportunities to improve the effectiveness of fitness trackers include incorporating BCTs that facilitate maintenance of behavior change in physical activity, such as instruction or demonstration of behavior, and providing information on the consequences of behavior [24], as well as incorporating BCTs to target sedentary behavior. Furthermore, public health physical activity guidelines ought to be used to inform the type of goals that are incorporated into fitness trackers.

Although this study highlights that low cost fitness trackers contain evidence-based BCTs known to promote physical activity, it is worth noting that only 1 fitness tracker contained BCTs effective for special population groups, such as adults with obesity and chronic illnesses. Further work is needed to determine if these low cost fitness trackers are sufficient as standalone interventions, especially for these special population groups.

Strengths and Limitations

The most recent taxonomy of behavioral change techniques was used to assess the content of the fitness trackers and their companion apps, and it compared the BCTs to those that have been found to be successful at improving physical activity, thus adding to the evidence base for the use of fitness trackers to support interventions to promote physical activity. This study focused on fitness trackers that are swim proof and cost less than Aus $150 to broaden the reach of fitness trackers to the community in terms of preferred and accessible physical activity, as well as affordability. A limitation is that the ratings may not be representative of the most current version of the fitness trackers assessed in this study because of frequent updates of fitness trackers and their associated apps. A further limitation is that this study only included fitness trackers under Aus $150 and did not cover the entire range of fitness trackers available. The small number of fitness trackers places a limitation on the calculation of Pearson correlation coefficient to assess the relationship between the cost of fitness trackers and the number of BCTs incorporated.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Description of behavior change techniques included in each fitness tracker.

[DOCX File, 35KB - mhealth_v7i7e12768_app1.docx]

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Abbreviations

BCT: Behavior Change Technique
BCTTv1: Behavior Change Technique Taxonomy v1
MET: Metabolic Equivalent Tasks

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Corrigenda and Addenda

Authorship Correction: A Community-Based Short Message Service Intervention to Improve Mothers' Feeding Practices for Obesity Prevention: Quasi-Experimental Study

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The authors of "A Community-Based Short Message Service Intervention to Improve Mothers' Feeding Practices for Obesity Prevention: Quasi-Experimental Study" (JMIR Mhealth Uhealth 2019;7(6):e13828) wish to change the order of the authors on the publication so that Xu Qian is listed last.

The previous order of authorship was as follows:

Hong Jiang, Mu Li, Li Ming Wen, Louise Baur, Gengsheng He, Xu Qian, Xiaoying Ma

The correct order of authorship is as follows:

Hong Jiang, Mu Li, Li Ming Wen, Louise Baur, Gengsheng He, Xiaoying Ma, Xu Qian

Additionally, the affiliations listed for author Gengsheng He have also been updated. Previously, only affiliation 2 was listed for this author:

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The revised listing identifies that Gengsheng He is associated with affiliations 1 and 2:

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The corrections will appear in the online version of the paper on the JMIR website on July 18, 2019, together with the publication of this correction notice. Because this was made after submission to PubMed, PubMed Central, and other full-text repositories, the corrected article also has been resubmitted to those repositories.

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Original Paper

Identifying Behavioral Phenotypes of Loneliness and Social Isolation with Passive Sensing: Statistical Analysis, Data Mining and Machine Learning of Smartphone and Fitbit Data

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Abstract

Background: Feelings of loneliness are associated with poor physical and mental health. Detection of loneliness through passive sensing on personal devices can lead to the development of interventions aimed at decreasing rates of loneliness.

Objective: The aim of this study was to explore the potential of using passive sensing to infer levels of loneliness and to identify the corresponding behavioral patterns.

Methods: Data were collected from smartphones and Fitbits (Flex 2) of 160 college students over a semester. The participants completed the University of California, Los Angeles (UCLA) loneliness questionnaire at the beginning and end of the semester. For a classification purpose, the scores were categorized into high (questionnaire score>40) and low (≤40) levels of loneliness. Daily features were extracted from both devices to capture activity and mobility, communication and phone usage, and sleep behaviors. The features were then averaged to generate semester-level features. We used 3 analytic methods: (1) statistical analysis to provide an overview of loneliness in college students, (2) data mining using the Apriori algorithm to extract behavior patterns associated with loneliness, and (3) machine learning classification to infer the level of loneliness and the change in levels of loneliness using an ensemble of gradient boosting and logistic regression algorithms with feature selection in a leave-one-student-out cross-validation manner.

Results: The average loneliness score from the presurveys and postsurveys was above 43 (presurvey SD 9.4 and postsurvey SD 10.4), and the majority of participants fell into the high loneliness category (scores above 40) with 63.8% (102/160) in the presurvey and 58.8% (94/160) in the postsurvey. Scores greater than 1 standard deviation above the mean were observed in 12.5% (20/160) of the participants in both pre- and postsurvey scores. The majority of scores, however, fell between 1 standard deviation below and above the mean (pre=66.9% [107/160] and post=73.1% [117/160]). Our machine learning pipeline achieved an accuracy of 80.2% in detecting the binary level of loneliness and an 88.4% accuracy in detecting change in the loneliness level. The mining of associations between classifier-selected behavioral features and loneliness indicated that compared with students with low loneliness, students with high levels of loneliness were spending less time outside of campus during evening hours on weekends and spending less time in places for social events in the evening on weekdays (support=17% and confidence=92%).

The analysis also indicated that more activity and less sedentary behavior, especially in the evening, was associated with a decrease in levels of loneliness from the beginning of the semester to the end of it (support=31% and confidence=92%).

Conclusions: Passive sensing has the potential for detecting loneliness in college students and identifying the associated behavioral patterns. These findings highlight intervention opportunities through mobile technology to reduce the impact of loneliness on individuals' health and well-being.

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KEYWORDS

mobile health; loneliness; machine learning; statistical data analysis; data mining; digital phenotyping

Introduction

Background

Loneliness in the United States and across the world is rising to an epidemic level [1]. According to the latest US Loneliness Index Report [2], nearly half of Americans report high levels of loneliness with an average loneliness score of 43.9. Of those surveyed, 46% reported sometimes or always feeling lonely and 47% reported feeling separated from others. The highest levels of loneliness were found among young adults aged 18 to 22 years who had an average loneliness score of 48.3. Loneliness is defined as a negative emotional experience caused by a discrepancy between the desired and achieved social contact [3] or perceived social isolation [1,4]. As opposed to aloneness, which is a state of being physically alone, loneliness relates to a subjective feeling and can occur in individuals despite having social relationships or being around others [5,6].

Social relationships are intricately tied to individuals' health, and a lack of social connection has an adverse impact on health and well-being [7,8]. In a landmark systematic review and meta-analysis of 148 studies examining social relationships and mortality risk, Holt-Lunstad et al [9] found that older adults with stronger social relationships had a 50% increased likelihood of survival than those with weaker social relationships. Subsequent research by this group found that social isolation, loneliness, and living alone were greater risks for mortality than obesity [10]. Importantly, loneliness has also been associated with higher risk for developing depression and other mental health problems [10].

Given the significance of loneliness on health and well-being outcomes, the goal of this study was to detect and understand loneliness through behavioral signals collected from smartphone and wearable devices. Wide usage of mobile devices provides an opportunity to passively collect daily behavioral traces that relate to mental health and well-being over a long period of time. We were interested in understanding (1) how well we could detect if someone was lonely by analyzing their daily digital behavioral signals and (2) what behavioral patterns were associated with loneliness.

Related Work

Pulekar et al [11] studied the first question in a small study with 9 college students over 2 weeks. Data logs of social interactions, communication, and smartphone activity were analyzed to detect loneliness and its relationship with personality traits. The study reports 90% accuracy in classifying loneliness using the smartphone features that were mostly correlated with the loneliness score. However, the small sample size, the short duration of the data collection phase, and missing details in the machine learning approach, especially the classification evaluation, make the results difficult to generalize and build on. Sanchez et al [12] used machine learning to infer the level of loneliness in 12 older adults who used a mobile app for one week. Call logs and global positioning system (GPS) coordinates were collected from the phones. A total of 4 models for family loneliness, spousal loneliness, social loneliness, and existential crisis were built with a reported accuracy of 91.6%, 83.3%, 66.6%, and 83.3%, respectively. However, similar to the results of the study by Pulekar et al, these results may fail to generalize because of the small sample and short duration of data collection.

A few studies have explored the second question using correlation analysis to understand relationships between single behavioral signals, such as level of physical activity, mobility, social interactions, and loneliness [13-15]. Wang et al [14] analyzed smartphone data collected from 40 students over a spring semester and found negative correlations between loneliness and activity duration for day and evening times, traveled distance, and indoor mobility during the day. A related study from the same group found statistically significant correlations (P<.01) between kinesthetic activities and change in loneliness but no relationship between loneliness and sleep duration, geospatial activity, or speech duration [13]. Gao et al [15] found that people with higher levels of loneliness made or received fewer phone calls and used certain types of apps, such as health and fitness, social media, and Web browsing, more frequently than those with low levels of loneliness. Our data mining approach, in addition to providing similar behavioral features to those reported by Wang et al [14], presents an innovative method for extracting the combined behavioral patterns in our participant population. For example, we can observe that compared with students with a low level of loneliness, students with a high level of loneliness unlock their phones in different time segments during weekends, spend less time off-campus during evening hours on weekends, and socialize less during evening hours on weekdays. To our knowledge, this study introduces, for the first time, an approach toward extracting combined behavioral patterns through data mining and their associations with a mental health outcome, such as loneliness, from passive sensing data.

Methods

Recruitment and Data Collection

Data collection was done as part of a campus-wide study at an American research university in the state of Pennsylvania to assess students' health and well-being. The participants were first-year undergraduate students recruited via advertisement on student mailing lists and Facebook groups. An identity document (ID) was assigned to each participant and documents connecting the ID and participant's name and demographics were kept separate. The data on the phone were anonymous and only identifiable through the participant's device ID. All data collection procedures in this study were approved by the university's Institutional Review Board (IRB: STUDY2016_00000421), including the collection of location data. Students were invited to an initial appointment in our lab to be screened for eligibility, provide written informed consent to participate in the study, and allow us to collect their data. At this appointment, participants downloaded the open-source AWARE data collection app [16] that was developed in our lab to track sensor data from their own Android or iOS smartphones and they received a Fitbit Flex 2 to track steps and sleep. Later, the students completed Web-based questionnaires for an initial assessment of their health and well-being. At the end of the study, students filled out the same questionnaires for post measurements. Out of the 188 first-year college students initially enrolled, 160 (61% female, 57% Asian, 34% white, 9% Hispanic, and 5% black) completed all pre- and postsemester surveys. Participants were informed about the purpose of the study during the initial appointment session. There was no deception or omission of study aims to the participants.

Data were collected passively from their smartphone and Fitbit devices and were continuously recorded over 16 weeks of the study (1 semester that was the participants' second semester at the university). The AWARE framework [17] is an open-source data collection app with supporting backend and network infrastructure, which collects sensor data unobtrusively from students' smartphones. It supports both Android and iOS platforms and can be downloaded from the App and Play stores. AWARE enabled us to record nearby Bluetooth addresses, Wi-Fi, location, phone usage (ie, when the screen status changed to on or off and locked or unlocked), and call and short message service (SMS) text messaging logs. The participants were asked to keep their Bluetooth and Wi-Fi on during the study. To assess calls to close contacts, we asked the participants to provide phone numbers of family members, friends on campus, and friends off campus that they most frequently contact. We also used a conversation plugin for AWARE (same as the one used by Wang et al [14]), which makes audio inferences, such as silence, voice, noise, or unknown. Furthermore, we equipped the participants with a Fitbit Flex 2 wearable activity tracker that records the number of steps taken and sleep status (asleep, awake, restless, or unknown). Students were instructed to wear the device on their nondominant hand. We chose Flex 2 based on a combination of factors including simplicity, waterproofness, battery life, and price. Fitbit Flex has shown to have moderate validity to track activities compared with ActiGraph [16]. Calls and phone usage were event-based sensor streams, whereas Bluetooth, Wi-Fi, location, sleep, and steps were sampled as time series. These time series data streams were sampled at different rates because of the capabilities of the hardware being used. Bluetooth and location coordinates were collected at 1 sample per 10 min, sleep at 1 sample per min, and steps at 1 sample per 5 min. Data from AWARE were deidentified and automatically transferred over Wi-Fi to our backend server on a regular basis, and data from the wearable Fitbit were retrieved using the Fitbit app programming interface (API) at the end of the study. The participants were asked to keep their phone and Fitbit charged and with them at all times.

Survey Data Processing

To assess loneliness, we used the revised University of California, Los Angeles (UCLA) loneliness scale, a well-validated and commonly used measure of general feelings of loneliness [18]. The participants provided ratings for each of the 20 questions (Textbox 1) using a scale of 1 (never) to 4 (always). A total of 9 items were reverse scored before all items were summed to create a total score. The total loneliness scores ranged from 20 to 80 with higher scores indicating higher levels of loneliness. As there is no standard cutoff for loneliness scores in the literature, each study has created arbitrary categorizations including the categories proposed in the study by Cacioppo et al [1]: High loneliness is defined as scoring 44 or higher, low loneliness is defined as scoring less than 28, and scores between 33 and 39 represent the middle of the spectrum. Although we could adapt these categories, our goal was to do a binary classification to detect the level of loneliness, which required dividing the loneliness scores into 2 categories. We also wanted to create cutoff scores that were independent of the population distribution but represented conceptual indicators of loneliness. Thus, as the answer choices provided were 1=never, 2=rarely, 3=sometimes, and 4=often, we determined that scores of 40 and below indicated that the participants were rarely or never experiencing loneliness and scores of 41 and above would indicate at least sometimes experiencing loneliness (a participant that answered rarely (score=2) to all 20 questions would have a total score of 40, suggesting that 40 indicates that the participant is rarely experiencing loneliness). We, therefore, used 40 as the cutoff point where the scores of 40 and below were categorized as no to low loneliness and the scores above 40 were categorized as moderate to high loneliness. For simplification, we refer to the no to low loneliness category as low loneliness and the moderate-to-high loneliness category as high loneliness. These categories were used as ground truth labels in our machine learning pipeline to infer the loneliness level. Although this choice can be replicated in other similar studies, further sensitivity analyses should be done to determine the optimal cutoff point for the UCLA scale.

Textbox 1. List of questions used in the University of California, Los Angeles, loneliness scale (questions marked with R were reverse scored).

R1. How often do you feel that you are in tune with the people around you?
2. How often do you feel that you lack companionship?
3. How often do you feel that there is no one you can turn to?
4. How often do you feel alone?
R5. How often do you feel part of a group of friends?
R6. How often do you feel that you have a lot in common with the people around you?
7. How often do you feel that you are no longer close to anyone?
8. How often do you feel that your interests and ideas are not shared by those around you?
R9. How often do you feel outgoing and friendly?
R10. How often do you feel close to people?
11. How often do you feel left out?
12. How often do you feel that your relationships with others are not meaningful?
13. How often do you feel that no one really knows you well?
14. How often do you feel isolated from others?
R15. How often do you feel you can find companionship when you want it?
R16. How often do you feel that there are people who really understand you?
17. How often do you feel shy?
18. How often do you feel that people are around you but not with you?
R19. How often do you feel that there are people you can talk to?
R20. How often do you feel that there are people you can turn to?

Loneliness in College Students: Statistical Analysis

As the first step, we analyzed the distribution of loneliness among our participants. As mentioned, we categorized the UCLA loneliness scores into low (≤40) and high (>40) levels of loneliness. We then calculated the distribution of the overall scores as well as the distribution of responses to each question in the UCLA loneliness scale. This analysis helps identify the common response level to each question. Furthermore, we calculated the differences between the pre- and postsemester loneliness scores to understand the change in loneliness across the semester. We repeated this analysis with each question and measured the amount of change in students' responses. We showed the distribution of questions being rated the same, above, or below the presemester loneliness in the post measurements, thus identifying the items that were more likely to change than others over time.

Behavior Patterns of Loneliness: Data Mining Analysis

In addition to capturing the relations between each behavioral feature and loneliness, we were also interested in extracting combined behavioral patterns that were associated with loneliness. We measured the proportion of our study population that was covered by these combinations of behavioral patterns and discussed the technological implications of these observations. We also explored associations between responses to individual questions and level of loneliness as well as behavioral features and level of loneliness.

We applied Apriori [19], a well-known frequent itemset algorithm for discovering associations among items in transactional datasets, to extract patterns between the overall loneliness level and combined questions as well as combined behavioral patterns that were most associated with the level of loneliness. Apriori extracts patterns in 2 steps: it first generates a set of frequent items that appear together and then extracts association rules that explain the relationship between those frequent items. The extracted rules must satisfy a degree of support and confidence in the dataset. For example, let A and B be 2 sets of items. An association (A→B) exists if items in A and B frequently appear together in transactions. Support is the percentage of transactions that contain both A and B, whereas confidence is the percentage of transactions containing A that also contain B [20], that is, support (A→B)=P(AUB) and confidence (A→B)=P(B|A). Note that the notation P(AUB) indicates the probability that a transaction contains the union sets of A and B (ie, it contains every item in A and B). This should not be confused with P(A or B), which indicates the probability that a transaction contains either A or B [20].

To simplify the pattern mining process, we further discretized the behavioral features into categories of low, moderate, and high using binning with equal frequency. We then applied Apriori on the selected feature set generated in the machine learning process described in the following section.

Detection of Loneliness Level and Change in Loneliness: Machine Learning Analysis

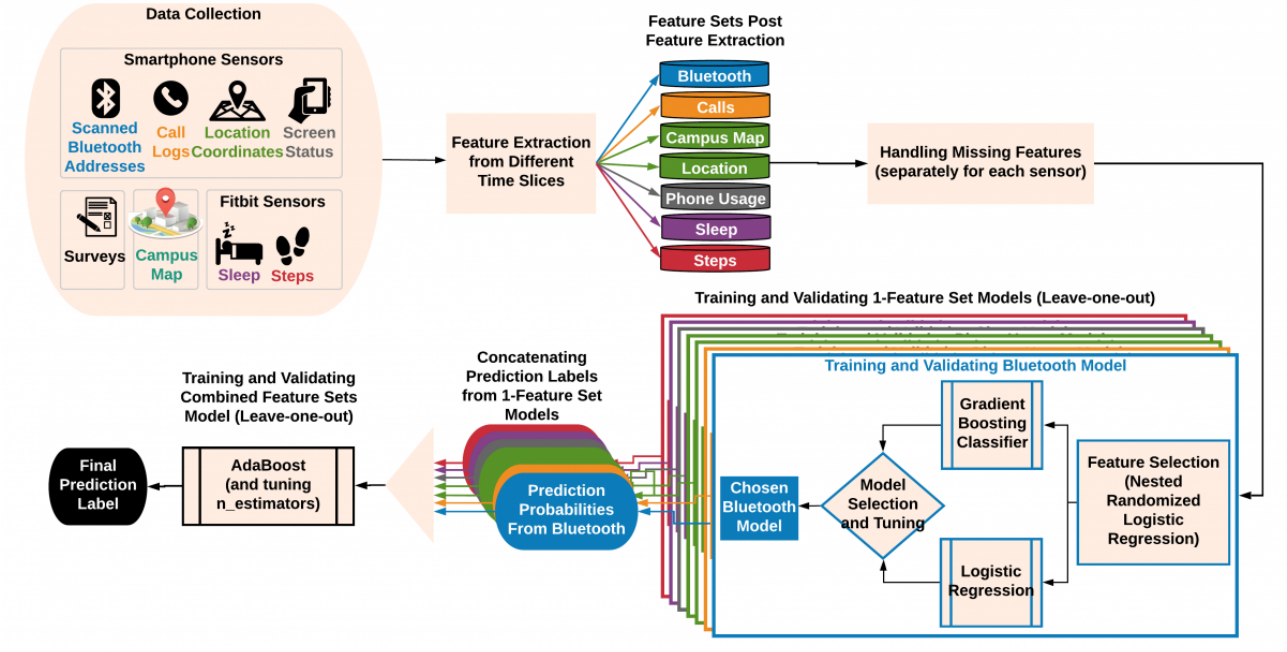
To explore the use of passive sensing in inferring the state of loneliness, we defined loneliness detection as a binary classification problem, where the aggregated behavioral data

over the semester were used as feature vectors to infer the level of loneliness (low or high). We followed the same categorization described earlier to label loneliness scores as low or high. Our modeling pipeline (Figure 1) handles each sensor separately (called 1-feature set) during the training and validation and provides a combined final classification outcome at the end. Using the 1-feature sets provides the possibility to examine the predictive power of each sensor alone and combined. Specifically, our approach comprised the following processes:

1. Passive data processing and feature extraction
2. Handling missing values
3. Training and validating models that use only 1-feature set for each of the following 7 feature sets: Bluetooth, calls, campus map, location, phone usage, sleep, and steps
4. Obtaining the final label for the outcome by combining detection probabilities from 1-feature set models

The processes are described in the following sections.

Figure 1. Machine learning pipeline including data collection, feature extraction, training and validation, and final output.



Passive Data Processing and Feature Extraction

Our data included time series data from Bluetooth, calls, SMS, Wi-Fi, location, phone usage, steps, and sleep. These sensing channels have the potential to capture daily behavioral patterns related to loneliness, namely, mobility and activity patterns, communication and social interaction, and sleep. We developed a generic and flexible feature extraction component (FEC) [21] to extract features from raw sensor data collected from the smartphones and Fitbit devices. FEC computes features from timestamped streams of data in specified time segments ranging from 5 min to several months. From the data streams, FEC extracts a set of common statistical features, such as minimum, median, mean, maximum, and standard deviation, as well as more complex behavioral features, such as movement regularity and travel distance. Each feature from every time series data was extracted from 45 time segments illustrated in Figure 2. First, we fetched all the available data (spanning over multiple days of the study) from a certain epoch or time of the day (all day; night, ie, 12 am-6 am; morning, ie, 6 am-12 pm; afternoon, ie, 12 pm-6 pm; and evening, ie, 6 pm-12 am) and for certain days of the week (all days of the week; weekdays only, ie, Monday-Friday; weekends only, ie, Saturday-Sunday). Then, we calculated features from these data aggregated over different levels of granularity (eg, whole semester, two-halves of the semester, and weekly). As there are 5 epochs, 3 days-of-the-week segmentations, and 3 levels of granularity, we get 5×3×3=45 time segments. Note that the 2 halves of the semester are not perfect halves. For simplicity, we refer to week 1 to week 6 (before midterms) as the first half and week 7 to week 16 (midterms and after midterms) as the second half. In total, we extracted 77,805 features from our time series data in combination with different time segments. The source code for extracting these features will be available upon request. The following describes features extracted in each behavior category.

Figure 2. Raw data from each sensor was preprocessed and then filtered by an epoch and a days-of-the-week option.

Mobility and Physical Activity Features

Features related to mobility were extracted from the GPS coordinates including location variance (sum of the variance in latitude and longitude coordinates), log of location variance, total distance traveled, average speed, and variance in speed. We followed the approach in the study by Tan et al [22], which used the Lomb-Scargle method [23] to extract movement regularity from location patterns that follow a 24-hour cycle. Additional features were extracted through the following process:

1. We calculated the movement speed from the distance covered and time elapsed between 2 samples. Samples with speed >1 km/h were labeled as moving, else static.
2. Samples labeled as static were clustered using density-based spatial clustering of applications with noise (DBSCAN), a density-based clustering algorithm [24] to find frequent places visited by the participant and labeled as global or local clusters. DBSCAN efficiently groups nearby spatial points together and distinguishes outlier points. Unlike other clustering algorithms, such as k-means, DBSCAN does not require knowing the number of clusters a priori. It is able to find inner clusters (clusters surrounded by other clusters) and is robust to outliers and noise. Global clusters were extracted using all data and local clusters were extracted when data were split into daily time segments described earlier.

These steps allowed us to extract the number of frequent places, number of transitions between places, radius of gyration [25], time spent at top 3 (most frequent) local and global clusters, percentage of time spent moving, and percentage of time spent in infrequent or rarely visited locations (labeled as −1 by DBSCAN). We also calculated statistics related to the length of stay at clusters, such as maximum, minimum, average, and standard deviation of the length of stay at local and global clusters, as well as location entropy and normalized location entropy across local and global clusters. Location entropy is higher when time is spent evenly across frequent places. Calculating features for both local and global clusters allowed us to capture different behaviors related to the user's overall location patterns (global) and the user's location patterns within a time slice (local). For example, time spent at top 3 global and local clusters capture the time spent at user's overall frequent places and user's frequent location in a particular time slice (eg, mornings on weekends). We assumed the place most visited by the participant at night to be their home location.

To approximate the home location, we performed abovementioned steps (1) and (2) on the location coordinates from all nights (12 am to 6 am) and assumed the center of the most frequented cluster to be the participant's home location center. As we do not know the radius of the home, we calculated two home-related features: time spent at home assuming home to be within 10 meters of the home location center and time spent at home assuming home to be within 100 meters of the home location center. We also analyzed the user's location patterns in relation to their college campus. First, we obtained a campus map of the participants' university. Then, we marked out the campus boundary and different types of buildings on campus by creating polygons on Google Maps using an online Geographical Information System. We annotated 6 categories of buildings and spaces—2 different houses that hold the most social events, student apartments, residential halls, athletic facilities, and green spaces. As academic buildings in this university are often collocated with other spaces, we assumed any on-campus space not belonging to these 6 categories to be an academic building. For every location sample, we assigned 1 of 8 location category labels (6 building/space types, academic, off campus). Then, the following features were extracted for each type of space: time spent at each location type in min; percentage of time spent at each location type; number of transitions between different spaces; number of bouts (or continuous periods of time) at space; number of bouts during which a participant spends 10, 20, or 30 min at the same space; and minimum, maximum, average, and standard deviation of the length of bouts at each space. The campus map features also included 2 multimodal features—study duration and social duration. These features fused data from location, phone usage, audio, and steps sensors.

Study duration was calculated by fusing location type labels with data from the phone usage and steps sensors. A participant was assumed to be studying if they spent 30 min or more in an academic building while being sedentary (fewer than 10 steps) and having no interaction with their phone. Social duration was calculated by fusing location type labels with data from the audio sensor. A participant was assumed to be social if they spent 20 min or more in any of the residential buildings or green spaces and the audio sensor inferred human voice or noise for 80% or more of that time. Other activity- and mobility-related features were extracted from the step counts collected by Fitbit. We calculated the total number of steps and the maximum number of steps taken in any 5-min period. Other features were extracted from bouts, where a bout is a continuous period of time during which a certain characteristic is exhibited. Examples of such features included the total number of active or sedentary bouts [26], and the maximum, minimum, and average length of active or sedentary bouts. We also calculated minimum, maximum, and average number of steps over all active bouts. Directly using the results from the study of Cacioppo et al [26], we determined that a bout is sedentary if the user takes less than 10 steps during each 5-min interval within the bout. As soon as the user takes more than 10 steps in any 5-min interval, they switch to an active bout.

Communication and Interaction Features

We used call and SMS logs to extract features including the number and duration of incoming, outgoing, and missed calls and messages to everyone, to family members, to friends off campus, and to friends on campus, number of correspondents overall, and number of correspondents who are family members, friends off campus, or friends on campus. We also extracted phone usage features that related to both communication and Web-based interaction. We used the logs of screen status (eg, on, off, lock, and unlock) over time. We extracted the number of unlocks per min, total time spent interacting with the phone, total time the screen was unlocked, the hour of the days the screen was first unlocked or first turned on, the hour of the days the screen was last unlocked, locked, and turned on, and the

maximum, minimum, average, and standard deviation of the length of bouts (or continuous periods of time) during which the participant was interacting with the phone and when the screen was unlocked. A participant is said to be interacting with their phone between when the screen status is unlock and when the screen status is off or lock.

As Bluetooth connections can be a proxy of social interaction, we also extracted features from Bluetooth by first classifying scanned Bluetooth devices into 3 groups of self (the participant's own devices), related (devices belonging to the participant's partner, roommates, or classmates), and others (unrelated devices). To classify scanned Bluetooth addresses into the 3 groups of self, related, and others, we did the following:

1. We calculated number of days each unique Bluetooth address was scanned at least once, that is, number_of_daysbti.
2. We calculated the average frequency of each unique Bluetooth address, that is, average_frequencybti = total_countbti / number_of_daysbti.
3. We Z-normalized the number_of_daysbti and average_frequencybti to give equal weight to both while optimizing score in step 4.
4. For each Bluetooth address, we computed score = number_of_daysbti + average_frequencybti.
5. We used K-means clustering to cluster score from step 4 for all Bluetooth addresses using K=2 and K=3.
6. The model with K=2 was chosen if the sum of squared distances between clustered points and cluster centers was smaller than what we got with K=3. Otherwise, we chose model with K=3.
7. If the model with K=2 was chosen, the cluster with higher scores contained the participant's own devices (self), whereas the other cluster contained other people's devices (others). If the model with K=3 was chosen, the cluster with the highest scores contained the participant's own devices (self), the cluster with the lowest scores contained other people's devices (others), and the remaining cluster contained devices of the participant's partners, roommates, or officemates (related). Once the Bluetooth addresses scanned were clustered into self and others or self, related, and others, we extracted features including the number of unique devices, number of scans of the most and the least frequent device, and sum, average, and standard deviation of the number of scans of all devices. Each round included all devices (ignores clusters), self and related cluster (combined), and others cluster.

Sleep Features

Sleep features were extracted from the sleep inferences (eg, asleep, restless, awake, and unknown) over time returned by the Fitbit API. We calculated the number of asleep samples, number of restless samples, number of awake samples, weak sleep efficiency (the sum of the number of asleep and restless samples divided by the sum of the number of asleep, restless, and awake samples), strong sleep efficiency (the sum of the number of asleep samples divided by the sum of the number of asleep, restless, and awake samples), count, sum, average, maximum, and minimum length of bouts during which the participant was asleep, restless, or awake, and the start and the end time of the longest and the shortest bouts during which the participant was asleep, restless, or awake.

Feature Matrix

After feature extraction, we obtained a feature matrix for each of the 7 feature sets derived from different sensors. In each of these feature matrices, each sample or record contained features extracted from one student. We aggregated our features over different time segments (described in Figure 2): over different weeks, in the two-halves of the semester, and across the whole semester. The features from all these time segments were concatenated to form the feature vector for each student. A scheme of the feature matrix is shown in Figure 3. The coding schema is described in the Multimedia Appendix 1 and a sample of selected features is presented.

Figure 3. The schema of the feature matrix used in the machine learning pipeline (each column is a feature and each row is a sample per participant).

device_id	f_steps_avg_length_active_bout_minutes_mo_wkdy_half_sem_2017-01-18	f_steps_avg_length_active_bout_minutes_mo_wkdy_half_sem_2017-03-01	...	f_call_duration_incoming_calls_seconds_af_wkdy_day_2017-01-18	f_call_duration_incoming_calls_seconds_af_wkdy_day_2017-01-19	...	f_blue_number_unique_devices_of_self_wkdy_sem_2017-01-18	...	f_screen_last_on_Hour_5_af_wkdy_sem_2017-01-18	...	f_loc_home_stay_time_percent_10m_ev_wkend_sem_2017-01-18	...	f_locMap_study_duration_minutes_af_sem_2017-01-18	...	f_steps_max_length_sedentary_bout_minutes_ni_sem_2017-01-18
1	20	13		69	172		3		62		0.0458971		200		610
2	17	21		226	21		1		48		0.100391		230		650
3	13	13		154	0		5		63		0.0789779		90		820
4	15	18		0	495		17		63		0.207094		200		1030
5	18	18		1964	109		2		54		0.075188		1160		1400
...	...	...	...	...	...	...	...	...	...	...	...	...	...	...	...

Handling Missing Values

We handled missing data on a 1-feature set basis: for each sensor, we removed a feature from the dataset if its value was missing for more than 30 participants, and we removed a participant from the dataset if 20% of their data were missing. The thresholds for removing data were determined empirically. We then imputed the remaining missing feature values with a −1. This was chosen because all feature values were above 0 and as such −1 could distinguish missing values. The same features calculated over different time segments were viewed independently, for example, if a feature was missing for a week for over 30 people, we removed that feature from that week only. As such, the number of samples that were used in training and validation for each feature set varied. For example, when training with semester-only features, the smallest feature set belonged to location (with 118 samples) and the largest sets were Bluetooth and phone usage (with 134 samples).

Building and Validating 1-Feature Set Models

Building and validating 1-feature set models followed 3 steps:

1. Feature selection
2. Training 2 algorithms, namely, logistic regression and gradient boosting, to build models of each feature set using selected features
3. Selecting the model with better accuracy

All these steps were done in a leave-one-student-out cross-validation, that is, at each step of training and feature selection, we built a separate model using data from n−1 students and tested it on the nth student. Note that the data for each student were represented as one sample in each feature set in the form of a vector.

Feature Selection

The wide range of behavioral features provides the possibility to draw insights into different types and granularity of behavior in relationship to loneliness. However, the large number of features makes it difficult for the classification algorithm to build a comprehensive model of data, especially when the size of the sample set (eg, number of participants) is proportionally smaller than the feature set. Therefore, we applied feature selection to reduce the number of features to a set that is representative of our data. We experimented with different feature selection methods including least absolute shrinkage and selection operator (LASSO) [27] and randomized logistic regression [28] that have been shown to perform well in selecting a stable set of features. In our case, because the number of features in each feature set was substantially larger than the sample size, those methods performed poorly, and the accuracy of models was low. We, therefore, applied randomized logistic regression in a hierarchical and nested manner on groups of features in each time segment. Randomized logistic regression creates several random subsamples of the training dataset, computes a logistic regression on each subsample, and selects features by optimizing their importance across all subsamples. We decomposed our feature space by grouping features from the same time segment and performed randomized logistic regression on each of these groups. The selected features from all groups (ie, all time segments) were then concatenated to give a new and much smaller set of features. Then, randomized logistic regression was performed again, this time on this new set of features to get the final selected features, thereby nesting the process. We call this method nested randomized logistic regression (NRLR). This method was performed in a leave-one-out manner such that the model used to detect an outcome for a person did not include those data from that person during the feature selection process.

Table 1 (columns 1-3) shows the number of features and number of samples for each feature set after handling missing values where all features were used as input to the training and validation. Table 1 (columns 4-7) shows a comparison between the features selected with LASSO and NRLR. Compared with LASSO, the average number of selected stable features (features selected in all cross-validation folds) is 3 times smaller in NRLR that substantially reduces the size of the feature vector.

Table 1. The list of feature sets with the number of features and data samples used in the machine learning pipeline after handling missing values and the number of selected features during the cross-validation process.

Feature set	Number of features	Number of samples	Number of features selected during cross-validation process			
			LASSO[a]		NRLR[b]	
			In all folds	In at least one fold	In all folds	In at least one fold
Bluetooth	3201	115	203	1026	278	1864
Calls	605	108	30	134	34	142
Campus map	16,381	111	66	455	12	161
Location	10,237	106	345	784	14	124
Screen	15,446	113	96	467	8	52
Sleep	5889	107	87	534	23	266
Steps	3055	107	270	485	0	8
Average	7831	110	157	555	53	374

[a]LASSO: least absolute shrinkage and selection operator.

[b]NRLR: nested randomized logistic regression.

Model Generation

For each feature set, we built a model of the selected features from that feature set to detect an outcome using 2 learning algorithms, namely, logistic regression and gradient boosting classifier. We chose logistic regression because it was used in our feature selection approach, and gradient boosting was chosen because it had shown to perform well on noisy datasets and learn complex nonlinear decision boundaries via boosting. Gradient boosting had been effectively used to detect similar outcomes in a previous study [29].

Model Selection

The generated models from logistic regression and gradient boosting were then evaluated by comparing their accuracy as a metric for postsemester and change in loneliness. The model that provided better accuracy was selected for the next step.

Combining Detection Probabilities From 1-Feature Set Models to Obtain Combined Models

The chosen 1-feature set model in the previous step gave us detection probabilities for each outcome label. The detection probabilities from all 7 1-feature set models were concatenated into a single feature vector and given as input to an ensemble classifier, AdaBoost with gradient boosting as the base

estimator, which then outputted the final label for the outcome. For the detection of postsemester loneliness, which is a binary classification, only the inferred probabilities of one of the classes (low or high) were concatenated, whereas for the detection of change in loneliness (multiclass classification: decreased loneliness, increased loneliness, and unchanged loneliness), the inferred probabilities of all classes were concatenated.

We also carried out a feature ablation study to analyze the effect that different feature sets had on the performance of the models, thereby understanding their salience. For this purpose, we concatenated detection probabilities from specific 1-feature set models instead of all 7 1-feature set models. We did this for all possible combinations of 1-feature set models to analyze the estimation power of each feature set in inferring loneliness level. There were 7 1-feature set models and 120 combinations of feature sets, as total combinations = combinations with 2 feature sets + ... + combinations with 7 feature sets = 120. We report the best accuracies obtained from these combinations.

Measures

We summarize our measures used throughout the paper as follows:

- Preloneliness score—total UCLA loneliness score measured at the beginning of the semester
- Postloneliness score—total UCLA loneliness score measured at the end of the semester
- Increased score—when postloneliness score was greater than preloneliness score
- Decreased score—when postloneliness score was less than preloneliness score
- Unchanged score—when postloneliness score was equal to preloneliness score

Loneliness level (pre- or postsemester)—2 categories:

- Low loneliness (LL)—total UCLA scores of 40 and below
- High loneliness (HL)—total UCLA scores above 40

- Change in loneliness level from pre to post—3 categories:
- Decreased loneliness (DL)—loneliness level changed from high at presemester to low in postsemester
- Increased loneliness (IL)—loneliness level changed from low in presemester to high in postsemester
- Unchanged loneliness (UL)—loneliness level remained the same in presemester and postsemester

Machine learning measures:

- Baseline accuracy—percentage of samples belonging to the majority class (here HL). This percentage is compared with the classification output to measure the performance of the machine learning algorithms.
- Accuracy—percentage of correctly classified samples (1 per student)
- Precision—percentage of classified samples that actually belonged to a class, for example, HL or LL
- Recall—percentage of class samples that were accurately classified
- F1—harmonic mean of precision and recall
- MCC—a measure of quality of binary classification. The value is between −1 and 1 where 1 indicates a perfect prediction, 0 indicates no better than random prediction, and −1 indicates total disagreement between prediction and observation.

Results

Loneliness in College Students

We analyzed the total UCLA loneliness scores for both presemester and postsemester surveys. The average score from the presemester surveys was above the cutoff point (mean 43.6, median 44, Q1=37, Q3=49, and SD 9.4) with 63.8% (102/160) of participants falling into the HL category (scores above 40). Similarly, at postsemester, the average loneliness score was above the cutoff (mean 43.3, median 43, Q1=37, Q3=50, and SD 10.4) with 58.8% (94/160) of participants falling into the HL category. Figure 4 shows the distribution of scores for both pre- and postsemester UCLA scores.

A paired test showed no significant difference between the two distributions (P=.73). We observed that the loneliness score for 12.5% (20/160) of participants was 1 standard deviation above the mean in both pre- and postsemester. The majority of scores, however, fell into the range between 1 standard deviation below and above the mean (pre=66.9% [107/160] and post=73.1% [117/160]). Table 2 shows the summary of the statistics.

Figure 4. Distribution of presemester University of California, Los Angeles, scores (mean 43.6, SD 9.4) and postsemester University of California, Los Angeles, scores (mean 43.3, SD 10.4). UCLA: University of California, Los Angeles.

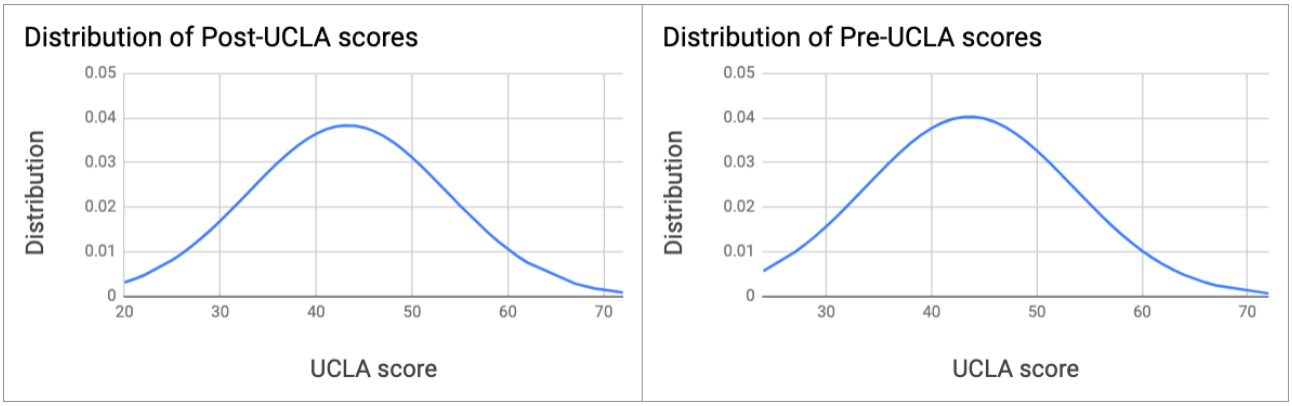


Table 2. Statistics of high and low loneliness scores measured by University of California, Los Angeles, scale in pre- and postsurveys.

Category	Count		Average		Min		Max	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post
All	160	160	43.6	43.3	—[a]	—	—	—
LL[b]	58 (36.2%)	66 (41.2%)	33.9	33.7	24	20	40	40
HL[c]	102 (63.8%)	94 (58.8%)	49.1	49.9	41	41	72	72

[a]Data not applicable.

[b]LL: low loneliness.

[c]HL: high loneliness.

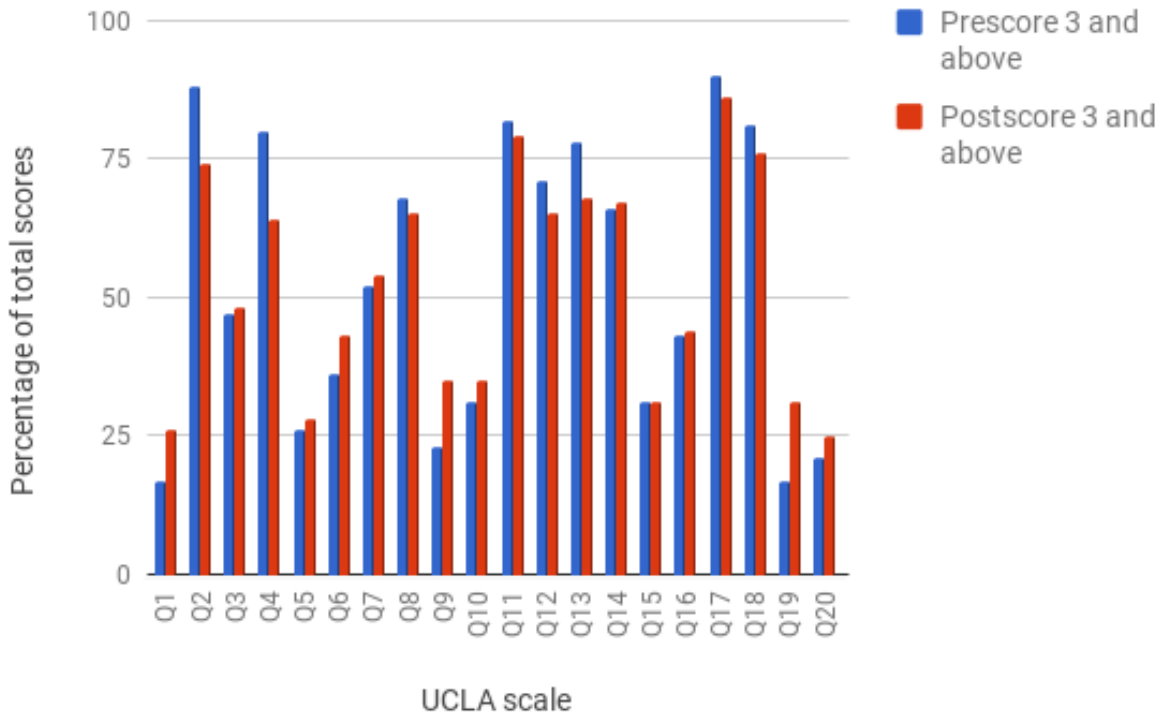
The percentage of participants with a high postloneliness score was 5% lower than those with high preloneliness scores (58.75% vs 63.75%), indicating an overall lower loneliness rate among students at the end of the semester. Only 6 participants who had low loneliness scores in the presemester survey showed a high level of loneliness in the postsemester survey, whereas 7 participants had an HL score in the presemester survey but an LL score in the postsemester survey. The average increase and decrease were 6 and 7 points, respectively. Overall, 17.5% (28/160) of the participants reported a more than 6-point increase in their postloneliness scores, 18.8% (30/160) reported a more than 7-point decrease, 58.2% (93/160) remained in the range of minor increase (between 1 and 6) or minor decrease (between 1 and 7), and 5.6% (9/160) experienced no change. The maximum increase in scores was 17 points (rising from 35 in presemester survey to 52 in post) and the maximum decrease in scores was 30 points (falling from 58 in the presemester survey to 28 in post). These observations indicated that although there were changes in loneliness scores among the majority of participants (154/160), these changes were mostly moderate and rarely caused the participants to fall into a different category of loneliness between the pre- and the postsemester surveys. Due to the relatively stable levels of loneliness, predicting change in loneliness levels was more challenging. However, as described in the following sections, using behavioral features in our machine learning pipeline, we were still able to infer change in loneliness with an accuracy above 88%.

We also examined the change in scores for each individual question (Table 3). Given our ultimate goal of measuring the power of passive sensing features in distinguishing loneliness behavior, we were curious to know the following: (1) by how much the score of each question changes from presemester to postsemester, (2) what questions had the highest change in score, and (3) whether there were associations between those changes and the behavioral features. Figure 5 shows the percentage of participants rating each question as 3 or above (sometimes or always). For example, the total rating for Q2 (How often do you feel that you lack companionship?) decreased by 14% from presemester to postsemester indicating fewer students felt a lack of companionship at the end of the semester than at the beginning. The largest changes were observed in Q4 (How often do you feel alone?) and QR19 (How often do you feel that there are people you can talk to?) with a total decrease of 16% and an increase of 14%, respectively. Although more analyses are needed to replicate these observations, they may be indicative of changes in specific experiences among students. For example, a decrease in the lack of companionship scores (Q2) may indicate that the participants gained more familiarity with the university environment and were more able to make friends by the end of the semester.

Table 3. Statistics of change in loneliness scores measured by University of California, Los Angeles, scale in pre- and postsurveys (N=160).

Change in loneliness score	Participants, n (%)
Increased score	
Overall	75 (47)
Increase between 1 and 6 points	47 (29)
Increase more than 6 points	28 (17)
Decreased score	
Overall	76 (47)
Decrease between 1 and 7 points	46 (29)
Decrease more than 7 points	30 (19)
Unchanged score	9 (6)

Figure 5. Comparison of pre- and postloneliness ratings of University of California, Los Angeles, questions (Q2, Q4, and Q19 have the largest change in postloneliness ratings). Q: question; UCLA: University of California, Los Angeles.



Mining Associations Between Overall Loneliness and University of California, Los Angeles, Question Scores

We applied the Apriori algorithm (described in the Methods section) to both the pre- and postsemester survey responses to extract associations between responses to each question and overall loneliness level. Our goal was to identify experiences expressed as responses to each question, which were mostly associated with loneliness in college students, and then examine whether any association between those experiences and passive behavioral features could be observed. We started with a minimum support of 10% and increased it in each iteration to obtain a minimal set of association rules with a maximum support. The optimal minimum support was achieved at 38%, that is, the extracted patterns were observed in at least 38% of the students. We stopped increasing the minimal support after 38% as no rules could be found for a support above that percentage. We kept the minimum confidence at 90%. As shown in Table 4, question 14 (How often do you feel isolated from others?) appears in both pre- and postsemester surveys and indicates that around 42% of students with responses of 3 or 4 to this question also had a high total loneliness score. Responses of 3 or 4 to question 13 (How often do you feel that no one really knows you?) appeared to indicate high total loneliness scores in the presemester survey with 49% support (almost half of the participant population) and 96% confidence. The same association was observed with question 12 (How often do you feel that your relationships with others are not meaningful?) in the postsemester survey with 41% support and 94% confidence.

Table 4. Association rules extracted from pre- and postsurvey responses.

Question response level (*sometimes or always*), scale from 1 to 4	Loneliness level (low or high)	Support, % (minimum support = 38%)	Confidence, % (minimum confidence 90%)
Presurvey			
Feeling no one really knows you well (UCLA[a]13 ≥ 3)	High	49	96
Feeling isolated (UCLA14 ≥ 3)	High	41	95
Postsurvey			
Relationships are not meaningful (UCLA12 ≥ 3)	High	41	94
Feeling isolated (UCLA14 ≥ 3)	High	42	94

[a]UCLA: University of California, Los Angeles.

Detection of Loneliness Level and Change in Loneliness

We ran our machine learning pipeline to infer 2 outcomes: postloneliness level (low or high) and change in loneliness level (IL, DL, and UL). For both outcomes, we used the set of all-epochs features extracted from all time slices and time slices as described in the processing section, as well as semester-aggregated (semester-level) features. Our goal was to identify a minimal set of features capable of accurately inferring loneliness level. Whereas the all-epochs features provided the opportunity to analyze behavior on a more fine-grained level, the semester-level features provided a reduced set that described the overall behavior of each participant during the semester. Figures 6 and 7 show the accuracy results for both outcomes and their comparison with the baseline (56.9%—the percentage of participants assessed at the HL level in the postsemester survey). The graphs show the accuracy obtained from sensor-specific features (1-feature set), all feature sets combined, and the set that provides the best overall accuracy. For detection of postloneliness, our machine learning pipeline achieved the highest accuracy of 80.2%, using all-epochs features in the best feature set that included call logs, location, location map, screen, sleep, and steps. This accuracy was 6.1% higher than the accuracy obtained from using all 7 feature sets (74.1%) and indicated that including Bluetooth features contributed to performance reduction. The all-epochs-Bluetooth-only features provided 55.6% accuracy, confirming their low prediction power in detecting postloneliness level. Except for Bluetooth, all other feature sets and their combinations achieved a higher (by at least 5.4%) accuracy than the baseline measure. The semester-level features, including the combination of Bluetooth, location, screen, and steps, provided the best set accuracy of 74.8%, which was 5.5% higher than the all features set (69.3%). The semester-level feature set for calls had the lowest accuracy of 55.2% (1.7% lower than baseline). One possible reason for this could be the large number of missing feature values for calls, meaning calls were being made to a large number of individuals that were not on the frequent contacts lists that the participants provided before the study semester. In general, the analysis with all-epochs features included provided better results than the analysis with semester-level features for detecting loneliness level (5.4% higher accuracy). As a point of comparison, we also used the features selected through LASSO in our pipeline to compare the performance (ie, accuracy). The average accuracy obtained from all feature sets was 56.7% which is below the baseline of 56.9%. This indicates that our more sophisticated feature selection approach was effective.

Table 5 summarizes the best results for both inferences distinguishing the performance of the classifiers to infer each class. The recall values (the percentage of correctly classified instances) indicate that the classifier correctly labeled HL instances 76.9% of the time using all-epochs features and 74.6% of the time using semester-level features.

Figure 6. Detection of postloneliness level (high loneliness or low loneliness) using all-epochs features and semester-level features. Each bar shows the accuracy followed by the number of samples used in the analysis in parentheses; the gray bar represents the baseline accuracy as measured by the percentage of samples belonging to the majority class here, that is, high loneliness. Sem: semester.

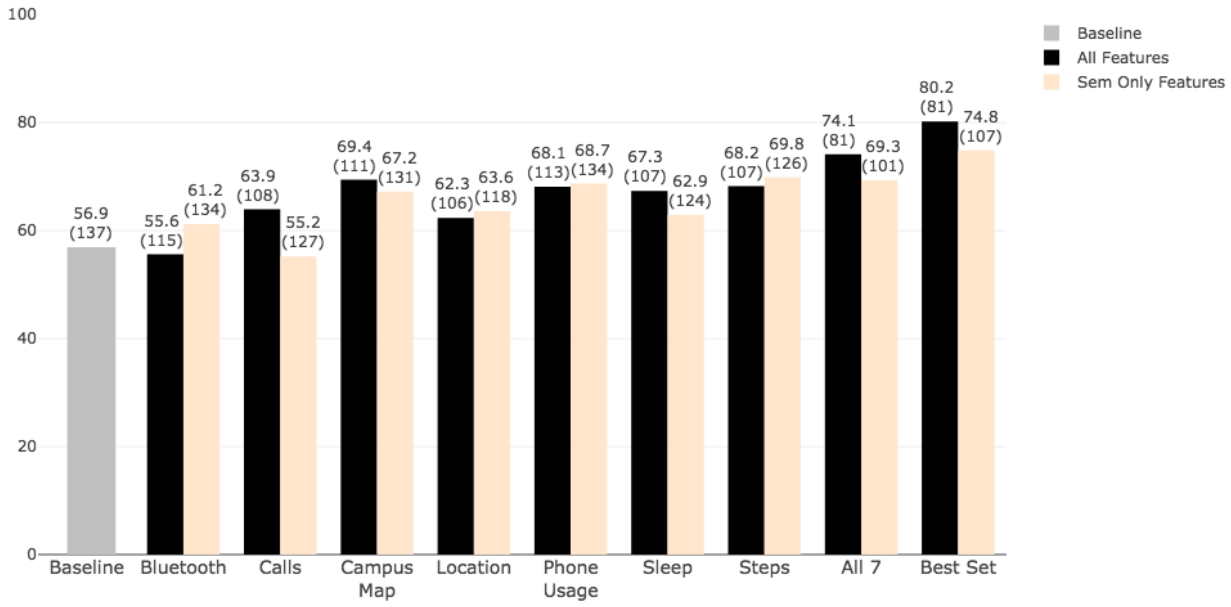


Figure 7. Detection of change in postloneliness level (decreased loneliness, increased loneliness, and unchanged loneliness) using all-epochs features and semester-level features. Each bar shows the accuracy followed by the number of samples used in the analysis in parentheses and baseline accuracy is the percentage of samples belonging to the majority class here, that is, unchanged loneliness. Sem: semester.

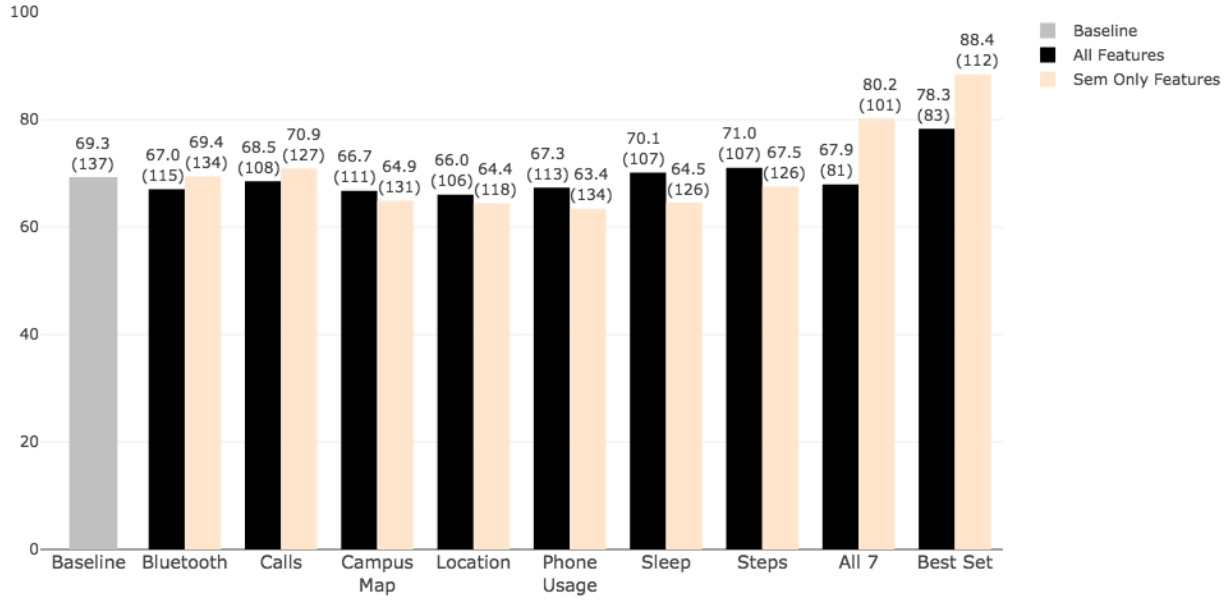


Table 5. The performance of models obtained from all-epochs features and semester-level features to detect loneliness level and change in loneliness.

Measure	Loneliness level						Change in loneliness							
	All-epochs features, baseline = 58.5%			Semester-level features, baseline = 58.5%			All-epochs features, baseline = 69.3%				Semester-level features, baseline = 69.3%			
	Average	HL[a]	LL[b]	Average	HL	LL	Average	DL[c]	IL[d]	UL[e]	Average	DL	IL	UL
Accuracy, %	80.2	—[f]	—	74.8	—	—	79.2	—	—	—	88.4	—	—	—
Precision, %	80.3	81.1	79.5	74.6	78.6	70.6	70.2	53.3	71.4	85.7	90.0	90.9	91.6	87.6
Recall, %	80.1	76.9	83.3	74.8	74.6	75.0	67.7	40	71.4	91.6	82.6	75.8	73.3	98.7
F1[g], %	80.1	78.9	81.3	74.6	76.5	72.7	68.5	45.7	71.4	88.5	81.0	68.9	81.5	92.8
MCC[h]	0.6	—	—	0.5	—	—	0.6	—	—	—	0.7	—	—	—

[a]HL: high loneliness.

[b]LL: low loneliness.

[c]DL: decreased loneliness.

[d]IL: increased loneliness.

[e]UL: unchanged loneliness.

[f]Data not applicable.

[g]F1: harmonic mean of precision and recall.

[h]MCC: a measure of quality of binary classification.

Detection of change in loneliness levels provided slightly different results. Using all-epochs features, the best feature set including calls and screen state achieved 78.3% accuracy, whereas the best set obtained with semester-level features—which included Bluetooth, calls, location, and location map—achieved 88.4% accuracy. In contrast to the postloneliness detection model, where the analysis with all-epochs features provided better results, in these models for detecting change, the semester-level features contributed to higher accuracy using the best set (88.4% with semester only vs 78.3% with all-epochs features) and all 7 sets (80.2% with semester only vs 67.9% with all-epochs features).

For increased loneliness, these recall values were 71.4% and 73.3%, respectively. Although more analyses are needed to replicate these results, we find that even though the all-epochs features provide slightly higher accuracy, these features only gave 2.3% better recall for detecting HL. We also find no statistically significant difference between the accuracies obtained from all-epochs features and semester-only features (P=.58). However, the selected all-epochs features during the training and validation process provided a fine-grained set of behavioral patterns associated with the loneliness level that were observed on a week-by-week basis as described below

(Tables 6 and 7). These patterns could not be extracted using semester-level features.

The most frequently selected features indicate their high impact in detecting loneliness (see Multimedia Appendix 1 for the list of selected semester-only features in each feature set that appear in more than half of the folds during the cross-validation). However, their selection as part of the analysis pipeline did not answer the question of how these features and their combinations related to loneliness. We, therefore, ran the Apriori algorithm (minimum support=10% and minimum confidence=90%) on these selected features to extract different combinations of behavioral features that were indicative of loneliness. Table 6 summarizes the extracted patterns using the selected features in each analysis (postloneliness detection and change in loneliness).

As shown in Table 6, low frequency of phone usage in certain hours during the weekend and morning hours, as well as spending less time outside of campus and at social-event houses in the evening and night were associated with HL. Recall that support is the percentage of the observed behavior patterns (left column in Tables 6 and 7) in the entire dataset (here the participant population), whereas confidence is the percentage of the samples with that observed pattern that satisfy a certain condition, for example, change in loneliness. For example, the pattern min length of phone usage [weekday] = low and min steps in active bouts [night, weekend] = low and min length of sedentary bouts [night, weekend] = low (third row in Table 6) is observed in 31% of the participants (support) out of which 92% (confidence) experienced a decrease in loneliness at the end of the semester.

As the question 14 on the UCLA scale (feeling of isolation) was most associated with one's total loneliness score (based on our analysis in previous sections), we also extracted patterns of daily behavior that were associated with scores on that question (feelings of isolation) using the same set of selected features. Table 7 shows the extracted patterns associated with feeling of isolation. For example, the participants with low feelings of isolation spend less time studying in the afternoon on weekends and spend a moderate amount of time in green areas in the morning. Also, higher overall level of activity and steps during the day and evening hours is associated with lower feelings of isolation.

Table 6. Extracted patterns showing how combinations of behavioral features selected by the machine learning algorithm are associated with high loneliness and decreased loneliness.

Pattern (features categorized into low, moderate, and high)	Postloneliness
Frequency of first screen unlock between 1 and 2 pm [weekend] = low and frequency of last screen lock between 10 and 11 am [morning] = low and time spent off campus [evening] [weekend] = low and max length of time spent at social-event houses [evening][night] [weekday] = low	• Postloneliness = high loneliness • Support = 17% • Confidence = 92%
Number of scans of the least frequent Bluetooth device belonging to self or others [weekend, week 2017-03-08] = low and number of scans of the least frequent Bluetooth device belonging to others [morning, weekend, week 2017-05-03] = high and last screen lock between 10 and 11 am [morning, weekday, week 2017-04-19] = low and Last screen lock between 2 and 3 pm [afternoon, weekday, week 2017-02-01] [week 2017-03-15] [weekday, week 2017-03-15] = low and time at local cluster 3 [afternoon] [weekend, week 2017-03-08] = low and last screen on between 3 and 4 pm [week 2017-02-01] = low and first screen on between 3 and 4 am [night] [weekday, half semester 2017-03-01] = low	• Postloneliness = high loneliness • Support = 30% • Confidence = 90%
Min length of phone usage [weekday] = low and min steps in active bouts [night, weekend] = low and min length of sedentary bouts [night, weekend] = low	• Change = decreased loneliness • Support = 31% • Confidence = 92%
Last screen unlock between 2 and 3 pm [afternoon, week 2017-03-29] = low and first screen on between 5 and 6 am [weekday, week 2017-03-15] = low and last screen unlock between 1 and 2 am [half semester 2017-03-01] = low and min length of sedentary bouts [morning, weekday] = low and first screen unlock between 5 and 6 pm [week 2017-02-08] = low and minimum length of sleep duration [weekend, half semester 2017-03-01] = low	• Change = decreased loneliness • Support = 50% • Confidence = 90%

Table 7. Extracted behavioral patterns associated with the feeling of isolation.

Pattern (features categorized into low, medium, and high)	UCLA[a]14 level	Support, % (minimum support = 10%)	Confidence, % (minimum confidence = 90%)
Number of scans of the least frequent Bluetooth device belonging to others [morning, weekend] = low and study duration [afternoon, weekend] = low and minimum stay in green areas [morning] = moderate	Feeling of isolation = low	18	92
Total sleep [morning, week 2017-03-01] = moderate and number of scans of the least frequent Bluetooth device belonging to others [evening, weekend, week 2017-02-01] [weekend, week 2017-02-22] [afternoon, weekday, week 2017-01-25] = moderate and number of scans of the least frequent Bluetooth device [night, weekday, half semester 2017-03-01] [night, week 2017-01-18] [night, weekday, half semester 2017-01-18] = low and first screen unlock between 10 and 11 am [weekday, week 2017-04-26] = low	Feeling of isolation = low	30	90
Time at frequent locations [afternoon, weekday] = low	Change = low to high	28	92
First screen unlock between 3 and 4 am [night, weekend] = low and average steps in active bouts [morning, weekend] = high	Change = high to low	28	92
Minimum length of sleep [weekend, week 2017-01-18] = moderate and number of scans of the least frequent Bluetooth device [night, weekday, half semester 2017-03-01] [night, weekday, half semester 2017-01-18] = low and first screen on between noon and 1 pm [afternoon, weekend, week 2017-04-26] = low and first screen on between 7 and 8 am [weekday, week 2017-03-15] = low and last screen lock between midnight and 1 am [half semester 2017-03-01] = low and first screen on between 3 and 4 am [night, weekday, week 2017-03-08] = low	Change = high to low	33	93

[a]UCLA: University of California, Los Angeles.

Discussion

Principal Findings and Comparison With Previous Research

This study reported a 3-fold analysis of loneliness among college students, exploring the potential of passively collected sensing data from mobile and wearable devices to estimate loneliness and identify behavioral data features associated with loneliness. Results showed that fine-grained behavioral features extracted from mobile and wearable time series data can detect low and high levels of loneliness with high accuracy and that these features can distinguish the behavior of students with high levels of loneliness from those with low levels of loneliness. For example, results showed that students with high levels of loneliness spend less time off campus and socialize less in the evening during weekends than students with low levels of loneliness.

We extend existing research on the study of loneliness in 5 ways. First, we collected behavioral data from a substantially large sample (n=160) of college students for a period of 16 weeks, a longer period of time compared with the current state of the research [11,12,14]. This provided the opportunity to analyze long-term behavior associated with loneliness through pattern mining and observe changes in behavior that are associated with changes in loneliness. Second, we extracted a much larger set of behavioral features from raw data collected on smartphones and wearable devices (77,805 features) and showed their impact in detecting the level of loneliness and the level of change in loneliness detection. The features provided a lens for observing more fine-grained behavior patterns associated with loneliness. Third, for the first time, we presented the associations between the level of loneliness and the combinations of behavioral features. This analysis provided a set of objectively extracted patterns that described behaviors associated with loneliness. Fourth, in addition to the overall level of loneliness, we mined associations between levels of loneliness and responses for each question. We found strong association patterns between pre- and postloneliness scores and the UCLA scale question related to feelings of isolation. We consequently mined associations between responses to this question and behavioral features and found that high level of activity and steps during the day and evening hours were associated with lower feelings of isolation. These results are important as they may provide objective measurements for experiences associated with different dimensions of loneliness (as assessed by specific questions on the UCLA scale) in the form of combined behavioral features. Finally, through a machine learning analysis, we estimated overall levels of loneliness and change in loneliness with a high accuracy of 80.2% and 88.4%, respectively. Other than the study by Pulekar et al [11] that analyzed 2 weeks of data from 9 students using a small set of features from smartphones only and the study by Sanchez et al [12] that inferred different types of loneliness in 12 older adults using one week of mobile data, we are unaware of any existing study to detect loneliness from longitudinal passive sensing data using machine learning.

Our sample of college students had HL scores, consistent with the latest US loneliness index [2], suggesting that this age group experienced the most loneliness of all generations surveyed. We also found that the feeling of isolation was a strong and consistent indicator of loneliness in both pre- and postsemester surveys. The feeling of nobody really knows you was a stronger indicator in the presemester survey. This may be a result of first-year college students still trying to form bonds with their classmates. On the other hand, relationships lacking meaning

was associated strongly with the postsemester loneliness scores, which might indicate that students were not having meaningful relationships with their peers. Although mining these associations is a novel approach and the observations are interesting, future analyses on similar datasets must be conducted to confirm these results.

We extracted a rich set of day-level features from the smartphone and Fitbit reflecting activity and mobility, communication, sleep, and phone usage patterns. We also generated a set of aggregated features on the semester-level. We used these sets of features in a machine learning pipeline to infer levels of loneliness and change in loneliness scores. We trained and evaluated an ensemble classifier on a leave-one-student-out cross-validation manner to explore how accurately the level of postsemester loneliness, as well as change in loneliness scores, could be estimated from passive behavioral features. We reported the average results of cross-validation for each outcome. We included feature selection as part of the training process to acquire a set of behavioral features that were repeatedly selected as impactful for the majority of students. Our analysis showed more fine-grained behavioral features were better at identifying the overall level of loneliness (80.2% accuracy), whereas the aggregated semester-level features better distinguished the level of change (88.4% accuracy). Although the higher accuracy achieved with the all-epochs features was modest considering the large number of features used in the pipeline, the analysis provided a set of features that could be used to mine detailed association patterns of loneliness on a week-by-week basis.

Our pattern mining approach, using the selected features, showed that patterns and timings of phone usage combined with spending less time off campus and at social-event houses during evening hours on weekends were most indicative of HL in college students. It also showed that lower phone usage and less activity after midnight was associated with a decrease in loneliness at the end of the semester. In addition to lower phone usage during night hours, we found that a high level of activity (especially in morning hours), less time studying on weekends, and spending more time in green areas were associated with feeling less isolated. These findings are consistent with the results of the study by Wang et al [14] that found negative correlations between loneliness and activity duration for day and evening. However, to our knowledge, this is the first study that reports on combinations of behavioral features observed in a study population.

Limitations

This study provides insights into understanding loneliness through passive behavioral features. However, it has a number of limitations. First, although we purposely chose university students as our study participants, our results may only generalize to this population. Second, despite the 1-semester duration of this study (which is considerably longer than most existing research on loneliness), studies with longer-term data collection periods may reveal additional patterns in behavior that could not be observed in one semester. Although our analyses provide novel and interesting insights into understanding loneliness behavior through the objective lens of passive sensing, more analyses on the same type of data are needed to provide enough evidence for generalizability of our results. Third, technical issues resulted in a large amount of missing data from many participants that had to be removed from the machine learning analysis, considerably reducing the size of the dataset. Although missing data is a common problem in data analysis, more careful and conservative planning and more stable software may reduce the risk of missing data. Fourth, as we could not find well-known methods in the literature for choosing our thresholds (eg, the cutoff score to indicate the level of loneliness or the number of steps for identifying activity bouts), we made those choices in consultation with the psychologists on our team. We understand that different thresholds may provide different results. However, our goal in this study was not to find the optimal thresholds but rather understand the experience of loneliness in college students and explore the feasibility of using passive sensing to detect loneliness and behavior patterns associated with it. Fifth, although students were instructed to wear the Fitbit on their nondominant hand, because of the nature of our study that collects data in the wild, we did not have much control over the ways students wore the Fitbit nor could we track whether or not the Fitbit was worn or charged. We acknowledge that these factors may affect the measurements related to activities and sleep. However, this is a technical challenge that we face with data collection in the wild and we are working on developing solutions that provide an accurate estimation of user's activity despite the variations in their wearing patterns. Finally, we developed a machine learning pipeline that could handle a large number of features, select a stable set of features, and use them in the training and validation process. For the first time, we also showed the potential of using data mining to explore the combination of behavioral features that are associated with a health outcome. The developed pipeline and our data mining approach can be adapted by the research community as a generic framework for studies assessing other outcomes. However, we acknowledge that the results obtained through the pipeline and Apriori are highly dependent on the parameter settings and processing steps and results may vary with different data and feature sets.

We plan to advance our machine learning pipeline to test different feature selection and learning algorithms and to automatically find the optimized parameters. Our future plans revolve around addressing some of the above limitations including more systematic threshold setting for both feature extraction and the outcome measure (loneliness level). We plan to experiment with multiple categories and thresholds in future study. We also plan to add more analyses to study the relationship among loneliness, depression, stress, and other mental health outcomes.

Conclusions

Our findings highlight the feasibility of using ubiquitous smartphone and wearable sensors to passively detect loneliness in college students and identify the behavioral patterns associated with loneliness. The findings suggest an approach for passively sensing loneliness and providing opportunities that could reduce loneliness by, for example, notifying family members and friends to provide social support, connecting the

person with similar people, or recommending activities, such as going off campus, spending time in green areas, or going to social events of interest. Building interventions based on empirical findings regarding the experience of loneliness could meaningfully affect students' well-being.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

List of semester-only features that were selected in our model for more than half of the folds during cross-validation.

[PDF File (Adobe PDF File), 97KB - mhealth_v7i7e13209_app1.pdf]

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Abbreviations

API: app programming interface
DBSCAN: density-based spatial clustering of applications with noise
DL: decreased loneliness
FEC: feature extraction component
GPS: global positioning system
HL: high loneliness
ID: identity document
IL: increased loneliness
LASSO: least absolute shrinkage and selection operator
LL: low loneliness
NRLR: nested randomized logistic regression
SMS: short message service
UCLA: University of California, Los Angeles
UL: unchanged loneliness

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