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Review

Behavior Change Techniques in Digital Health Interventions for Midlife Women: Systematic Review

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Abstract

Background: Digital health interventions are efficacious in health-promoting behaviors (eg, healthy eating and regular physical activity) that mitigate health risks and menopausal symptoms in midlife. However, integrated evidence-based knowledge about the mechanisms of change in these interventions is unclear.

Objective: This systematic review aimed to evaluate studies on behavior change techniques (BCTs) and mechanisms of change in digital health interventions aimed at promoting health-enhancing behaviors in midlife women (aged 40-65 years).

Methods: A systematic literature search of the electronic databases PubMed, Web of Science, PsycINFO, and Cochrane Central Register of Controlled Trials in the Cochrane Library was conducted. In total, 2 independent reviewers selected the studies for inclusion, extracted data, and completed BCT mapping of eligible studies. The mechanism of action and intervention functions of eligible studies were evaluated using the behavior change wheel framework. Reporting of psychological theory use within these interventions was explored using the Theory Coding Scheme. Mode of delivery, psychological theory, and BCTs were presented as descriptive statistics.

Results: In total, 13 interventions (including 1315 women) reviewed used 13 (SD 4.30, range 6-21) BCTs per intervention on average. The “Shaping knowledge” and “Repetition and substitution” behavior change categories were used most frequently, with 92% (12/13) of the interventions implementing at least one of the BCTs from these 2 categories. Only 13.98% (169/1209) of the 93 available BCTs were used, with “Instructions on behaviour” most frequently used (12/13, 92%). The behavior change wheel mapping suggests that half of the intervention content aimed to increase “Capability” (49/98, 50% of the intervention strategies), “Motivation” (41/98, 42%), and “Opportunity” (8/98, 8%). “Behavioural Regulation” was the most frequently used mechanism of action (15/98, 15%), followed by increasing “Knowledge” (13/98, 13%) and “Cognitive and Interpersonal skills” (10/98, 10%). A total of 78% (7/9) of the intervention functions were used in the studies to change behavior, primarily through “Enablement” (60/169, 35.5%), whereas no study used “Restriction” or “Modelling” functions. Although 69% (9/13) of the interventions mentioned a psychological theory or model, most (10/13, 77%) stated or suggested rather than demonstrated the use of a theoretical base, and none reported explicit links between all BCTs within the intervention and the targeted theoretical constructs. Technological components were primarily based on web-based (9/13, 69%) modes of delivery, followed by phone or SMS text message (8/13, 62%) and wearables (7/13, 54%).

Conclusions: The findings of this review indicate an overall weak use of theory, low levels of treatment fidelity, insignificant outcomes, and insufficient description of several interventions to support the assessment of how specific BCTs were activated. Thus, the identified limitations in the current literature provide an opportunity to improve the design of lifestyle health-enhancing interventions for women in midlife.

Trial Registration: PROSPERO CRD42021259246; https://tinyurl.com/4ph74a9u

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KEYWORDS

menopause; midlife; women's health; lifestyle; behavior change technique; BCT; behavioral intervention; digital health; mobile health; mHealth; menopausal symptom; behavior change; review; mobile phone

Introduction

Background

Approximately 3.5 million women aged 50 to 65 years are employed in the United Kingdom and experience menopausal symptoms (eg, hot flushes, disturbed sleep, depression, and cognitive dysfunction) [1] that can contribute to job dissatisfaction and decreased commitment to work [2]. The impact can be bidirectional, with symptoms such as poor concentration, poor memory, and sickness absence impairing job performance [3] and the workplace exacerbating menopausal symptoms [4]. Moreover, an individual's health-related quality of life in midlife is influenced by many additional nonmenopausal factors such as lifestyle, physical activity (PA), and social integration [5]. Evidence suggests that midlife for women represents a critical window for preventing chronic disease and optimizing health and functioning, whereas it is increasingly recognized that a healthy lifestyle may mitigate such health risks [6]. Improvements in diet, PA, and lifestyle can provide an effective intervention to manage menopause symptoms, improve health-related quality of life [7], and reduce menopause-related health risks [8,9] (eg, neurodegenerative diseases, particularly Alzheimer disease [1,10], and increased cardiovascular disease risk [11], low bone-mineral density, fractures, and osteoporosis [12,13]).

Behavior change interventions (BCIs) aimed at promoting population-level participation in key behaviors have been widely applied in the general population [14] and, to some degree, also in midlife women [15,16]. Women in midlife are willing to make positive health behavior changes but need support (eg, social connectivity [17]) for those changes to be effective [18]. However, changing established behavior patterns can be challenging as it requires addressing a strong psychological, environmental, or social gradient [19]. BCIs are typically complex and involve many interacting components and, therefore, a theoretical understanding of how the intervention causes behavior change is needed to strengthen the effects of BCI on clinical outcomes [20]. A recent scoping review [21] identified limitations in describing PA interventions in midlife women, with only 59% of the 51 studies specifying an underlying theoretical model. Many studies provided a limited description of how behavior change techniques (BCTs) were activated to achieve desired outcomes and provided limited insight into how the BCTs were received by midlife women [21]. As a result, interpreting designs and evaluations of complex interventions can be challenging without sufficient description of key intervention content [22] and, therefore, characterizing interventions by BCTs can be insightful in understanding the effectiveness of interventions [23].

The use of psychological theory in the development of BCIs (including digital BCIs) is associated with greater intervention effects [24-26]. Although there is a wide range of theoretical models of behavior (eg, the theory of planned behavior [27] and the Health Belief Model [28]), health-promoting interventions that are based on a single theory have generally been shown to be more effective in changing behavioral intentions than actual behavior [29,30]. Therefore, integrated theories have been proposed to overcome this limitation by drawing their hypotheses from several different theories with the aim of providing a more comprehensive explanation of behavior [31]. Theoretical frameworks such as the Theoretical Domains Framework (TDF) [32] integrate insights of multiple behavioral theories to identify relevant constructs that may be implicated in various health behaviors. Together with the capability, opportunity, and motivation-behavior (COM-B) model [33] that aims to identify the sources of target behavior, they form the behavior change wheel (BCW) framework [19]. The BCW framework provides a systematic and theoretical basis for understanding and changing behavior [19]. It has been used extensively to develop and evaluate the implementation of interventions in health care settings [34-36] and lifestyle (eg, smoking cessation [37], alcohol use prevention [38], sedentary behavior [39], PA [40], and dietary patterns [41]) but also in other areas such as personal transportation habits [42].

Behavioral interventions to promote PA in midlife women have been traditionally delivered face-to-face or in group settings [43]. However, the use of digital technology to change health behaviors has increased exponentially in recent decades, primarily after the introduction of smartphones in 2009 [44]. Moreover, digital health technology (ie, apps, wearables, and websites) has the potential to increase scalability through broader user reach [43] throughout the day, improve intervention effectiveness [17], and achieve greater cost-efficiency [45,46]. Indeed, digital health interventions (DHIs) are both feasible [47,48] and acceptable among midlife women [17,49,50]. Digital health technologies (including therapeutic interventions, online support communities, and web-based consultations) can provide important means for midlife women to obtain evidence-based menopause-related health information and recommendations, social and health practitioner support, and symptom tracking [51].

Objectives

The development of the BCT taxonomy [52,53] and methods for assessing the extent to which behavioral interventions are theory-based allows for more sophisticated coding of intervention content and insight into how and why the intervention promoted behavior change. Thus, the primary aim of this systematic review was to (1) assess the frequency and type of BCTs and BCT categories (representing groups of BCTs) used in DHIs with midlife women, (2) understand the mechanism of action proposed to affect changes in the behavioral outcome, and (3) appraise the intervention functions or broad categories of means by which the studies proposed to change behavior using the BCW. In addition, this review

identified the theoretical grounding (or the extent of behavior change theory used) in the DHIs using the Theory Coding Scheme (TCS) [54] and determined the technological features (mode of delivery) used in these studies.

Methods

The structure of this paper follows the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines [55] as the basis for reporting findings from the selected trials. The study protocol was registered in PROSPERO (CRD42021259246).

Selection Criteria

In accordance with PRISMA guidelines, the Population, Intervention, Comparison, Outcome, and Study Design tool was deployed.

Population

Women aged 40 to 65 years of all ethnicities and health conditions— including healthy women, those with overweight, and those with obesity—as well as survivors of breast cancer and women with a high risk of hypertension were included. These broad criteria were used to explore the impact of behavior change theory on lifestyle improvements rather than the interaction with these disease states.

Interventions

Studies describing interventions where the stated aim was to improve diet, PA, sleep, menopausal symptoms, and body composition by promoting changes in health behaviors, including healthy eating (single nutrients or whole dietary patterns) and PA (frequency or intensity), were considered. Only studies with participants randomized to a group that was explicitly asked to use digital technology (eg, wearables, mobile apps, and websites) as a mode of intervention delivery were considered. No other restrictions were placed on intervention type and delivery or duration.

Comparison

Control or other treatment groups involving health education, assignment of no digital health technology, or altered (ie, frequency or intensity) or no PA or diet intervention were included.

Outcome

The primary health outcomes were changes in PA (ie, frequency and intensity), diet (ie, fruit and vegetable intake and single nutrient intake), body composition (ie, body weight, lean muscle mass, and waist circumference), and frequency or intensity of menopausal symptoms (ie, vasomotor symptoms, sleep, bone health, anxiety, and depression). Although these health outcomes were included in the search criteria, they were not part of this review's assessment of study designs (described in the study aims). However, when available, the outcomes of the interventions were extracted as part of the description of the studies to allow the main outcomes to be presented in the relevant context.

Study Design

Both experimental (ie, randomized controlled trials and quasi-experimental studies) and nonexperimental (ie, observational studies) studies were included, with a minimum of 2 arms for randomized controlled trials, pilot studies, and feasibility studies.

Search Strategy

Literature searches were conducted by HS and SD between February 2021 and April 2021. Articles published before April 2021 and available in English were searched in the following databases: PubMed, Web of Science, PsycINFO, and Cochrane Central Register of Controlled Trials in the Cochrane Library. The search criteria included the following terms: ("midlife") AND ("mHealth" OR "eHealth" OR "digital") AND ("diet" OR "physical activity" OR "menopaus* symptom*" OR "lifestyle" OR "weight loss" OR "mental health" OR "depression" OR "sleep"). The filters used were "Randomised Controlled Trials" and "Clinical Trials;" the species selected was "Humans" only; and the language selected was "English" only. The search was limited to studies published between January 2009 and April 2021, reflecting the increased use of digital technology to change health behaviors after the introduction of smartphones in 2009 [44]. Interventions published before 2009 focusing on older technologies such as pedometers were not considered. Additional hand searches of relevant journals were performed, which included *JMIR mHealth and uHealth*, *Menopause*, and *Climacteric*.

Data Extraction and Collection Process

The studies were screened using titles and abstracts, and those that did not meet the inclusion criteria were excluded. The following information was extracted from each study: author, behavior change theory, intervention type, study design, country, participant ethnicity, intervention length, participant age and health risk, comparison group, and significant between-group differences in main outcomes. Data from each eligible study were populated into a prepared Microsoft Excel template to evaluate their eligibility and observe any missing data. Two reviewers (HS and SD) independently extracted the data, and this was checked for accuracy. Any disagreements were resolved through discussion, and a third reviewer was not required.

The first template included key information on each study, such as the intervention type and length, behavior change theories used, outcomes, and mean age of the participants. Multiple studies from the same trial were merged, and information was extracted to gain a full picture of the intervention, ensuring that the reported descriptive statistics were not double-counted. The authors of the original reports were contacted to obtain further details if insufficient information was included in the published documents. A reminder was sent if no responses were received after 2 weeks.

The use of BCTs and clusters of BCTs as defined by the Behavior Change Technique Taxonomy v1 (BCTTv1 [53]) was synthesized (and coded) for each included study. The number of individual BCTs included in each study was counted (range 0-93), and the mean value and SD were reported. Furthermore, the use of behavior change categories and combinations of

techniques and categories or clusters was investigated for each included study. Each study and group of related studies (ie, weight loss, lifestyle, and menopause symptoms) was mapped into this framework. The overarching synthesis bringing the studies together by providing a systematic and theoretical basis for understanding behavior was based on the COM-B model [33], TDF [32], and BCW [19]. The BCW links to theory-based frameworks (ie, the TDF and BCTTv1) to understand behavior for specifying intervention content [56]. Using the TDF or the COM-B model, intervention designers can make a behavioral diagnosis of what needs to change for the desired behavior to occur and, in the evaluation of interventions, the framework can help identify the mechanism of action (ie, how an intervention is working) [56]. Explicit links between the COM-B model and TDF domains are provided in the BCW guide [19].

The BCW also supports evaluating intervention functions (consisting of education, persuasion, incentivization, coercion, training, restriction, environmental restructuring, modeling, and enablement) by identifying broad categories of means by which interventions can change behavior [56]. For example, a digital health app designed to promote healthy eating may contain an educational element (eg, providing new information about the benefits of healthy eating) but may also be presented in a way that is intended to be persuasive (eg, generating feelings of worry about the health consequences of eating unhealthy foods) [56].

The use of psychological theory in the studies was examined using the TCS [54] to assess the extent to which behavior change theory was used to design the interventions in each study. These data were extracted by HS and reviewed for accuracy by SD. The overall score for each study was assessed as having weak (score 0-7), moderate (score 8-15), or strong (score 16-23) levels of theory use [57]. Finally, the technological and nontechnological components of each study were extracted and mapped into predefined categories that were created based on the review of the included studies. Frequencies of individual modes of delivery were reported together with the frequencies of related groups of passive and action-based components. The quality assessment was completed using the Physiotherapy Evidence Database scale [58], and the Cochrane risk-of-bias tool for randomized trials [59] was used to assess the risk of bias in randomized trials (these data are presented in Multimedia Appendix 1 [48,60-73]).

Treatment Fidelity Assessment

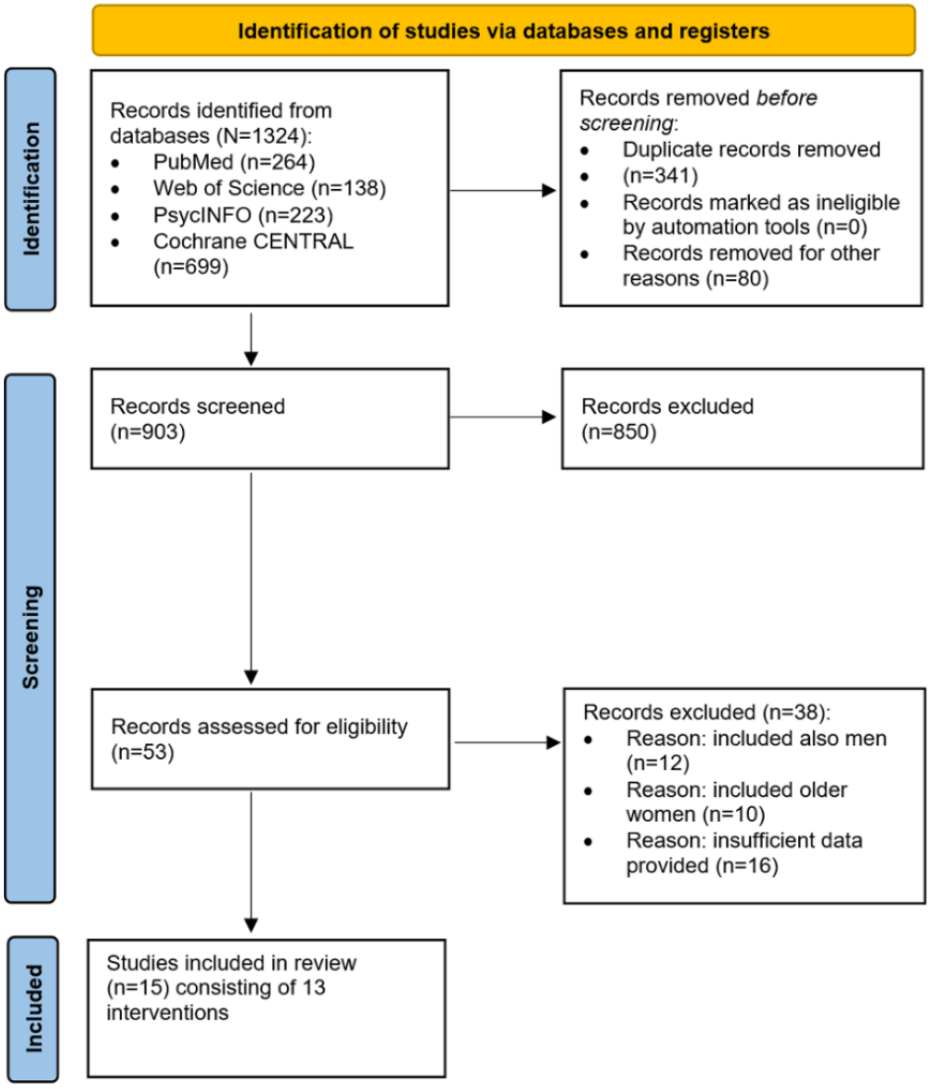
Treatment fidelity facilitates theory testing, with high levels often associated with alterations in the mechanisms of change (eg, increased PA and healthier eating) hypothesized to affect the outcomes [74]. According to Borrelli [74], high fidelity constitutes 80% to 100% integrity, whereas 50% constitutes low-fidelity scoring. By describing methodological strategies that are applied to monitor and enhance the reliability and validity of health BCIs [75], treatment fidelity helps increase scientific confidence that the changes in the outcome of interest (dependent variable) are due to the manipulation of other variables (independent variables) by the researchers [74]. This is achieved through assessment of the degrees to which the intervention is implemented as intended and the study arms differ along critical dimensions [74]. In interventions that produce nonsignificant effects, treatment fidelity helps uncover whether these effects are due to the omission or addition of active or inactive components or to an ineffective treatment [74]. The treatment fidelity of the studies included in this review was assessed using a 29-item checklist [74] grouped into 5 domains. These are (1) design of study (6 items), (2) monitoring and improving provider training (7 items), (3) monitoring and improving delivery of treatment (9 items), (4) monitoring and improving receipt of treatment (5 items), and (5) monitoring and improving enactment of treatment skills (2 items) [75], termed henceforth study design, training, delivery, receipt, and enactment [41].

Results

Study Selection

Initial searches highlighted 1324 records from databases and included 5 additional records from the *Menopause*, *Climacteric*, and *JMIR* journals. Screening the titles highlighted 25.76% (341/1324) of duplicates and an additional 6.42% (85/1324) of records that were excluded for other reasons. The full-text–reviewed 53 eligible studies provided the remaining 15 (28%) studies (investigating 1661 women) comprising 13 intervention designs (involving 1308 women) that were included in the systematic review. Figure 1 illustrates the study selection process based on the PRISMA flow [55].

Figure 1. Study selection flow diagram based on the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) statement [55].



Study Characteristics

Of the 15 studies included, 3 (20%) had weight loss [60-62] as their primary aim. A total of 8 studies focused on improving lifestyle factors, including 2 (13%) on diet [48,63] and 6 (40%) on PA [64-69]—with 1 (7%) study on PA and diet [69] and 1 (7%) study on PA and sleep [68]. A total of 27% (4/15) of the studies focused on improving menopausal symptoms [70-73] such as vasomotor symptoms (eg, hot flushes and night sweats) and bone health [72]. The characteristics of two interventions (Activity and Technology [ACTIVATE] [67,68] and the Women's Wellness Program [WWP] [69,73]) were each reported in 13% (2/15) of the studies and are described only once (Table 1). Of the 13 interventions, 9 (69%) interventions originated in the United States, 3 (23%) in Australia, and 1 (8%) in South Korea. The length of the studies ranged from 8 weeks to 12 months (median 12 weeks). In 69% (9/13) of the interventions, the participants were overweight or obese and, in 31% (4/13), participants were breast cancer survivors. A total of 7% (1/15) of the studies reported having participants with a high risk of hypertension. White individuals participated in 73% (11/15) of the studies, Asian individuals participated in 20% (3/15) of the studies, and 7% (1/15) of the studies had a mix of White and African American participants.

The average age of the participants was 52.25 (SD 4.79, range 45.7-61.6) years. The inclusion criterion was a minimum of 2 participant groups or arms, with 20% (3/15) of the studies (ie, ACTIVATE [67,68], WWP [69,73], and Striving to be Strong [72]) consisting of 3 arms. The comparison groups were either a control group or groups with reduced BCI frequency (eg, diet tracking with no feedback [48]), technology (eg, no technology [69,73] or no SMS text messages [65]), or PA type (eg, endurance group [61]). Where appropriate, an additional review of the studies was provided in three categories (ie, weight loss, lifestyle, and menopausal symptoms) to allow for a more meaningful comparability of the interventions. The outcomes of the studies provided mixed results, with 33% (5/15) reporting statistically significant differences between the intervention and control groups in the primary measured outcomes. This represented 33.18% (434/1308) of all the intervention participants combined (Table 1). Finally, all studies combined (15/15, 100%) had a mean retention rate of 84% (SD 12.6%, range 59%-100%).

Table 1. Characteristics of the studies included in the review (N=15).

Study	Behavior change theory[a]	Intervention									
		Type[b]	Study design	Comparison group	Length	Country	Participant ethnicity	Health risk[c]	Participants, N[d]	Age, mean (SD)	*P* value[e]
Grossman et al [61]	Several BCTs[f]	Weight loss	2-arm feasibility pilot	Endurance group	16 weeks	United States	White	Obesity	11	59.0 (5.33)	No
Hartman et al [62]	SCT[g]	Weight loss	2-arm pilot	Usual care	6 months	United States	White	Breast cancer and overweight or obesity	54	45.7 (4.0)	Yes[h]
Park and Kim [60]	Several BCTs	Weight loss	2-arm quasi-experimental RCT[i]	Control group	12 weeks	South Korea	South Korean	Abdominal obesity	67	51.3 (11.31)	Yes[h]
Cadmus-Bertram et al [64]	CALO-RE[j] framework	Lifestyle (PA[k])	2-arm RCT	Control group	16 weeks	United States	White	Overweight or obesity	51	58.6 (6.5)	No
Finkelstein et al [65]	Several BCTs	Lifestyle (PA)	2-arm crossover pilot	No SMS text message group	8 weeks	United States	White and African American	Obesity	27	52.0 (12.0)	Yes[h]
Fukuoka et al [66]	SCT (Bandura) and SCM[l]	Lifestyle (PA)	3-arm parallel RCT	Control group	12 weeks	United States	White	Overweight or obesity	210	52.4 (11.2)	Yes[h]
Lynch et al [67] and Nguyen et al [68]	MI[m] and several BCTs	Lifestyle (PA and sleep)	2-arm RCT	Control group	12 weeks	Australia	White	Breast cancer and overweight or obesity	83	61.6 (6.4)	Yes[h] and no
McGuire et al [69] and Anderson et al [73]	SCT (Bandura)	Lifestyle (PA) and menopausal symptoms	3-arm equivalency RCT	No-technology group (group B)	12 weeks	Australia	White	Breast cancer and overweight or obesity	225	50.9 (5.9)	No
Ryan et al [63]	ITHBC[n]	Lifestyle (diet)	2-arm repeated-measure experimental RCT	Usual care	6 months	United States	White	N/A[o]	148	50.11 (5.53)	No
Steinberg et al [48]	Several BCTs	Lifestyle (diet)	2-arm feasibility RCT	Control group (active)	12 weeks	Australia	White	Hypertension	59	49.9 (11.9)	No
Im et al [70]	SET[p] (Bandura)	Menopausal symptoms	2-arm repeated-measure RCT	Control group	12 weeks	United States	Asian American	N/A	29	45.7 (4.0)	No
Im et al [71]	SET (Bandura)	Menopausal symptoms	2-arm repeated-measure RCT	Control group	12 weeks	United States	Asian American	Breast cancer	91	51.3 (11.31)	No
Ryan et al [72]	IFSMT[q]	Menopausal symptoms	3-arm prospective repeated-measure longitudinal RCT	Waitlist	12 months	United States	White	Overweight	260	50.57 (5.19)	No

[a]Behavior change theory consisted of (1) several behavior change techniques; (2) the Social Cognitive Theory; (3) the Coventry, Aberdeen, and London-Refined framework; (4) the Self-Efficacy Theory; (5) the Integrated Theory of Health Behavior Change; and (6) the Individual and Family Self-Management Theory.

[b]Intervention outcome types included (1) weight loss, (2) lifestyle (physical activity), (3) lifestyle (diet), (4) lifestyle (sleep), and (5) menopausal symptoms.

[c]Health risks included (1) obesity, (2) breast cancer, (3) overweight or obesity, (4) hypertension, (5) overweight, and (6) abdominal obesity.
[d]Number of participants in the intervention.
[e]Statistically significant between-group differences.
[f]BCT: behavior change technique.
[g]SCT: Social Cognitive Theory.
[h]$P<.05$.
[i]RCT: randomized controlled trial.
[j]CALO-RE: Coventry, Aberdeen, and London-Refined.
[k]PA: physical activity.
[l]SCM: Stages of Change Model.
[m]MI: Motivational Interviewing.
[n]ITHBC: Integrated Theory of Health Behavior Change.
[o]N/A: not applicable.
[p]SET: Self-efficacy Theory.
[q]IFSMT: Individual and Family Self-Management Theory.

BCTs and Categories Used

Overall, the 13 interventions used a range of 6 to 21 BCTs (mean 13.0, SD 4.3, median 13), representing 6% to 23% (median 14%) of the available 93 BCTs from the BCTTv1 [53] (Table 2). Nine BCTs (ie, "instructions on behaviour," "feedback on behavior," "habit formation," "behavioural practice/rehearsal," "action planning," "prompts/cues," "goal setting (behaviour)," "self-monitoring of behaviour," and "graded tasks") were used by more than half (7/13, 54%) of the interventions. In addition, two BCTs (ie, "instructions on behaviour" and "feedback on behaviour") were used by 92% (12/13) and 85% (11/13) of the interventions, respectively (Multimedia Appendix 2 [48,60-73]). Examples of "instructions on behaviour" included providing participants with DVD-guided training instructions, coaching calls that included instructions on meal planning and increasing vegetable intake, or daily video clips about healthy diet and weight maintenance. Examples of "feedback on behaviour" included receiving individualized weekly feedback on activity recording and adherence to the dietary program and, upon recording food intake, receiving immediate feedback on how many calories are left until the participant's daily goal is reached. The next two frequently implemented BCTs—"habit formation" and "behavioral practice/rehearsal"—were each implemented in 77% (10/13) of the interventions. Examples of "habit formation" included researchers sending 3 messages per week or reinforcing content through daily messages and videos. "Behavioural practice/rehearsal" was implemented by providing weekly activity planning with participants to identify and reflect on their barriers to exercising behavior change through journal activities, reflections, and discussion. Finally, approximately 69% (9/13) of the interventions used the "action planning" or "prompts/cues" BCTs.

There was no single cluster of BCTs from which all 13 interventions selected at least one BCT (ie, no behavior change category reached 100%), and only 44% (7/16) of the behavior change categories were used by more than half (7/13, 54%) of the interventions (Table 3). The most frequently used seven categories or clusters of BCTs—from which more than half of the interventions (7/13, 54%) used at least one BCT—were "shaping knowledge," "repetition and substitution," "feedback and monitoring," "goals and planning," "social support," "associations," and "antecedents." Furthermore, 54% (7/13) of the interventions used at least one BCT in 16 of the available behavior change categories, whereas four clusters of BCTs (ie, "regulation," "identity," "self-belief," and "covert learning") were not used by any study (Table 3).

Table 2. Number of behavior change techniques (BCTs) and BCT categories used across all studies.

	Grossman et al [61]	Hartman et al [62]	Park and Kim [60]	Cadmus-Bertram et al [64]	Finkelstein et al [65]	Fukuoka et al [66]	Lynch et al [67] and Nguyen et al [68]	Anderson et al [73] and McGuire et al [69]	Ryan et al [63]	Steinberg et al [48]	Im et al [70]	Im et al [71]	Ryan et al [72]	BCTs per category, n (%)[a]	Mean (SD)[b]
Goals and planning (9 BCTs)	4	5	1	3	—	4	4	3	5	2	__[c]	—	3	34 (20)	2.62 (1.85)
Feedback and monitoring (7 BCTs)	4	2	4	3	2	2	2	1	2	4	—	—	2	28 (17)	2.15 (1.34)
Social support (3 BCTs)	1	—	—	—	—	1	1	1	1	2	2	1	1	11 (7)	0.85 (0.69)
Shaping knowledge (4 BCTs)	1	1	1	1	1	1		1	1	1	1	1	1	12 (7)	0.92 (0.28)
Natural consequences (6 BCTs)	—	—	—	—	—	1	1	1	—	—	1	1	—	5 (3)	0.38 (0.51)
Comparison of behavior (3 BCTs)	1	—	—	—	—	—	—	1	1	1	—	—	1	5 (3)	0.38 (0.51)
Associations (8 BCTs)	—	2	1	—	1	1	2	1	1	2	—	1	—	12 (7)	0.92 (0.76)
Repetition and substitution (7 BCTs)	3	1	5	1	2	3	2	3	3	—	2	2	3	30 (18)	2.31 (1.25)
Comparison of outcomes (3 BCTs)	1	1	1	—	—	—	—	1	1	—	—	1	—	6 (4)	0.46 (0.52)
Reward and threat (11 BCTs)	2	—	—	2	—	2	—	—	2	2	—	—	3	13 (8)	1.00 (1.15)
Regulation (4 BCTs)	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Antecedents (6 BCTs)	3	1	1	1	1	1	1	—	—	—	—	—	1	10 (6)	0.77 (0.83)

	Grossman et al [61]	Hartman et al [62]	Park and Kim [60]	Cadmus-Bertram et al [64]	Finkelstein et al [65]	Fukuoka et al [66]	Lynch et al [67] and Nguyen et al [68]	Anderson et al [73] and McGuire et al [69]	Ryan et al [63]	Steinberg et al [48]	Im et al [70]	Im et al [71]	Ryan et al [72]	BCTs per category, n (%)[a]	Mean (SD)[b]
Identity (5 BCTs)	—	—	—	—	—	—	—	—	—	—	—	—	—		
Scheduled consequences (10 BCTs)	1	—	—	1	—	—	—	—	—	—	—	—	1	3 (2)	0.23 (0.44)
Self-belief (4 BCTs)	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Covert learning (3 BCTs)	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
BCTs per study, n (%)[d]	21 (12)	13 (8)	14 (8)	12 (7)	7 (4)	16 (9)	13 (8)	13 (8)	17 (10)	14 (8)	6 (4)	7 (4)	16 (9)	169 (100)[e]	13.00 (4.30)

[a]The total number of BCTs used across all 13 interventions for each behavior change category. In the table, the number of BCTs in each study is represented by a number. Studies with absent BCTs in each behavior change category are marked with —.

[b]The average number of BCTs used in each behavior change category across all 13 interventions and the SD of the mean number of BCTs used in each behavior change category.

[c]Not applicable.

[d]The total number of BCTs used within each intervention and the percentage of BCTs each study used from the total number of BCTs across all studies.

[e]The sum of the total number of BCTs used across all 16 behavior change categories and all 13 interventions.

Table 3. Behavior change technique (BCT) category results by study type (ie, all, weight loss, lifestyle, and menopause symptoms) where at least one BCT was used in each BCT category.

BCT categories	Scoring for all studies with ≥1 BCT, %	Scoring for weight loss studies with ≥1 BCT, %	Scoring for lifestyle studies with ≥1 BCT, %	Scoring for menopause symptom studies with ≥1 BCT, %
Goals and planning	77	100	88	50
Feedback and monitoring	85	100	100	50
Social support	69	33	75	100
Shaping knowledge	92	100	75	100
Natural consequences	38	0	50	75
Comparison of behavior	38	33	38	50
Associations	69	67	88	50
Repetition and substitution	92	100	88	100
Comparison of outcomes	46	100	25	50
Reward and threat	46	33	50	25
Regulation	0	0	0	0
Antecedents	62	100	63	25
Identity	0	0	0	0
Scheduled consequences	20	33	13	25
Self-belief	0	0	0	0
Covert learning	0	0	0	0

BCW Mapping

Overview

A total of 89% (8/9) of the BCW intervention functions were used in the interventions. The most commonly used intervention functions were “enablement” (60/169, 35.5%), “training” (32/169, 18.9%), “persuasion” (23/169, 13.6%), and “education” (18/169, 10.7%). “Incentivisation” (14/169, 8.3%), “environmental restructuring” (7/169, 4.1%), and “coercion” (2/169, 1.2%) were used to a smaller degree. “Restriction” and “modelling” were not used by any intervention. The COM-B model at the core of the BCW showed that 50% (49/98) of the intervention strategies focused on increasing “capability,” 42% (41/98) focused on increasing “motivation,” and 8% (8/98) focused on providing “opportunity.” Furthermore, a breakdown of the “capability” component suggests that 42% (41/98) were linked to “psychological capability” and 8% (8/98) were linked to “physical capability.” The “opportunity” components show that 3% (3/98) and 5% (5/98) were related to “social” and “physical opportunity,” respectively. Finally, expanding the “motivation” component suggests that 35% (34/98) and 7% (7/98) were linked to “reflective” and “automatic motivation,” respectively (Multimedia Appendix 3). The TDF framework components within the COM-B model of the BCW indicate that the mechanism of action for the BCTs used most frequently was “behavioural regulation” (15/98, 15%), primarily in the “goals and planning” (6/15, 40%; eg, instructions to rotate through 5 different workouts before progression and setting an initial weight loss goal) and “repetition and substitution” (6/15, 40%; eg, progression from 60 minutes of exercise in week 1 to 250 minutes of exercise in week 15 and sending 3 SMS text messages per week) behavior change categories. Additional TDF domains used most frequently within the “repetition and substitution” behavior change category were increasing “knowledge,” “skills,” and “cognitive and interpersonal skills.” “Motivation” was increased primarily through “beliefs about capabilities” (eg, providing daily feedback on steps walked to help the participants monitor and adjust goals) and “professional or social role and identity” (eg, providing monthly face-to-face group meetings and access to a web-based forum to discuss experiences and receive individual and group coaching support). “Opportunity” was increased primarily by “physical environmental restructuring” such as providing instructions on modifications to food and exercise environments (eg, stocking the kitchen with healthy foods and packing exercise clothes ahead of time; Multimedia Appendix 3).

Weight-Loss Intervention Group

A total of 20% (3/15) of the studies aimed to induce weight loss in midlife women [60-62], with all using exercise and diet interventions. The mean frequency of BCTs across the 3 weight loss studies was 16 (SD 4.36, range 13-21). The BCT categories “goals and planning,” “feedback and monitoring,” and “repetition and substitution” were used most frequently, with 10, 10, and 9 BCTs, respectively. The BCW mapping suggests that increasing “capability” was implemented in 55% (42/77) of the behavior change interactions, followed by increasing “motivation” in 36% (28/77) of the interactions and increasing “opportunity” in 9% (7/77) of the interactions. Furthermore, the “psychological capability” TDF domain was used the most frequently, specifically through “behavioural regulation.”

Lifestyle Intervention Group

Of the 8 studies included in the lifestyle group of interventions, 3 (38%) aimed to improve PA through a PA program [64-66].

A total of 25% (2/8) of the studies aimed to improve well-being through diet [48,63]. The McGuire et al [69] study of WWP trial aimed to improve PA through diet and exercise. In total, 25% (2/8) of the studies were from the ACTIVATE trial; one aimed to improve sleep by improving PA [68] and another to improve PA through exercise and coaching [67]. The mean frequency of BCTs across the lifestyle studies was 13.13 (SD 3.00, range 7-17). The BCT categories "goals and planning," "feedback and monitoring," and "repetition and substitution" were used most frequently, with 25, 18, and 16 BCTs, respectively. The BCW mapping shows that motivation was used in 45% (31/69) of BCTs, similar to capability at 46% (32/69) followed by increasing "opportunity" at 9% (6/69). The "Psychological capability" TDF domain was used the most frequently, with "behavioural regulation" followed by increasing "knowledge" (eg, self-monitoring food intake and PA) and "building competencies" (eg, encouragement to enter consumed foods in real time and receiving immediate feedback on goal progression).

Menopause Symptom Intervention Group

A total of 27% (4/15) of the studies were included in the menopause symptom interventions group [70-73] among which one study [73] measured menopausal symptoms such as depression, anxiety, and somatic and vasomotor symptoms using the Greene Climacteric Scale [76]. The intervention was based on promoting healthy lifestyle behaviors, emphasizing a healthy diet and regular PA. Im et al [70] aimed to improve menopausal symptoms by emphasizing PA. By contrast, the aim of the study by Im et al [71] was to decrease menopausal symptoms through education and coaching. Ryan et al [72] measured bone mineral density among three groups (2 intervention and 1 control). The study used an ecological momentary assessment software to encourage the participants to increase their calcium intake, PA, balance, and strength [72]. The average frequency of BCTs across the 4 menopause symptom studies was 10.50 (SD 4.80, range 6-16). The BCT categories "repetition and substitution," "goals and planning," "social support," and "shaping knowledge" were used most frequently, with 10, 6, 5, and 4 BCTs, respectively. The BCW mapping shows that "motivation" was used in 44% (24/55) of BCTs, similar to "capability" at 47% (26/55) followed by increasing "opportunity" at 9% (5/55). The BCW mapping suggests that the "psychological capability" TDF domain was used the most frequently, specifically through "behavioural regulation."

Extent of Theory Use

The overall mean total use of theory score (based on the TCS) for all interventions was 8/23 (SD 3.87, range 4-15), which represents a weak level (score 8-15; Multimedia Appendix 4 [48,60-73]). Individual interventions were scored, with 62% (8/13) categorized as weak (score 0-7) and the remaining 38% (5/13) scoring moderate levels (score 8-15). No study achieved a strong score (score 16-23). Of the 13 interventions, 7 (54%) explicitly reported that they were based on theory (item 5; Multimedia Appendix 4). Of these 13 interventions, 7 (54%) were based on a single theory (item 3), none reported using theory to recruit study participants (item 4), and 3 (23%) reported using theory to tailor BCTs to recipients (item 6). Of these 13 interventions, none explicitly reported links between all BCTs within the intervention and the targeted theoretical constructs (item 7), whereas 4 (31%) reported targeting all the constructs within a specified theory with specific BCTs (item 10). A total of 62% (8/13) of the interventions reported measuring theoretical constructs after the intervention, and 62% (8/13) measured constructs both before and after the intervention (item 12). However, only 62% (8/13) of interventions reported statistically significant mediated effects (item 16d). Only 23% (3/13) of the interventions reported suggestions for theoretical refinement based on their findings (item 19). The review of the 6 TCS categories suggests that 77% (10/13; mean 3/7, SD 1.25) of the interventions stated or suggested rather than demonstrated theoretical base (being based on theory; category 1). All 13 interventions targeted theoretical constructs that predicted behavior (category 2; mean 2.69/7, SD 1.84).

Behavior Change Theories Used

Although all 13 interventions mentioned behavior change, a specific behavior change theory was mentioned in 69% (9/13) of the interventions. The most frequently used behavior change theories included the Self-Efficacy Theory (SET) and Social Cognitive Theory (SCT), each being implemented in the design of 15% (2/13) of the interventions. The Stages of Change Model; Individual and Family Self-Management Theory; Integrated Theory of Health Behavior Change; Motivational Interviewing; and Coventry, Aberdeen, and London-Revised [77] framework were each used in 7% (1/15) of the studies. The remaining 27% (4/15) of the studies that mentioned behavior change reported using several BCTs (Table 1).

Modes of Delivery Used in the Studies

Overview

The studies used a combination of technological and nontechnological components. Websites were used in 69% (9/13) of the interventions, and phone or SMS text messages were used in 62% (8/13) of the interventions, followed by wearables, which were used in 54% (7/13) of the interventions (Multimedia Appendix 5 [48,60-73]). Apps, email, electronic documents, and ecological momentary assessment were used in 46% (6/13), 23% (3/13), 15% (2/13), and 8% (1/13) of the interventions, respectively. In addition, 65% (46/71) of the technology interactions with the participants in all studies were provided in a passive manner without the participants' active involvement (eg, providing health and lifestyle information such as recipes, tips, and frequently asked questions). By contrast, 35% (25/71) of the interactions were provided in an action-based manner. Evaluation of technological features provided in the interventions showed that the top 3 interactions included health or lifestyle information, which was provided in 24% (16/68) of all the interactions; activity tracking, which was provided in 19% (13/68) of the interactions; and health or lifestyle lessons, which were provided in 10% (7/68) of the interactions. Furthermore, social media and support provided 7% (5/68) of the interactions; web-based health coaching provided 3% (2/68) of the interactions; and barrier tracking, activity tracking, and health education each provided 3% (2/68) of the interactions. Other technological features such as reminders or prompts, social support, health information, health

feedback, health activity, social support, practical support, diet tracking, and follow-up each provided 1% (1/68) of the interactions. Nontechnological components such as face-to-face interactions and providing hard-copy intervention material were used by 38% (5/13) and 46% (6/13) of the interventions, respectively.

Weight-Loss Intervention Group

In addition to technical components, 13% (2/15) of the studies [61,62] also used nontechnological components such as face-to-face meetings and providing a hard copy of the intervention material. Of the technical components, 67% (8/12) were passive, whereas 33% (4/12) were action based.

Lifestyle Intervention Group

Of the technical components, 69% (24/35) were passive, whereas 31% (11/35) were action based. Most studies (6/8, 75%) also used nontechnical components such as face-to-face meetings and hard-copy study documentation.

Menopause Symptom Intervention Group

Of the technical components, 62% (16/26) were passive, whereas 38% (10/26) were action based. Only the WWP study by Anderson et al [73] used nontechnical components such as face-to-face meetings and a hard copy of the program book.

Fidelity of the Studies

Of the 13 interventions, 8 (62%) included an assessment of all 5 domains (Multimedia Appendix 6 [48,60-73]). The greatest average proportion of adherence to treatment fidelity across all 13 interventions was in the "Enactment" domain at 50% (0.50). The lowest mean proportion of adherence to strategies was found in the "Receipt" domain, where, on average, only 26% (0.26, SD 0.25) of strategies were reported among the studies. Finally, the mean proportion of adherence to strategies in the "Treatment," "Training," and "Delivery" domains was 45% (0.45, SD 0.18), 34% (0.34, SD 0.22), and 32% (0.32, SD 0.14), respectively. The mean proportion of adherence to treatment fidelity strategies included across all 5 domains for all studies was 0.39 (SD 0.14, median 0.41). On the basis of the fidelity scoring by Borrelli [74], where 50% constitutes low-fidelity scoring, 85% (11/13) of the interventions scored a low treatment fidelity across all 5 domains. In total, 13% (2/15) of the studies, both by Ryan et al [63,72], scored >0.50 in the medium treatment fidelity range (ie, 0.51 to 0.79), with 0.62 and 0.59 treatment fidelity. For details of scoring for each component of the treatment fidelity domain, see Multimedia Appendix 6.

Discussion

Principal Findings

This review systematically reviewed 13 interventions that aimed to improve weight loss (3/15, 20%), lifestyle (8/15, 53%), and menopause symptoms (4/15, 27%) through DHIs in midlife women. Six BCTs (ie, "Feedback on behaviour," "Prompts/cues," "Action planning," "Instructions on behaviour," "Behavioural practice/rehearsal," and "Habit formation") were used in at least 80% (4/5) from the studies that showed significant between-group differences in main outcomes. This group of studies used an average of 12.6 BCTs (range 7-16, median 13), representing 13.98% (169/1209) of all BCTs available from the BCTTv1 taxonomy. The most frequently used six clusters of BCTs (ie, "Feedback and monitoring," "Associations," "Repetition and substitution," "Antecedents," "Shaping knowledge," and "Goals and planning") were used by >80% (4/5) of the studies. Four clusters of BCTs (ie, "Social support," "Natural consequences," "Comparison of outcomes," and "Reward and threat") were used by only 20% (1/5) to 40% (2/5) of the studies. Six other clusters (ie, "Regulation," "Identity," "Self-belief," "Covert learning," "Comparison of behaviour," and "Scheduled consequences") were not used, which may indicate that the BCTs within these clusters were unexplored or potentially found inappropriate for these interventions. Although the findings indicate which BCTs are used more frequently in health-enhancing DHIs with midlife women, the high level of heterogeneity in the design of the interventions and selection of specific BCTs suggests that the designs of these interventions cannot be generalized across various contexts. DHIs should consider the unique experiences and needs of women in midlife, including marginalized women, to improve their sociodemographic diversity.

In this review, 78% (7/9) of BCW intervention functions were identified, with a strong emphasis on "enablement" (eg, encouragement to set an initial weight loss goal and self-monitoring food intake and PA) by increasing capability beyond education and training. "Training" and "persuasion" were also commonly used, whereas "restriction" and "modelling" were not used at all. In a nondigital lifestyle BCI (involving adult men and women), 5 (56%; 5/9) of the intervention functions were used (ie, "enablement," "training," "persuasion," "restriction," and "education"), whereas "incentivization," "coercion," and "modelling" were not used and were found to be inappropriate in the context of the intervention [78]. In another nondigital lifestyle behavior change review, education (eg, nutritional label reading and a resistance training booklet for exercise) was the most commonly used intervention function, being present in 81% of the interventions [79]. "Enablement" (eg, self-management techniques to foster self-efficacy and arranging support from friends and family) and "training" (eg, home-based exercise training, guided exercise training, and hands-on cooking classes) were also emphasized, whereas "coercion" and "restriction" were not used in any of the interventions [79]. Overall, "education," "enablement," and "training" were used commonly across digital and nondigital intervention types, whereas "coercion" or "restriction" were used less commonly.

When comparing digital and traditional face-to-face (ie, nondigital) lifestyle health-enhancing interventions, there are apparent commonalities and differences in the BCT clusters typically used within interventions. Previous reviews have highlighted that only a fraction (34%; 32/93) of the BCTs were used across all interventions, with the "Feedback and monitoring" and "Goals and Planning" BCT clusters used more commonly in traditional lifestyle interventions [79,80], which aligns with what was observed in this review. Contrary to previous reports on traditional lifestyle interventions, this study demonstrated that DHIs in midlife women were more likely to

use "Repetition and substitution" (ie, habit formation) techniques [79,80]. This difference may be due to the just-in-time nature of digital technologies, which allows for the implementation of behaviors that may emerge rapidly, unexpectedly, and ecologically and that are usually less accessible with in-person approaches [81].

In other DHIs, certain BCTs were found to be more frequently applied on particular technological platforms. For example, the most frequently used BCTs in lifestyle interventions using mobile apps were "feedback on behaviour" (84%; 26/31), "self-monitoring of behaviour" (77%; 24/31), and "goal setting" (61%; 19/31) [82]. Although these BCT features were apparent in the mobile app–based interventions included in this review, they were not universally applied. Equally, digital PA BCIs used primarily a combination of "goal setting," "self-monitoring," and "motivation," whereas digital healthy eating interventions primarily targeted "self-monitoring," "goal setting," and "feedback on behaviour" [82]. Similarly, in this review, "feedback on behaviour" (11/13, 85%), "goal setting" (8/13, 62%), and "self-monitoring" (8/13, 62%) were in the top 10 BCTs used across all technological platforms in all studies. In gamification platforms, for example, the most frequently used BCTs were "education" and "reward" as these are important features of gamification [44]. This highlights that almost all the key BCTs can be used on a mobile platform, most likely because of the flexibility and accessibility of this technology [44]; therefore, interventions can be easily tailored to the context in which they are being applied. Health interventions for midlife women must be cognizant of the multiple co-occurring stressors that are born from psychosocial and physiological transitions during this period [83]. Interestingly, DHIs have been suggested to be most effective in facilitating problem-solving, encouraging self-efficacy, and reducing the impact of stress associated with behavior change [24].

This review highlighted a varied use of theories of behavior and behavior change to design DHIs, with SET and SCT being most commonly used in DHI research to date. Interventions informed by these theories can effectively enhance PA in midlife women [18,84]; however, the application of theory to BCT intervention functions has been poorly reported or used [54,57]. In this review, although 69% (9/13) of the interventions mentioned behavioral theory, more than half (8/13, 62%) had weak scores (based on TCS) in applying theory to the intervention. In cases where the intervention was reportedly based on theory (ie, SCT, SET, and the Stages of Change Model), none of the studies in this review explicitly linked all theoretical constructs with BCTs and vice versa. As such, having a theoretical understanding of behavior change is necessary to maximize the potential efficacy of interventions [85].

A critical component of intervention delivery is establishing theoretical fidelity and ensuring that a theory is adequately reflected in the intervention's design and implementation [74]. The overall poor reporting of treatment fidelity in this review (with only 2/15, 13% of the interventions reporting medium treatment fidelity [63,72]) is similar to other reviews that considered fidelity [41,74,86]. Although 69% (9/13) of the interventions in this review mentioned a theory, the treatment design domain achieved only a low mean proportion of treatment fidelity. When intervention effects are not significant, treatment fidelity helps understand whether this is due to the omission or addition of active or inactive components or whether it is due to an ineffective treatment [74]. However, it is important to highlight that a lack of effect may reflect implementation failure rather than genuine ineffectiveness and, through the evaluation process, implementation problems can be identified [20]. Although this review combined treatment fidelity for studies that did and did not achieve statistically significant group differences, an accurate estimate of the relationship between theory use and intervention effectiveness can only be obtained from studies that reach high fidelity of delivery [87]. DHIs incorporating behavior change theory offer a unique opportunity to refine and strengthen the theory. Unfortunately, none of the studies in this review reported refining or developing a theory to strengthen intervention effectiveness. Moller et al [88] explored potential improvements for applying behavior change theories in the context of digital health and suggested that digital technologies may potentially provide high fidelity of delivery owing to their ability to measure engagement levels objectively. Furthermore, digital technologies can also access large data sets generated by ecologically valid measures of behavior, emotion, physiology, and thinking in real time and everyday contexts [88]. Therefore, considering treatment fidelity in DHIs is essential to estimate the confidence with which intervention effects can be attributed to BCTs.

Although extending the interpretation of the findings to the effectiveness of certain BCTs was outside the scope of this review, it should be noted that identifying effective BCTs and a combination of BCTs for a given behavior in a given context presents a major challenge [89]. Research evaluating the effectiveness of BCTs and BCT combinations uses a range of observational and experimental methods, each with strengths and limitations [89]. For example, van Rhoon et al [90] drew conclusions on the effectiveness of specific numbers and types of BCTs in weight loss DHIs based on the BCTs that were present in interventions producing clinically significant weight loss outcomes. However, this method led to the inability to identify the mechanisms by which the BCTs and digital features influenced the target behavior. In addition, this method runs the risk of including BCTs that do not add to effectiveness but happened to be included in the effective interventions [89]. Furthermore, although other evaluation methods such as meta-analyses can provide generalizable conclusions [89], poor quality in intervention description and high heterogeneity in the designs may not allow for statistical analysis of the effectiveness of individual BCTs or a combination of BCTs on the intervention outcomes [21,44,78,91,92]. Making confident estimates of the effectiveness of BCTs and BCT combinations for a given behavior delivered in a particular way in a given setting to a given target population requires synthesis of information from diverse sources [89]. This challenge provides an opportunity for future research to develop a strategy that systematically combines the strengths of the different methods and that links these constructs in an ontology of BCIs [89].

The outcomes of this review suggest that the effects of BCTs on behavior are difficult to determine because of high

heterogeneity in the designs of the interventions and low level of treatment fidelity and theoretical grounding. It is also important to note that, although the BCW provides a systematic and theory-guided method for identifying components of interventions and types of interventions that are expected to be effective, it does not provide a detailed blueprint for the design of specific BCIs [19]. Therefore, the BCW framework should be applied with a level of flexibility, as acknowledged by its authors [78]. Furthermore, although theory-based intervention design is critical for intervention effectiveness [20], the involvement of key stakeholders in the development process of interventions through coproduction increases the likelihood of the intervention meeting user needs and their implementation [20,93]. Although most of the participants in the studies in this review were White individuals (9/13, 69% of the interventions), research shows that menopausal symptom experiences vary among women with different sociodemographic characteristics, including ethnicity, income, and education [94-96]. The lack of diversity in the sociodemographic characteristics of the studies and the apparent lack of evidence on how to culturally adapt DHIs provide an opportunity to explore these topics in future research. In addition, co-designing theory- and evidence-based interventions with Patient and Public Involvement in all stages of the design process [92,97-99] would be beneficial to ensure that digital health lifestyle BCIs for midlife women are acceptable, feasible, and more effective. To date, there has been no such study undertaken and, therefore, this represents an opportunity for researchers to advance the field by improving both the quality and replicability of such interventions.

Strengths and Limitations

The process of identification of the BCTs requires classification and coding of intervention descriptions [77] using the BCTTv1 [53] for each study. The level of detail necessary for BCT coding was limited in the studies. As such, this review contains a possible subjectivity limitation in categorizing, reviewing, and mapping behavior change theories and BCTs. To mitigate this limitation, two researchers (HS and SD) interpreted and coded the BCTs to reduce any bias (also acknowledged in other research [44]). Similarly, to reduce bias in interpreting and coding, the TCS items (also acknowledged in other research [41]) were completed by 2 researchers. Improving the description of the intervention design and delivery is essential for improving BCT coding to better facilitate scientific evaluation and translational processes in future studies.

Furthermore, the number of health-promoting studies designed specifically for midlife women is limited. This review contains a small number of studies with limited sociodemographic (ie, the participants in 9/13, 69% of the interventions were White individuals) and socioeconomic (ie, all the included studies came from high-income countries) backgrounds and attempts to assess the quality of evidence that may not be generalizable to all digital health BCIs with midlife women. Future research should consider the unique needs of women of diverse sociodemographic and socioeconomic backgrounds in their intervention designs to make their findings applicable to more women.

Conclusions

This review identified studies aiming to promote lifestyle improvements in midlife women using digital technology and assessed their designs through the application of the BCW framework. The assessment identified gaps in the process of designing digital health BCIs. The studies obtained weak to moderate scores in their theoretical grounding, and their description of intervention components, intervention functions, and BCTs was also weak. The low level of treatment fidelity suggests that the interventions may not have delivered what the researchers intended to deliver (also acknowledged elsewhere [41]) and that the interventions may not be replicable. This suggests, as also highlighted by Michie et al [89], that there is a need for better tools and intervention design guidelines to facilitate better selection and use of behavioral theories. Although the findings indicate which BCTs are used more frequently in specific groups of interventions, the high level of heterogeneity in the design of the interventions and selection of specific BCTs suggests that the designs of these interventions cannot be generalized across different contexts. Instead, applying the principles underlying the design of these groups of interventions through systematically co-designing theory- and evidence-based interventions with midlife women may be more efficacious. Further research is needed to validate such intervention designs and their application in feasibility and acceptability studies. A closer collaboration between behavioral science and solution design is needed to bridge this gap and increase the effectiveness of digital health behavior change technologies.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Quality assessment results.
[PDF File (Adobe PDF File), 198 KB - mhealth_v10i11e37234_app1.pdf]

Multimedia Appendix 2
Behavior change theory mappings across all studies.
[PDF File (Adobe PDF File), 273 KB - mhealth_v10i11e37234_app2.pdf]

Multimedia Appendix 3
Behavior change wheel mapping of all studies.
[PDF File (Adobe PDF File), 136 KB - mhealth_v10i11e37234_app3.pdf]

Multimedia Appendix 4
Theory Coding Scheme scoring across all studies.
[PDF File (Adobe PDF File), 116 KB - mhealth_v10i11e37234_app4.pdf]

Multimedia Appendix 5
Technological components used in each study.
[PDF File (Adobe PDF File), 93 KB - mhealth_v10i11e37234_app5.pdf]

Multimedia Appendix 6
Treatment fidelity of the studies.
[PDF File (Adobe PDF File), 198 KB - mhealth_v10i11e37234_app6.pdf]

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Abbreviations

ACTIVATE: Activity and Technology intervention
BCI: behavior change intervention
BCT: behavior change technique
BCTTv1: Behavior Change Technique Taxonomy v1
BCW: behavior change wheel
COM-B: capability, opportunity, and motivation-behavior
DHI: digital health intervention
PA: physical activity
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
SCT: Social Cognitive Theory
SET: Self-Efficacy Theory
TCS: Theory Coding Scheme
TDF: Theoretical Domains Framework
WWP: Women's Wellness Program

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Review

The Management Perspective in Digital Health Literature: Systematic Review

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Abstract

Background: New digital health technologies are considered one solution to challenges in the health sector, which include rising numbers of chronic diseases and increased health spending. As digitalization in health care is still in its infancy, there are many unanswered questions about the impact of digital health on management.

Objective: This paper assesses the current state of knowledge in the field of digital health from a management perspective. It highlights research gaps within this field to determine future research opportunities.

Methods: A systematic review of digital health literature was conducted using 3 databases. The chosen articles (N=38) were classified according to a taxonomy developed for the purpose, and research gaps were identified based on the topic areas discussed.

Results: The literature review revealed a slight prevalence of practical (n=21, 55%) over theoretical (n=17, 45%) approaches. Most of the papers (n=23, 61%) deal with information technology (IT) and are, therefore, focused more on technology and less on management. The research question in most of the papers (n=31, 82%) deals with the creation of concepts, and very few (n=4, 11%) evaluate or even question existing solutions. Most consider the main reason for digitalization to be the optimization of operational processes (n=26, 68%), and 42% (n=16) deal with new business models. The topic area discussed most frequently was found to be eHealth (n=30, 79%). By contrast, the field of tech health with topics such as sensors receives the least attention (n=3, 8%), despite its significant potential for health care processes and strategy.

Conclusions: Three main research propositions were identified. First, research into digital health innovation should not focus solely on the technology aspects but also on its implications for strategic and operational management. Second, the research community should target other domains besides eHealth. Third, we observed a lack of quantitative research on the real impact of digital health on organizations and their management. More quantitative evidence is required regarding the expected outcome and impact of the implementation of digital health solutions into our health care organizations.

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KEYWORDS

digital health; management; health care management; literature review; health technology; eHealth; data health; trend health; tech health

Introduction

Background

Any list of the significant trends that influence the way we manage our organizations will certainly include digitalization. It is not surprising, therefore, that digital health is a major area of interest in the health care sector. Public health literature, popular media, and health care services all increasingly focus on this topic [1]. At the same time, a uniform definition of the term 'digital health' has yet to be established [2]. Furthermore, when discussing digitalization in the health care sector, the terms Medicine 4.0, Health 2.0, and 'connected health' are used alongside and sometimes interchangeably with digital health.

It should be emphasized that digital health has the potential to radically change the strategy, operations, and culture of health care providers. In particular, it can offer cost-effective, patient-centered solutions [3], which could drastically simplify access to data as well as the exchange and generation of data for the benefit of patients and health care professionals [4].

Furthermore, digital health can add value not only at the level of the overall health care sector but also to individual organizations; therefore, it also has a significant management perspective.

When discussing digital health solutions and taking advantage of the great potential associated with them, individual health care organizations and their managers are confronted with major decisions. In order to be able to continue to compete in the health care market, health care managers need guiding frameworks and sound advice from scientific sources on how to exploit the potential of digital health and how to cope with the associated changes in the best possible way. We felt it was important, as a result, to assess the impact that digital health has on the field of health care management. The reverse effect, the impact of management on digital health, is beyond the scope of this study.

Previous Research and Research Gap

Limited information is currently available on the impact of digital health from a management perspective. In a literature review of digital transformation cases by Ivančić et al [5], only 2 out of 29 papers analyzed addressed the health care sector. A literature review by Henriette et al [6] on digital transformation identified just one paper about the health sector. Admittedly, these reviews have the following limitations: (1) they were not targeted at the health care sector specifically, and (2) they had a very narrow focus on the transformative aspect of digitization.

Research Problem, Questions, and Methods

This study addresses the lack of health care–related data in the literature on digital transformation identified above. In particular, it discusses the results of a literature review we conducted on the impact of digital health on health care management.

To this end, we followed the recommendations of Tranfield et al [7]. In addition to a comprehensive overview of digital health in the health care sector, we wanted to incorporate a broader, 'big picture' view of the impact of digital health on health care management. According to Thompson et al [8], health care managers and their tasks can be defined as follows:

> *The profession that provides leadership and direction to organizations that deliver personal health services, and to divisions, departments, units or services within those organizations [8].*

Since there are many definitions of digital health, we used the following broad definition of digital health:

> *Digital health is the utilization of modern information and communication technologies (ICT) in the health care sector to improve the quality, the efficiency, and the focus on patients' needs [9].*

This holistic definition includes, for example, the many existing digital devices and apps used to diagnose and treat disease, simplify the self-treatment of chronic diseases, and monitor health parameters and daily behavior patterns. The definition also encompasses completely different technologies such as software used by health care providers to optimize their daily operations and train their staff.

The objective of this systematic review was to provide health care managers with an overview of digital health literature from a management perspective and uncover any potential research gaps in this field.

Methods

The literature review we conducted is based on the approach by Tranfield et al [7] and is depicted in Multimedia Appendix 1. In the following section, the study design is presented in more detail.

Search Strategy

In March 2019, two researchers were tasked with searching the 3 databases ABI/Inform Global, WISO, and PubMed for studies published between 2000 and 2019. The search was limited to freely available full-text articles published in English. To take into account the management perspective of digital health, the search terms "digital," "health," and "manage*" were used in different combinations.

Reference lists of systematic reviews were searched for additional studies not captured by our initial systematic research. Once the search was complete, duplicates were removed, and the citations were uploaded to a secure internet-based platform.

Selection Criteria and Data Collection

Multimedia Appendix 2 defines the specific inclusion criteria for each database and shows the documentation of the search terms with the corresponding hits per database.

Studies were included according to the following inclusion criteria: (1) studies were published between January 1, 2000, and December 31, 2019, on Web of Science Core collection; (2) studies were published between 2009 and 2019 on ABI/Inform Global or PubMed; (3) studies were published in English; (4) full-text articles were freely available; and (5) studies were relevant to our subject.

Exclusion criteria included the following: (1) a lack of thematic focus (eg, 'health' or 'digital' were not the main topic or digital health was only discussed in passing); (2) studies focusing on digitalization as a means to transforming customer experience; and (3) unpublished literature, conference abstracts, and letters or editorials. Since our goal was to provide a first and extensive overview of digital health literature from a management perspective, there were no restrictions on the type of study designs reviewed.

The 2 reviewers each selected studies for possible inclusion based on title and the content of the abstract. Studies deemed to fulfill the inclusion criteria were analyzed in full-text review. Any disagreements were discussed between the reviewers, and a third party was involved to help reach consensus if necessary. Full data extraction, including characteristics of included articles, was completed by one reviewer and verified by the second reviewer.

Analysis Framework

To analyze the literature we had identified as relevant, we developed a taxonomy with the following 6 dimensions:

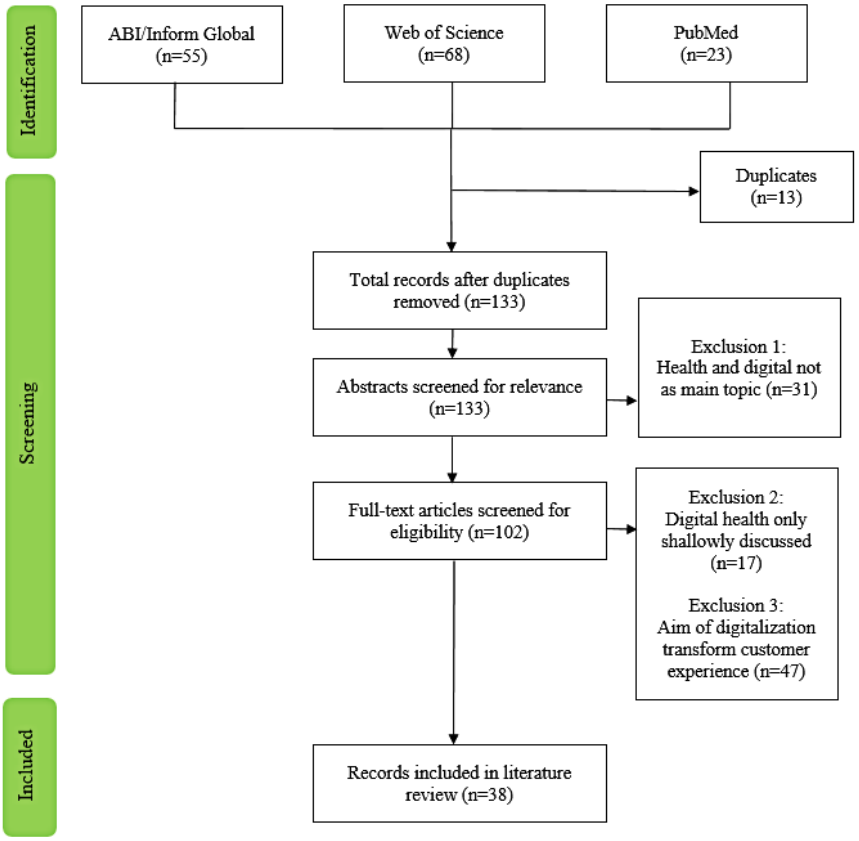
1. Research approach. Publications can derive their knowledge from real implementations or theoretical thinking. In line with Brandao de Souza [10], we classified the articles as 'case-based' or 'conceptual.' This classification is relevant since, from the distribution of both types, we can derive statements on the maturity level of the overall implementation of digital health in the health care market.
2. Research question type. Wytrzens et al [11] defined 5 basic types of research question that categorize articles according to their primary objective, as follows: description, explanation, creation or concept, evaluation or criticism, and forecasting or prediction. This differentiation permits statements on the focus and core objective of a study.
3. Management discipline. The objective of this category was to assess whether various business management disciplines are treated in a balanced way. To do so, we used the same catalog that Harvard Business Publishing [12] uses to structure their publications. Since some of the articles were also in the legal and public health fields, these two dimensions were added to the Harvard Business Publishing categorization. The dimension 'general management' is used for any residual topic that does not fit well into the Harvard taxonomy.
4. Reason for digitalization. Like any other organization, health care organizations should always ask themselves why they want to introduce digital health solutions into their operations. In line with the message in Simon Sinek's popular management book, "Start With Why" [13], we tried to understand the rationale for digitalization. We differentiated between the two goals of improving operational processes and creating new business models. This is a concept used by the Massachusetts Institute of Technology Center for Digital Business [14]. Their research has shown that it is primarily the business process, business model, or customer experience that can improve overall business outcomes. For our literature research, we wanted to focus on the management aspect, so we excluded all 'customer experience' publications.
5. Content domain. To analyze the content of the papers chosen, we used the following 4 digital health subcategories created by Angerer et al [2]: trend health (lifestyle), eHealth (exchange of data), tech health (hardware), and data health (software). During the coding, we added a fifth additional domain that we called 'overarching challenges,' where the focus was on the challenges in the implementation and use of different technologies found in practice.
6. Implementation approach. To answer the question of how the health care sector implements its digitalization initiatives, the examples of practices, principles, and tools from Angerer et al [2] were taken and supplemented with new elements discovered during the screening process.

Results

Selection

The search resulted in 133 unique citations, which were screened by our researchers. Based on the articles' titles and abstracts, 31 were excluded, resulting in 102, which were subjected to a full-text screening. This process left us with 38 papers that met the inclusion criteria for our review (Figure 1). Their reference lists were searched, but no additional studies were added. Multimedia Appendix 3 shows all publications eventually included in this study.

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flowchart of literature research procedure [15].



Analysis Based on Research Approach

Table 1 outlines the distribution of papers by research approach. Of the 38 papers included, 21 (55%) papers are case based, and 17 (45%) papers are theory based. This led us to conclude that this subject area is well balanced in terms of theory-based versus practice-based articles.

Table 1. Number of papers by research approach (N=38).

Research approach	Number of papers, n (%)
Case-based papers	21 (55)
Theory-based papers	17 (45)

Analysis Based on Research Question Type

As depicted in Table 2, the objective of 31 (82%) papers was to design new digital concepts to overcome practical problems in health care. The second most pursued goal in 7 (18%) papers was to predict future health care scenarios. As frequently stated, the health care sector is still in its digital infancy; therefore, it seems highly plausible that the most popular research questions will deal with future, hypothetical situations, or concepts. We found it surprising that only 4 (11%) papers were (critical) evaluation papers, since they have one of the most vital roles of the scientific management community.

Table 2. Number of papers by objective of the research question (N=38)[a].

Research question type	Number of papers, n (%)
Creation or concept	31 (82)
Forecasting or prediction	7 (18)
Description	6 (16)
Evaluation or criticism	4 (11)
Explanation	3 (8)

[a]One paper can include more than one category; therefore, the sum can be larger than 100%.

Analysis Based on Management Discipline

As shown in Table 3, the discipline most frequently addressed in 23 (61%) papers is IT management. This finding is consistent with the findings of a literature review by Reis et al [16] on digital transformation in general and shows that IT is still the main driver of digital health (ie, technology push). From a management perspective, strategy should lead the way (ie, technology pull), yet only 4 (11%) reviewed papers addressed this underresearched topic. In a hospital setting, for example, this could imply that the IT department with its technological perspective is in the driver's seat. Yet this can be problematic, as the digital health strategy should support the overall organizational strategy. Another indication that digital health is still primarily a result of technology push is that people-focused disciplines, such as human resources, ethics, and organizational behavior, are underrepresented.

Table 3. Number of papers by management discipline (N=38)[a].

Management discipline	Number of papers, n (%)
Information technology management	23 (61)
Public health	9 (24)
General management	5 (13)
Strategy	4 (11)
Human resources management	3 (8)
Operations management	3 (8)
Entrepreneurship	2 (5)
Marketing	2 (5)
Business ethics	1 (3)
Organizational behavior	1 (3)
Legal issues	1 (3)

[a]One paper can include more than one discipline; therefore, the sum can be larger than 100%.

Analysis Based on Reason for Digitalization

The digitalization of the health care system is discussed in just over two-thirds (n=26, 68%) of all papers (Table 4). This comes as no surprise, since increasing the efficiency and effectiveness of health care today seems to be the primary focus of the majority of stakeholders [17]. Transforming business models through digitalization is much more radical and challenging, which may explain the comparatively low number of articles addressing this (n=16, 42%).

Table 4. Number of papers by the reason for digitalization (N=38)[a].

Reason for digitalization	Number of papers, n (%)
Operational process	26 (68)
Business model	16 (42)

[a]One paper can include several dimensions; therefore, the sum can be larger than 100%.

Analysis Based on Content Domain

The vast majority of the papers (n=30, 79%) deal with different issues related to eHealth (Table 5). This is consistent with a survey published by the World Health Organization [18], which revealed that 58% of its member countries already have an eHealth strategy. Arak and Wójcik [19] held that eHealth is the key to addressing the challenges of modern health care systems. Electronic health records are a very popular subtopic of the eHealth papers reviewed (n=11, 29%).

The second most frequently mentioned dimension is data health (n=12, 32%). The majority of the papers in this category (n=7, 18%) deal with methods to analyze data. This digital health dimension is relatively close to the next dimension—overarching challenges (n=7, 18%)—where the focus is on challenges related to the implementation and use of different technologies found in practice. The biggest issue, by far, is personal data privacy. Both dimensions being so close to each other is not unusual, since data analysis always touches on security issues as well.

The dimensions occurring least frequently in the literature reviewed are trend health (n=5, 13%) and tech health (n=3, 8%). The latter is in line with our expectations for 2 reasons. First, we focused on management literature, and highly technical papers—where the hardware itself plays a major role—are unlikely to be published in business-oriented journals. Second, many of the technologies within the domain, such as 3D printing or robotics, are not yet widely spread in a health care context. More remarkable, however, is the low number of just 5 papers for trend health–related publications. From a business perspective, lifestyle solutions can be significant revenue drivers, as seen in the success of activity tracking devices. A possible explanation for this low count might be the bias of researchers to focus their activities on more 'serious' digital health aspects closer to conventional medicine.

Figure 2 is a summary graphical representation of the content findings from our digital health literature search. The innermost (white) layer of the circle represents the 'why' and shows that operational processes are the main reason for digital transformation in the papers analyzed. The second layer represents the 'where' and shows clearly that eHealth is addressed most often in scientific articles. The outermost layer illustrates the 'what'; it shows that electronic health records and IT systems are the topics mentioned most frequently.

Table 5. Distribution of publications by content domain (N=38)[a].

Content domain	Total papers	Conceptual studies	Case-based studies
eHealth (exchange of data)	30 (79)	16 (42)	14 (37)
Data health (software)	12 (32)	5 (13)	7 (18)
Overarching challenges	7 (18)	2 (5)	5 (13)
Trend health (lifestyle)	5 (13)	1 (3)	4 (5)
Tech health (hardware)	3 (8)	1 (3)	2 (5)

[a]One paper can be part of several dimensions, so the sum can be larger than 100%.

Figure 2. Distribution of reviewed publications. CAD: computer-aided design; IoT: internet of things; IT: information technology.

Discussion

Main Findings

This literature review provides an overview of digital health literature from a management perspective and uncovers research gaps. In general, it shows that digitalization in the health care sector is still in its infancy, and therefore, there are still significant knowledge gaps concerning health care management. In the following section, we present the 3 important avenues for future research derived from our literature review.

The first finding regarding the 'management discipline' is that most papers analyzed focus on the IT domain and its technological aspects. Understanding technology is certainly key, as new IT solutions can enable management practices that were not previously possible. However, the technological perspective alone is not sufficient, as we strongly agree with Henriette et al [6] that "digital transformation is more than just a technological shift." The implementation of digital health solutions could have major implications in many areas, such as for the senior management of a hospital [20]. For them, an innovation that would create the ability to track material and persons with sensors in real time could revolutionize the daily operational processes in larger hospitals. Consequently, we need more initiatives in which technology and management experts work together through all the development and implementation

phases. True innovations can only happen when digital health technology is successfully integrated into daily operations and day-to-day management processes. Our first research proposition is hence to take more into consideration the implications for the management and leading of health care organizations, as follows:

- Future digital health research should not merely focus on the technology aspects. Instead, it should have a more holistic approach and further study the implications the technology has for the strategic and operational management of health care organizations.

The second research proposition refers to 'content domains.' We identified a strong focus on eHealth topics, as this has been the domain with the longest implementation history (eg, telemedicine was introduced to Australia back in the 1980s). Nevertheless, other fields could be of equal or greater importance when their implementation becomes more widespread. We base these expectations on the many publications forecasting a radical transformation of health care owing to different developing technologies (eg, in the field of big data, as in the review by Kruse et al [21]). Therefore, we advocate a more balanced examination of the 5 content domains presented in this paper, as follows:

- Explore the management perspective of all the different content dimensions of digital health in appropriate depth.

A final imbalance was found in the distribution of 'research questions.' An overwhelming number of papers create concepts for a possible digital health future. From a business perspective, these provide mostly anecdotal descriptions of the impact such solutions might have on the management of health care organizations. We suggest this is due to the relative youth of digital health in our current systems and a lack of widespread real-life application and experience. However, as more and more concepts become a reality, we would encourage the scientific community to take further steps. Future research should analyze in greater detail the real value of implementation. Practitioners and academics alike need more evidence regarding the expected outcome and impact of digital health on our health care organizations. Future research initiatives could, for example, examine the input and outcomes of digital health implementation by employing a quantitative study design. The quantification of the impact of digital health solutions on clinical outcomes has been the focus of many studies (eg, [22,23]). We encourage scholars to conduct methodologically similar pre-post studies, analyzing the effect on management process and business performance. A solid foundation is needed to result in meaningful recommendations for managers. Therefore, our last research avenue for exploration is the following:

- Broaden the research focus to include quantitative analysis of the impact of digital health on health care management and organizational design.

Strengths

This study presents contributions to an underresearched area of digital health from a management viewpoint. Within the scope of our review, we examined the most relevant publications to access the impact of digital health on health care management. All of the available publications were published between 2010 and 2019, with more literature published from 2016 to 2019 emphasizing the growing interest in digital health. The findings of our systematic review are the first step toward giving health care practitioners an overview of digital health in the field of health care management and enabling them to handle the ongoing digital transformation in the best possible way. By unveiling the actual status of digitalization in the health care sector and showing significant knowledge gaps, we set the stage for further research on how best to support health care practitioners through the process of digital transformation. To achieve this in the best possible way, we conducted three research proposals for future research avenues based on the research gaps identified.

Limitations

It is important to note some limitations associated with the study design. The researchers have a background in health care management and are based in Europe. We did not control for the geographical location of the papers analyzed, but our assumption is that most of the papers dealt with findings from North American and European organizations. A potential concern is therefore the generalization of the findings to other parts of the world. Furthermore, we focused on 3 specific databases as part of our systematic search. Therefore, it cannot be ruled out that the inclusion of further databases, such as Embase, might have yielded additional relevant publications. However, the studies published on Embase often coincide with those on PubMed, which was included in our search strategy. A final limitation is that no unpublished literature was reviewed or evaluated. However, due to the inclusion of various databases, we assume that the noninclusion of further publications is rather low. We therefore believe that with our approach, we have nevertheless achieved our aim to provide a first overview for practitioners.

Conclusions

To our knowledge, this study is the first overview of the impact of digital health from the health care management viewpoint. This paper relies on a systematic literature review of both conceptual and case-based papers on digital health. As our main contribution, we have developed three research proposals for future research avenues based on the research gaps identified. The big question is not whether further developments in digital health will have an impact on our health care organizations but how prepared managers are to deal with these changes. We note that most publications are still concerned with possibilities, but as more and more of these possibilities become a reality, managers need to be able to be proactive and, what is more, shape their organizations accordingly. We believe this paper has created some insights for the digital health research community on how best to support health care practitioners through the process of digital transformation.

Authors' Contributions

AA and EK designed the study. EK wrote the first manuscript draft. AA, JS, and SB wrote the final manuscript. All authors were involved in preparing the manuscript, and they all read and approved the final manuscript. This paper has not been published elsewhere.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Literature review stages.
[DOCX File , 29 KB - mhealth_v10i11e37624_app1.docx]

Multimedia Appendix 2
The specific inclusion criteria for each database.
[DOCX File , 14 KB - mhealth_v10i11e37624_app2.docx]

Multimedia Appendix 3
All publications eventually included in this study.
[DOCX File , 18 KB - mhealth_v10i11e37624_app3.docx]

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Abbreviations

IT: information technology

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Review

Health-Related Indicators Measured Using Earable Devices: Systematic Review

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Abstract

Background: Earable devices are novel, wearable Internet of Things devices that are user-friendly and have potential applications in mobile health care. The position of the ear is advantageous for assessing vital status and detecting diseases through reliable and comfortable sensing devices.

Objective: Our study aimed to review the utility of health-related indicators derived from earable devices and propose an improved definition of disease prevention. We also proposed future directions for research on the health care applications of earable devices.

Methods: A systematic review was conducted of the PubMed, Embase, and Web of Science databases. Keywords were used to identify studies on earable devices published between 2015 and 2020. The earable devices were described in terms of target health outcomes, biomarkers, sensor types and positions, and their utility for disease prevention.

Results: A total of 51 articles met the inclusion criteria and were reviewed, and the frequency of 5 health-related characteristics of earable devices was described. The most frequent target health outcomes were diet-related outcomes (9/51, 18%), brain status (7/51, 14%), and cardiovascular disease (CVD) and central nervous system disease (5/51, 10% each). The most frequent biomarkers were electroencephalography (11/51, 22%), body movements (6/51, 12%), and body temperature (5/51, 10%). As for sensor types and sensor positions, electrical sensors (19/51, 37%) and the ear canal (26/51, 51%) were the most common, respectively. Moreover, the most frequent prevention stages were secondary prevention (35/51, 69%), primary prevention (12/51, 24%), and tertiary prevention (4/51, 8%). Combinations of ≥2 target health outcomes were the most frequent in secondary prevention (8/35, 23%) followed by brain status and CVD (5/35, 14% each) and by central nervous system disease and head injury (4/35, 11% each).

Conclusions: Earable devices can provide biomarkers for various health outcomes. Brain status, healthy diet status, and CVDs were the most frequently targeted outcomes among the studies. Earable devices were mostly used for secondary prevention via monitoring of health or disease status. The potential utility of earable devices for primary and tertiary prevention needs to be investigated further. Earable devices connected to smartphones or tablets through cloud servers will guarantee user access to personal health information and facilitate comfortable wearing.

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KEYWORDS

digital public health; earable; wearable; biomarker; health status; disease monitoring; prevention strategy; Internet of Things; systematic review; mobile phone

Introduction

Background

ITs for monitoring health-related indicators have been developed and are continually being upgraded. Wearable devices are a major part of new health monitoring schemes related to out-of-hospital health care, occupational medicine, and sports science and technology [1-3]. As the world's population continues to age, the benefits of the improved cost-effective health care that this technology can provide will increase [4,5]. The biomarkers that can be detected by diverse wearable biosensors include electrocardiography (ECG) data, heart rate (HR), blood pressure, body and skin temperature, and respiration rate [1,6].

The Internet of Things (IoT) has been combined with various technologies used in our daily lives. The IoT is a versatile platform that can obtain data from an object and transmit them to an internet server to manage status in real time [7,8]. Wearable IoT is a branch of IoT technology applied to networking and communication of wearable devices [9]. Wearable IoT devices can track physiological activity in an interconnected manner. Wearability should be considered when designing monitoring systems; it is important that the devices are small [9,10].

The ear is a promising location for biosensors detecting critical conditions or diseases given its potential for noninvasiveness [3,11]. Ear electroencephalography (EEG) is used to calculate the surface potential of the ear, which varies with ear topography [12]. The tympanic membrane is associated with the vasculature of the ear canal, to which sensors can be attached to detect physiological signals. When blood is discharged from the basilar artery to the tympanic membrane through the internal carotid artery, the flow through the arteries involves anastomoses made by several branches of the external carotid, anterior tympanic, posterior auricular, stylomastoid, and maxillary arteries [3,13,14]. The internal carotid artery passes through the circle of Willis and brain, and *bifurcation anastomosis* plays an important role in monitoring physiological biomarkers related to the blood supply to the hypothalamus for thermoregulation. Measurements of core temperature in 2 parts of the ear canal supplying blood to the brain confirmed thermal equilibrium. Blood flow is a reliable indicator of ear vascularization even when users are sick [3,15,16].

Wearable devices that are worn around the ear are named "earable" or "hearable." Kurosawa et al [17] first proposed the term "earable" in 2017 to refer to a novel earphone-type wearable sensor. On the basis of this prototype, they developed several earable models for various uses [18-21]. Ota et al [22] expanded the earable device concept, defining such a device as a "wearable electronic designed to be worn around the ear." Hunn [23] coined the term "hearable" in 2014 to refer to a device "that fits in or on an ear that contains a wireless link, whether that's for audio, or remote control of audio augmentation." The potential use of hearable devices for the measurement of vital signs has been reviewed extensively [3,24]. Hearables are a promising type of hearing device for individuals with hearing loss [25]. As "earable" indicates only the device position whereas "hearable" suggests both ear position and involvement in hearing function, we conceptualize hearables as a subset of earables, which in turn are a subtype of wearables (Multimedia Appendix 1). According to this view, the recently increasing interest in new devices worn in or around the ear is related mainly to earables as their relevant functions are not limited to hearing.

In total, 2 recent reviews have demonstrated that valuable information can be obtained using earables, although the term "hearables" was used in these reviews. In 2020, Mase et al [3] reviewed the use and performance of hearable-based physiological monitoring. Among the 39 articles that they identified, the main physiological parameters described were temperature (24 articles), HR or pulse rate (12 articles), and oxygen saturation (3 articles) monitored in daily life. In 2021, Ne et al [24] evaluated the challenges and capabilities of physiological signal monitoring. They reported that ear signal acquisition yielded satisfactory outcomes relative to gold-standard monitoring. For better application in the future, improvements in wireless connectivity, battery life, the impacts of motion and environmental artifacts, and comfort are required.

An important function of wearable devices is health status monitoring, which enables preventive action. For example, several wrist- and arm-worn devices have been developed to detect epileptic seizures. The signals from the device sensor are based on electrodermal activity and HR changes; these are used to detect the preictal state before a seizure. Seizure events can be detected based on shaky motor movements and then logged and reported [26]. A second example concerns dietary management. Studies are being performed to develop a technology to detect food intake patterns through a wearable device. Examples include an in-ear microphone that detects and characterizes food intake, a watch-type device that tracks wrist movements during meals, and a necklace-like wearable sensor system for automatic ingestion monitoring. These technologies can be applied in dietary interventions and as tools to improve dietary behavior, which consequently contributes to the prevention or reduction of the incidence of obesity and eating disorders [27]. Risk factors for noncommunicable diseases (eg, physiological factors, tobacco use, alcohol abuse, unhealthy diet, lack of physical activity, and overweight or obesity) can be controlled through device reminders promoting healthy behaviors [4]. Although earable devices can measure diverse biomarkers, their application in disease prevention has not been well studied.

To facilitate the preventive uses of earable devices, broad preventive strategies are required. The significance of prevention using earable devices follows the vision of digital public health (DPH), which aims to expand health promotion from the

individual level to the population level using information and communications technology. DPH involves disease prevention, the facilitation of population participation, the promotion of value-based health care, and the provision of universal health coverage [28]. The accessibility and functionality of earable devices are promising features for prevention in DPH.

The Centers for Disease Control and Prevention defines the prevention stages outlined in Textbox 1 [29,30].

The DPH vision suggests that earable devices may be used as accessible instruments that expand the scope of preventive services and activities. The use of earable devices for the continuous monitoring of diverse essential biomarkers may provide additional possibilities at each stage of prevention. Advances in earable devices may facilitate disease prevention by promoting healthier lifestyles. Thus, a review of the existing research on the applications of earable devices is needed.

Textbox 1. Definitions of prevention stages according to the Centers for Disease Control and Prevention.

Definitions of prevention

- Primary prevention: intervening before the disease process begins through measures such as vaccination, adjusting dietary habits, or quitting tobacco use
- Secondary prevention: screening for early diagnosis of diseases (eg, mammography for breast cancer and regular blood pressure testing for cardiovascular disease)
- Tertiary prevention: slowing down or attenuating disease progression via different measures after the onset of the disease (eg, chemotherapy for cancer, rehabilitation for injuries, and screening for complications)

Objectives

In this study, we first conducted a systematic review of the application of earable devices for prevention. Second, we proposed updated definitions of the prevention stages in which earable devices may be applied. Third, we explored future research directions for wearable devices to maximize IoT-related functionality in the health care field. As we focused on applications related to prevention, we excluded studies that were related only to hearing problems.

Methods

Design

The PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) format [31] was used to summarize the major studies related to the use of earable devices for health care. This review was conducted to identify the health-related indicators measured using earable devices and the current state of these devices' development and use.

Search Strategy

We conducted a comprehensive search of the PubMed, Web of Science, and Embase databases to identify relevant articles published in English between 2015 and 2020 (Table S1 in Multimedia Appendix 2). We searched publication titles, keywords, and abstracts. We used standardized Medical Subject Heading keywords provided by PubMed and Emtree in Embase as well as free-text words.

We used the terms "earable" OR "hearable" OR ("ear" AND ["wearable" OR "wearability"]) in all databases. As alternative terms for "wearable," related Medical Subject Heading terms ("wearable electronic devices") and Emtree terms ("wearable computer" and "wearable sensor") were also used.

Inclusion and Exclusion Criteria

In total, 1193 articles were identified. After excluding duplicate publications, 83.4% (995/1193) of the articles were screened. Articles with abstracts not aligning with the study objectives or inclusion criteria were also omitted, and 51 articles were ultimately included in the analysis.

The review included original articles that focused on the physiological and physical influences of the body (except for auditory function) in human participants that were published in full-text format in English. We excluded articles not related to humans (eg, animal studies) and those that focused solely on ear function or ear disease (eg, hearing loss, hearing aids, and hearing aid signal processing). Studies related to hearing were excluded as such functions were already reviewed in a recent study [25]. In addition, editorials and letters were excluded (Table S2 in Multimedia Appendix 2).

Study Selection

Three authors (JC, SJ, and HK) selected articles for inclusion in four steps. First, they independently identified and screened publication titles, keywords, and abstracts to identify relevant articles. Second, the abstracts of relevant articles were screened for eligibility. Third, the full-text versions of eligible articles were selected according to the inclusion and exclusion criteria by consensus. Finally, additional articles were identified by manual searching of the reference lists of the relevant articles under consideration.

Data Collection and Extraction

The following five main categories of data were extracted from the selected studies (Multimedia Appendix 3 [12,18-22,32-76]): (1) publication details (first author and publication year), (2) target health outcomes (study outcomes related to health status or targeted disease), (3) biomarkers (biosignals produced from sensors to detect the target health outcomes), (4) sensor type (energy form used for data collection during health status analyses), (5) sensor position (earable sensor position used for data collection), and (6) prevention stage (most relevant prevention stage for the earable device).

Three authors (JC, SJ, and HK) extracted the data using a common data collection form. To validate the extraction, a test set of 20% (10/51) of the selected articles was compiled using systematic random sampling. The 3 authors independently

extracted data from the test set and had a consensus discussion to standardize the extraction methods. Data extraction was finalized according to the resulting standard procedure.

Quality Assessment

The quality of this systematic review was assessed using AMSTAR-2 (A Measurement Tool to Assess Systematic Reviews) [77]. The quality of the review satisfied 9 out of 13 items that applied to systematic reviews without meta-analysis (Table S3 in Multimedia Appendix 2).

Results

Article Characteristics

The literature review identified 1193 articles as potentially relevant and finally included 51 articles that fulfilled the inclusion criteria (Figure 1).

The number of published articles was relatively low in 2015 and 2016 but sharply increased since 2017 to >10 per year. The research topics were diversified and were particularly related to health-related indicators and sensor types, whereas the position of the earable device largely remained constant—in the ear canal—in most studies (26/51, 51%; Multimedia Appendix 4).

We observed that research on earable devices for health promotion, health monitoring and diagnosis, treatment, and rehabilitation is progressing. Table 1 classifies the earable devices according to five domains: “target health outcomes,” “biomarkers,” “sensors,” “sensor position,” and “preventive stage.”

Reported uses of earable devices were diet-related activity monitoring (9/51, 18% of the articles) [19,32-39]; brain status monitoring (7/51, 14% of the articles) [40-45,78]; cardiovascular disease (CVD) monitoring (5/51, 10% of the articles) [46-50]; central nervous system (CNS) disease monitoring and diagnosis (5/51, 10% articles) [51-54,79]; head injury monitoring (4/51, 8% of the articles) [55-58]; and monitoring of heart status [59-61], respiration [20,62], and sleep disorders [63,64] (7/51, 14% of the articles). Earable devices were used to monitor multiple diseases and health conditions in 16% (8/51) of the studies, namely, brain, cardiac, and respiratory functions [65]; cardiovascular status, sweating, and motion [66]; HR and breathing rate [67]; respiration and posture [21]; metabolic functions in relation to fever, insomnia, fatigue, and depression [22]; gait classification [68]; cardiovascular, metabolic, and mental disorders, including stress and pain response [69]; and chronic stress, cognitive dysfunctions, depression, and CVD [70]. In another 12% (6/51) of the studies, earable devices were used to monitor various aspects of health status, namely, thermoregulation [71], fertility [72], heat stress [73], tongue movements [18], facial expressions [74], and physical activity [75].

EEG was used for monitoring in 22% (11/51) of the studies [40,41,43-45,51-54,63,78], body movements were monitored in 12% (6/51) of the studies [18-21,33,75], and body temperature was monitored in 10% (5/51) of the studies [22,64,71-73]. Photoplethysmography (PPG) was used for monitoring in 8% (4/51) of the studies [32,48,60,69], acceleration stress was monitored in 8% (4/51) of the studies [55-58], and ECG was used for monitoring in 6% (3/51) of the studies [49,50,59]. A total of 25% (13/51) of the articles reported the monitoring of multiple exposure- and disease-related biomarkers (ie, EEG outputs, breathing signals, and mechanical plethysmography [MPG] outputs [65]; ECG outputs, lactate levels, and head acceleration [66]; ECG, ballistocardiography, and PPG outputs [46]; PPG and bioacoustics outputs and vibrations [36]; PPG and bioacoustics outputs [34]; ear canal shape, electromyography [EMG] outputs, and occlusal force [39]; acceleration stress, body temperature, and HR variability [HRV] [68]; EEG, electro-oculography, and EMG outputs [42]; EEG and ECG outputs [70]; ear canal shape, muscle movement, and acoustic signals [35]; EMG outputs, ear canal pressure, and muscle movement [38]; PPG outputs and air pressure [61]; and body potential, EMG outputs, and capacitance [74]). Other biomarkers measured in the studies included oxygen saturation [62], caloric vestibular stimulation [79], breathing signals [67], ear pulse waves (EPWs) [47], and EMG outputs [37].

Electrical sensors were described in 37% (19/51) of the articles on device development [37,40-45,47,49-54,59,63,70,74,78]. Photosensors were described in 18% (9/51) of the articles [18-20,32,33,48,60,62,69], mechanical sensors were described in 10% (5/51) of the articles [45,55-58], and thermal sensors were described in 6% (3/51) of the articles [72,73,79]. Acoustic sensors were used to monitor cardiac and respiratory status to improve patient safety [67]. The aforementioned sensors were attached to the devices in isolation. A total of 27% (14/51) of the articles described the use of more complex sensors, including 12% (6/51) of cases in which electrical, mechanical, optical, and pressure sensors were used in combination [38,39,46,61,65,68] and 6% (3/51) of cases in which sensors of electricity and heat were used [22,64,71]. Amperometric and potentiometric sensors were used in 1 multisensory device [66]. Another sensor combination was optical plus acoustic or mechanical sensors [21,34-36]. In total, 51% (26/51) of the articles described devices for the ear canal, which was the primary device location, used in almost half of the studies [18-22,33,38,40,42-45,47,50,58,60-65,67,68,71,72,74]. The devices were positioned behind the ear in 16% (8/51) of the studies [35,37,51,54-57,59] and around the ear [41,66,70] or on the earlobe [32,48,69] in 12% (6/51) of the studies. The devices were placed in the inner ear in 4% (2/51) of the studies [73,75] and in the concha in 2% (1/51) of the studies [34]. In total, 16% (8/51) of the articles described multiple body positions for sensor attachment. In 8% (4/51) of the studies, sensors were attached to the ear canal and concha [52,53,78,79]. Additional locations for sensor attachment included around the ear [36], near the ear adjacent to the mastoid and neck [46], in the oral cavity at the masseter muscle [39], and on the head [49].

Most of the studies (35/51, 69%) were concerned with secondary prevention [21,22,39-41,44-71,73,78], although 24% (12/51) were related to primary prevention [20,32-38,42,43,72,75], and 8% (4/51) were related to tertiary prevention [18,19,74,76].

Figure 1. Flowchart of the search strategy and literature selection process.

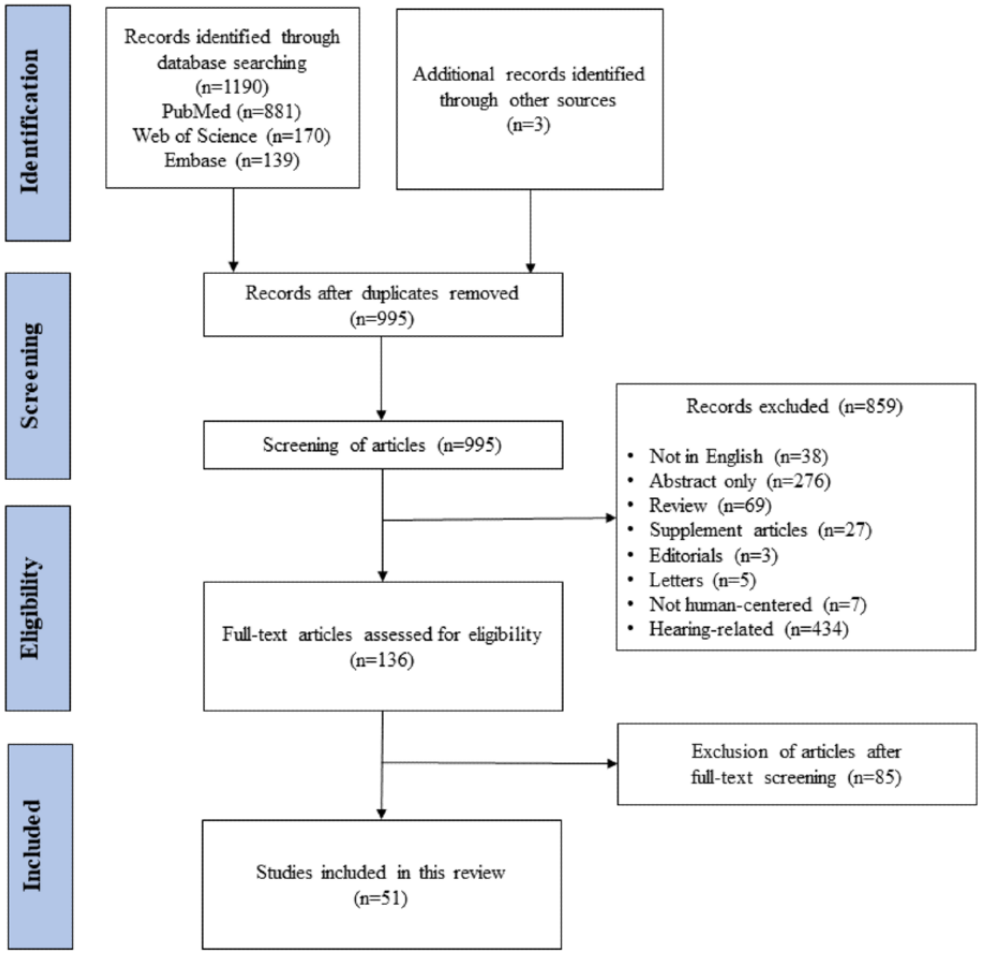


Table 1. Characteristics of the earable devices described in the articles (N=51).

Health-related characteristics	Studies, n (%)
Target health outcomes	
Diet-related	9 (18)
Brain status	7 (14)
Cardiovascular disease	5 (10)
Central nervous system disease	5 (10)
Head injury	4 (8)
Heart status	3 (6)
Respiration	2 (4)
Sleep disorder	2 (4)
Combination	8 (16)
Other	6 (12)
Biomarker	
EEG[a]	11 (22)
Body movements	6 (12)
Body temperature	5 (10)
PPG[b]	4 (8)
Acceleration stress	4 (8)
ECG[c]	3 (6)
Combination	13 (25)
Other	5 (10)
Sensor type	
Electrical	19 (37)
Photo	9 (18)
Mechanical	5 (10)
Thermal	3 (6)
Acoustic	1 (2)
Combination	14 (27)
Sensor position	
Ear canal	26 (51)
Behind the ear	8 (16)
Around the ear	3 (6)
Earlobe	3 (6)
Inner ear	2 (4)
Ear concha	1 (2)
Multiple	8 (16)
Prevention stage	
Primary	12 (24)
Secondary	35 (69)
Tertiary	4 (8)

[a]EEG: electroencephalography.

[b]PPG: photoplethysmography.

[c]ECG: electrocardiography.

Target Health Outcomes

Tables 2-4 show the cross-tabulated data for target health outcomes and biomarkers. In total, 22% (11/51) of the studies measured health outcomes related to the brain and head using different sensor types (electric and mechanical) and biomarkers (EEG and body movements). A total of 14% (7/51) of the studies used electric sensors for detecting EEG signals [40-45,78], and 8% (4/51) used mechanical sensors capturing acceleration stress [55-58].

Three different sensor types (electric, photo, and a combined sensor [46]) and four different biomarkers (ECG, PPG, EPWs, and combined biomarkers) were used to measure CVD-related outcomes in 10% (5/51) of the studies. In total, 4% (2/51) of the articles reported the use of an electric sensor for ECG detection [49,50], 2% (1/51) of the articles described the use of a photosensor for PPG detection [48], and another article (1/51, 2%) described the use of an electrical sensor for EPW detection [47].

Two sensor types (electrical and thermal) and two biomarkers (EEG and caloric vestibular stimulation) were used in 10% (5/51) of the studies to measure the outcomes of CNS disease. A total of 8% (4/51) of the studies investigated the utility of electrical sensors for detecting EEG signals in the CNS [51-54], and 2% (1/51) of the studies used thermal sensors for caloric vestibular stimulation as a disease treatment [79].

In total, 10% (5/51) of the studies explored dietary outcomes using combinations of photosensors, acoustic sensors, and mechanical sensors [34-36,38,39]. Four biomarkers (body movements, PPG and EMG outputs, and a combined biomarker) were used for PPG, bioacoustic signaling, pressure, strain, and vibration detection. In addition, photosensors were used to detect body movement in 4% (2/51) of the studies [19,33], and PPG [32] and EMG [37] outputs were used in 2% (1/51) of the studies each.

A total of 14% (7/51) of the studies (aiming to monitor heart status, CVD, metabolic diseases, and mental disorders) involved the use of electric sensors and photosensors for ECG and PPG detection [32,48-50,59,60,69]. A photosensor was included in a device to detect respiration indicators, and body movements and oxygen saturation were used as biomarkers [62]. Earable devices have also been developed to monitor sleep status, including electric and multisensory devices (eg, “auditory temperature”) [64]. Biomarkers were used by some devices to detect sleep disorders, EEG, and body temperature. Various sensors targeting different biomarkers have been used to detect health status indexes. For example, ECG was used to measure cardiovascular activity, sweating, and motion [66]. Combinations of electric, amperometric, potentiometric, and mechanical sensors were used by some devices for measuring various target health outcomes and vital functions (eg, brain, cardiac, and respiratory functions) via biomarkers such as EEG, MPG, and bioacoustic (breathing) signals.

Health conditions monitored using the devices included metabolic disorder, fever, fatigue, insomnia, and depression [22,69]. Core body temperature was used as a biomarker for a device with a photosensor and mechanical sensor [22,71,73]. Some studies were concerned with novel target health outcomes, including respiration and posture status measured based on body movements determined by a combination of a photosensor and mechanical sensor [20,62]; heart and breathing rates measured using bioacoustic signals and acoustic sensors [67]; temporomandibular joint function determined based on the number of chews and changes in the shape of the ear canal; and EMG signals and occlusal force measured using a combination of photo, electric, and pressure sensors [19]. We also identified studies that measured tongue movements and changes in the shape of the ear canal as detected by a photosensor with the goal of overcoming physical disabilities [18]. A total of 6% (3/51) of the studies monitored fertility, heat stress, and thermoregulation based on body temperature using a single thermal sensor or a combination of electric and thermal sensors [71-73].

Table 2. Target health outcomes (n≥5) by sensor type and biomarkers.

	Target health outcomes, n (%)			
	Diet-related (n=9)	Brain status (n=7)	Cardiovascular disease (n=5)	Central nervous system disease (n=5)
Sensor types				
Electrical	1 (11)	7 (100)	3 (60)	4 (80)
Photo	3 (33)	—[a]	1 (20)	—
Mechanical	—	—	—	—
Thermal	—	—	—	1 (20)
Acoustic	—	—	—	—
Combination	5 (56)	—	1 (20)	—
Biomarkers				
EEG[b]	—	6 (86)	—	4 (80)
Body movements	2 (22)	—	—	—
Body temperature	—	—	—	—
ECG[c]	—	—	2 (40)	—
Acceleration stress	—	—	—	—
PPG[d]	1 (11)	—	1 (20)	—
Combination	5 (56)	1 (14)	1 (20)	—
Other	1 (11)	—	1 (20)	1 (20)
Total (column; N=51)	9 (18)	7 (14)	5 (10)	5 (10)

[a]Not available.

[b]EEG: electroencephalography.

[c]ECG: electrocardiography.

[d]PPG: photoplethysmography.

Table 3. Target health outcomes (n<5) by sensor type and biomarkers.

	Target health outcomes, n (%)			
	Head injury (n=4)	Heart status (n=3)	Respiration (n=2)	Sleep disorder (n=2)
Sensor types				
Electrical	—[a]	1 (33)	—	1 (50)
Photo	—	1 (33)	2 (100)	—
Mechanical	4 (100)	—	—	—
Thermal	—	—	—	—
Acoustic	—	—	—	—
Combination	—	1 (33)	—	1 (50)
Biomarkers				
EEG[b]	—	—	—	1 (50)
Body movements	—	—	1 (50)	—
Body temperature	—	—	—	1 (50)
ECG[c]	—	1 (33)	—	—
Acceleration stress	4 (100)	—	—	—
PPG[d]	—	1 (33)	—	—
Combination	—	1 (33)	—	—
Other	—	—	1 (50)	—
Total (column; N=51)	4 (8)	3 (6)	2 (4)	2 (4)

[a]Not available.

[b]EEG: electroencephalography.

[c]ECG: electrocardiography.

[d]PPG: photoplethysmography.

Table 4. Target health outcomes by sensor type and biomarkers (miscellaneous).

	Target health outcomes, n (%)		Total (row; N=51), n (%)
	Combination (n=8)	Other (n=6)	
Sensor types			
Electrical	1 (12)	1 (17)	19 (37)
Photo	1 (12)	1 (17)	9 (18)
Mechanical	—[a]	1 (17)	5 (10)
Thermal	—	2 (33)	3 (6)
Acoustic	1 (12)	—	1 (2)
Combination	5 (62)	1 (17)	14 (27)
Biomarkers			
EEG[b]	—	—	11 (22)
Body movements	1 (12)	2 (33)	6 (12)
Body temperature	1 (12)	3 (50)	5 (10)
ECG[c]	—	—	4 (8)
Acceleration stress	—	—	4 (8)
PPG[d]	1 (12)	—	3 (6)
Combination	4 (50)	1 (17)	13 (25)
Other	1 (12)	—	5 (10)
Total (column; N=51)	8 (16)	6 (12)	51 (100)

[a]Not available.

[b]EEG: electroencephalography.

[c]ECG: electrocardiography.

[d]PPG: photoplethysmography.

Applications to Prevention

Table 5 presents the cross-tabulated data for target health outcomes, preventive stage, biomarkers, and sensor types. The first section of the table cross-tabulates health or disease status and preventive stage. Some studies of dietary status [32-39], brain status [42,43], respiration [20], and other outcomes [72,75] were classified as primary prevention. Other studies of brain status [40,41,44,45,78], CVD [46-50], CNS disease [51-54,79], heart status [59-61], respiration [62], diet monitoring to help patients with gastric cancer [19], sleep disorders [63,64], and combinations of health status with other outcomes [71,73] were classified as secondary prevention; this category was the largest. Earable devices were used for tertiary prevention in 8% (4/51) of the studies and were applied to support people with hand disability by sensing their tongue motion to operate a portable audio player [18]. Gait classification provided information related to Parkinson disease [68], and human body potentials provided information related to facial expressions in patients with locked-in syndrome [74] and for the stimulation treatment of patients with Parkinson disease [76].

Biomarkers used in the primary prevention studies included body movements [20,33,75], EEG [43], body temperature [72], PPG [32], and combined biomarkers (eg, PPG plus bioacoustics, with or without vibration or air pressure measurements; or including EEG, electro-oculography, and EMG [34-36,38,42]). Biomarkers used in secondary prevention studies included EEG [40,41,44,45,51-54,63,78], body temperature [22,64,71,73], ECG [49,50,59], PPG [48,60,69], body movement [21], oxygen saturation [62], EPWs [47], and combinations of biomarkers (eg, EMG and ear canal shape to estimate occlusal force [39]; ECG and lactate level in relation to head acceleration [66]; body movements, temperature, and HRV [68]; EEG, acoustic signals, and MPG [65]; ECG combined with ballistocardiography and PPG [46]; EEG and ECG [70]; and PPG and air pressure [61]). The biomarkers used in the tertiary prevention studies were body movements and ear canal shape [18,19], caloric vestibular stimulation [79], and combined biomarkers including human body potentials [74].

Sensor types according to prevention stage are detailed in Table 5. Sensors used in the primary prevention studies included photosensors [20,32,33], electric sensors [37,42,43], thermal sensors [72], and mechanical sensors [75]. Photosensors and acoustic sensors were also used in combination with no mechanical sensor [34,36]. Mechanical, acoustic, electrical, and pressure sensors were used in 2% (1/51) of the studies [35,38]. Sensors used in the secondary prevention studies were electric [40,41,44,45,47,49-54,59,63,70,78], mechanical [55-58], photo [48,60,62,69], thermal [73], acoustic [67], and combined [21,22,39,46,61,64-66,68,71]. Sensors used in the tertiary prevention studies were photosensors [18,19], electrical sensors [74], and thermal sensors [76].

The sensor positions used in the primary prevention studies were the ear canal [20,33,38,42,43,72], behind the ear [35,37], the concha [34], the earlobe [32], the inner ear [75], and multiple positions [36]. The sensor positions in the secondary prevention studies were the ear canal [21,22,40,44,45,47,50,58,60-65,67,68,71], behind the ear [51,54-57,59], around the ear [41,66,70], the earlobe [48,69], and multiple positions [39,46,49,52,53,78]. The sensor positions in the tertiary prevention studies were the ear canal [18,19,74] and multiple positions [76].

Table 5. Outcomes measured using the earable devices by prevention stage.

	Prevention stage, n (%)			Total (row; N=51), n (%)
	Primary (n=12)	Secondary (n=35)	Tertiary (n=4)	
Target health outcomes				
Diet-related	7 (58)	1 (3)	1 (25)	9 (18)
Brain status	2 (17)	5 (14)	—[a]	7 (14)
Cardiovascular disease	—	5 (14)	—	5 (10)
Central nervous system disease	—	4 (11)	1 (25)	5 (10)
Head injury	—	4 (11)	—	4 (8)
Heart status	—	3 (9)	—	3 (6)
Respiration	1 (8)	1 (3)	—	2 (4)
Sleep disorder	—	2 (6)	—	2 (4)
Combination	—	8 (23)	—	8 (16)
Other	2 (17)	2 (6)	2 (50)	6 (12)
Biomarkers				
EEG[b]	1 (8)	10 (29)	—	11 (22)
Body movements	3 (25)	1 (3)	2 (50)	6 (12)
Body temperature	1 (8)	4 (11)	—	5 (10)
PPG[c]	1 (8)	3 (9)	—	4 (8)
Acceleration stress	—	4 (11)	—	4 (8)
ECG[d]	—	3 (9)	—	3 (6)
Combination	5 (42)	7 (20)	1 (25)	13 (25)
Other	1 (8)	3 (9)	1 (25)	5 (10)
Sensor type				
Electric	3 (25)	15 (43)	1 (25)	19 (37)
Photo	3 (25)	4 (11)	2 (50)	9 (18)
Mechanical	1 (8)	4 (11)	—	5 (10)
Thermal	1 (8)	1 (3)	1 (25)	3 (6)
Acoustic	—	1 (3)	—	1 (2)
Combination	4 (33)	10 (29)	—	14 (27)
Total (column; N=51)	12 (24)	35 (69)	4 (8)	51 (100)

[a]Not available.

[b]EEG: electroencephalography.

[c]PPG: photoplethysmography.

[d]ECG: electrocardiography.

Discussion

Summary of Review Results

We assessed the health-related indicators measured using earable devices and the utility of these devices for public health. Earable devices can measure various health and disease states related to morbidity and, thus, can be used to propose solutions for health care systems in real time [80]. The detection of various health-related indicators has improved since earable devices were first introduced. Most of the earable devices in our review

measured single health outcomes using 1 biomarker and sensor. However, several studies (3/51, 6%) assessed multiple health outcomes using combinations of biomarkers and sensors.

Most of the health outcomes assessed by the studies in this review were related to diet (assessed through mastication monitoring), brain status, CNS diseases, heart conditions, CVDs, head injury, respiration, and sleep disorders (monitored in real time). Biomarkers of health outcomes and conditions included EEG, muscle and body movements, body temperature, PPG, ECG, and acceleration stress. Electrical sensors were used to obtain physiological information and convert it into electrical signals, including EEG and ECG. Photosensors were mostly used to detect PPG to monitor heart and dietary status. In addition, body movements were detected using used photosensors to assess physical disability and diet and respiration quality. Mechanical sensors were mostly used to monitor head injuries based on head location and acceleration. Thermal sensors were used to monitor body temperature and aid in the treatment of Parkinson disease. Regarding the positions of the sensors, nearly half of the devices were inserted into the ear canal. Sensors attached behind the ear obtained EEG signals for head injury management or head acceleration and location information to detect CNS disease. PPG data were obtained through sensors on the earlobe; these data were relevant to CVDs and mastication.

The preventive applications of earable devices are classified according to the characteristics of target health outcomes and the biomarkers used for detection. In primary prevention studies, healthy diet was the most common outcome measure based on mastication or occlusal force determined using photosensor signals reflecting changes in ear canal shape. Most studies were related to secondary prevention, indicating that a constant trend in earable device application is risk factor monitoring. Biomarkers such as EEG, ECG, PPG, body temperature, and acceleration stress were monitored as target health outcomes. EEG was used to provide evidence of CNS disease, sleep disorders, and stress in cases of symptoms such as seizures, sleep disturbance, and negative emotions. The risk of CVD was detected using ECG and PPG sensors, which captured heart condition indicators such as the HR and pulse rate to identify prodromal conditions (eg, atrial fibrillation, ventricular bigeminy, hypertension, and hemodialysis). Physical impacts after head injuries such as concussion were monitored using acceleration stress data from mechanical sensors. Combined sensor applications enabled multi-disease monitoring for research, including that on common health problems (eg, fever, fatigue, insomnia, and depression), diseases (eg, CNS diseases, CVDs, metabolic disorders, and mental disorders), and motion. For tertiary prevention, Taniguchi et al [19] explored the provision of dietary support via earable devices detecting ear canal shape and occlusal force for patients with gastric cancer. Wilkinson et al [76] evaluated the effectiveness of caloric vestibular stimulation for patients with Parkinson disease. Burgos et al [68] developed earable devices to target physical activity in real life by detecting gait and HRV, which can be applied to older adults, individuals with obesity, and patients with disabilities.

Key Messages of the Review

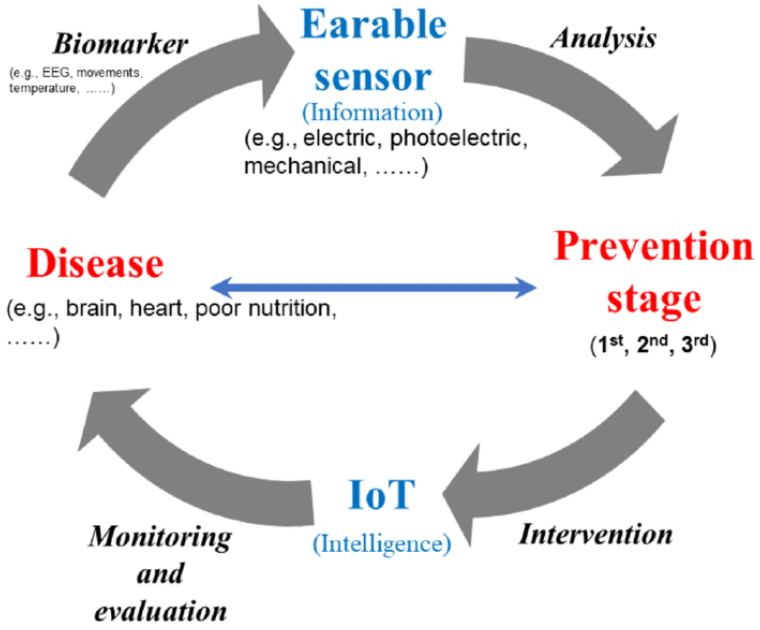
Earable devices can obtain ECG, PPG, glucose, body temperature, acceleration, and pressure data as biomarkers of health and disease status. A previous systematic review identified four domains: health and safety monitoring, chronic disease management, disease diagnosis and treatment, and rehabilitation [9]. Biomarkers of health conditions and diseases can be obtained through earable devices to aid prevention and management.

The application of the IoT to personal health management via earable sensors promotes secondary prevention through real-time health status monitoring [9,81]. In the context of primary prevention, earable devices can improve health behaviors. In terms of tertiary prevention, wearable devices can support body parts functioning with difficulties because of physical disabilities [81].

The mobile health platform is used to engage the public in research, for example, on devices developed for supporting various body parts. SMS text messages and smartphone apps are commonly used for public engagement [9,82]. Wearables for the health and medical field are promising but still have shortcomings in terms of user-friendliness, security and privacy, and technical issues [83]. Earable devices are an alternative platform that may overcome these shortcomings. However, more research and development are needed [3].

Earable devices with built-in sensing technology can accurately transmit digital health care information for use for preventive strategies. A health care and prevention framework was devised based on keywords extracted from earable device studies (Figure 2). The horizontal axis (red) represents health care access, including target health conditions and prevention stages that can potentially improve health outcomes. Health care information derived from earable devices is useful for all preventive processes related to health improvement in personal care, monitoring and diagnosis, and treatment and rehabilitation. The vertical axis (blue) represents technology access, which ranges from information collection using earable sensors to the integration of the collected information with broader contextual knowledge to aid the design and implementation of appropriate interventions at the appropriate time. The diagonal arrow (black) indicates the activity at each stage. Information about a disease is transmitted in the form of a biomarker and analyzed and classified according to the prevention stage. Health care interventions based on IoT assistance and technology are implemented to monitor and assess conditions of target health outcomes.

Figure 2. Health care and prevention framework for earable devices. EEG: electroencephalography; IoT: Internet of Things.



Earable Devices in the IoT Era

In the IoT era, devices for protecting against excessive noise, hearing aids, and an in-ear EEG brain-computer interface have been developed. Physiological and electrophysiological data, ear canal deformation, dynamic measurements, medical condition management, and biosignal data can be obtained or achieved through in-ear devices. Communication can also be enhanced via stimulation with electricity and light, energy harvesting, and noise cancellation [84]. Earable devices based on IoT demonstrate improved data collection and processing accuracy, timely alarm-warning signals, and high usability and consumer acceptability [9,81].

Improvements in earable devices and their applications compared with older devices were discussed in some of the reviewed articles (18/51, 35%). Emotion monitoring has been reported using a headset and Bluetooth device for use in the home and remotely, respectively [44]. ECG data from athletes, firefighters, and pilots have been collected via a mono-earphone compatible with a smartphone [73]. EEG [41,45,52], body movements [18-21,75], and core body temperature [22,64,71,72] data can also be obtained through smartphone apps in real time using in-house software and through tablets. A study described a web-based personal coaching system based on sensors and smartphone apps (the "SPLENDID" system) [36]. Another study showed that earable device–based sleep quality monitoring systems can improve sleep quality in the community setting [85]. Suggested functions for earable devices in the IoT era include data processing for personal health care. Accumulated data demonstrate the stability of data sets collected through cloud servers available only to the individual concerned and related users [9,80].

Applications of Earable Devices for Disease Prevention

The current focus with respect to wearable device–based personal health care is on improving diagnostics and health behaviors. Additional considerations include gathering microenvironmental data relevant to disease risk and merging multiple strata of health care into a single integrated form [9,86]. The National Health Plan 2030 in Korea provides a systematic framework for the prevention of various health risks to improve the lifelong health of individuals. In particular, the plan includes a goal to "develop health-friendly environments" with a focus on the "application of innovative information technology" [87]. The development of useful wearable devices is expected to facilitate the achievement of the National Health Plan 2030 goals.

Regarding primary prevention in the context of eHealth, interventions and guidelines pertaining to diet, mental workload, ovulation, and respiration are needed. Strategies emphasizing the monitoring of health status can improve health. As wearable devices are capable of real-time monitoring, intervention before disease manifests is possible [4,10,81]. Smartphone apps using diary or daily chart functions can be used to track dietary behaviors, and earable devices can obtain chewing and food intake data automatically [32]. Mental workload measurement is also valuable to reduce the likelihood of occupational accidents via alerts [43]. Ovulation and respiration data can also be obtained instantaneously, facilitating pregnancy planning and meditation, respectively [20,72].

Regarding secondary prevention, vital signs can be monitored using earable devices to aid disease diagnosis. Brain monitoring (EEG) can help diagnose CNS diseases, and cardiac monitoring (ECG, PPG, and other biomarkers) can help detect CVDs using well-established display options. Body temperature and body movement can also be measured for secondary preventive purposes. Earable devices have been validated as a replacement for traditional biomarker detection methods. A study in this review using caloric vestibular stimulation as a treatment for Parkinson disease was classified as secondary prevention and was the only study to use this treatment [76].

The use of earable devices for tertiary prevention may be improved, but 2% (1/51) of the studies suggested that hands-free (ear-worn) devices could be used in the future for motion

detection in individuals with disabilities to facilitate self-management [18].

The effective use of earable devices involves when and how the devices should be used. For primary prevention, earable devices can be used to monitor healthy lifestyle factors such as physical activity and eating habits. Physical activity monitoring using earable devices should encompass leisure, work, and travel times, similar to smartwatch device monitoring. The use of earable devices to monitor eating habits may provide unique advantages over smartwatch use [38]. The use of these devices for secondary prevention can be facilitated by collaboration with clinicians who assess the need for continuous monitoring of specific biomarkers such as EEG, ECG, or acceleration stress. Several studies have focused on the use of earable devices for the monitoring of seizures, brain injuries, sleep disorders, arrhythmias, and myocardial infarction [45,49-51,53-58,63]. Clinicians can determine the specific timing of monitoring according to patients' needs.

The collection and analysis of data from earable devices typically require smartphone connection to an IoT platform that includes a central database system. The amount of information collected is substantially increased by the use of multimodal sensors. Furthermore, data collection can be expanded through the simultaneous use of earable devices, smartwatches, and smartphones. The development of IoT technology for the real-time analysis of data from various devices is expected. However, data from different devices are currently downloaded separately and used in combined analyses. User-friendly smartphone apps that summarize earable device data will help users plan their health management [38,72].

The capacity of earable devices with IoT platforms for continuous monitoring and in-depth analysis is expected to shift the focus of prevention toward active health promotion. Thus, we propose improved definitions of prevention linked to the use of earable devices (Textbox 2).

Prevention based on individual efforts is not effective. Public health services and policies should be directed toward the empowerment of individuals through the provision of supportive tools and environments.

Textbox 2. Improved definitions of prevention linked to the use of earable devices.

Improved definitions of prevention

- Primary prevention: intervention before the disease process begins through the avoidance of health risk factors and practice of health-promoting behaviors with continuous monitoring of health status to maintain motivation
- Secondary prevention: screening for early diagnosis and prediction of the risk of disease occurrence via intelligent analysis of monitoring data
- Tertiary prevention: attenuation of disease progression via appropriate treatment and rehabilitation and improvement of the quality of life via the enhancement of self-management ability with the assistance of a smart care platform

Role of IoT in Earable Devices for Monitoring Health Outcomes

IoT-based earable devices will make microlevel monitoring possible and, thus, improve health care through their interactions with other, nonwearable devices. Earable devices based on IoT will facilitate personal health care and also help physicians [88,89]. These devices will allow the health status of patients to be continually tracked, particularly older adult patients who live alone; if any changes in health status occur, the devices can alert family members or health care providers immediately. In addition to the monitoring capabilities of earable devices based on the IoT, they can help physicians manage their patients' treatments more effectively. They can also help health care facilities function in an orderly manner [89,90] as the devices can be tracked in real time within hospitals. Moreover, they can be used to monitor environmental conditions and the hygiene, body temperature, and location of medical staff [88,91].

New technologies allow for the remote treatment of patients [85,92,93]. Mobile apps can provide guidance at the population level, including on medications and habits, and effective strategies for mitigating the risk of stroke and CVD [93,94].

Validity of Earable Device Measurements

Most studies of earable devices have determined that the use of biomarkers in experimental or real-environment settings is sufficiently valid to replace conventional standards of measurement. Patient-independent and patient-specific models of EEG-based detection using a behind-the-ear device compared with a professional's visual seizure annotation and the use of a data-driven algorithm, respectively, showed that device detection had 65.7% sensitivity and 94.4% specificity compared with visual recognition. Similar results were obtained in comparison with the automated algorithm; the patient-independent model indicated that device detection had 64.1% sensitivity and 2.8 false-positive detections per 24 hours, and the patient-specific model yielded values of 69.1% sensitivity and 0.49 false-positive detections per 24 hours. Thus, the patient-specific model confirmed the best performance of behind-the-ear EEG detection [54]. The performance of body movement detection with an earable device was assessed using chew counts in gum-chewing and almond-eating tests; the device showed 95.8% precision, better than recall (93.7%), reflecting accurate counting and the ability to distinguish chewing from other activities [19]. Body temperature detection by an earable device for ovulation detection and prediction in 34 participants was evaluated and based on the relative distance of the estimated from the nearest self-reported ovulation day, the device showed improved detection accuracy, with 92.3% sensitivity and 23.1% to 31.6% greater predictive power [72]. PPG-based monitoring for CVD detection was evaluated using parameter values in a learning data set, and the lowest level of sensitivity and specificity was 90.9% [48]. Acceleration stress measurement using an earable device, used primarily in head impact monitoring, was evaluated in youth soccer players. Random and systematic errors were

calculated, and areas under the curve were used to confirm the device's capacity in on-field settings. Cutoff values for prediction were 100% in structured training sessions and 65% in regular soccer sessions, although improvement is needed because of the overestimation of impact exposure and random error [58].

Implications

A considerable number of studies included in this review (34/51, 66.7%) focused on single-target health outcomes with the use of single sensors, although some were concerned with multiple health outcomes and involved the use of several sensors. The use of multiple sensors increases the accuracy of activity analysis, and the collection of physiological data in real time is useful for the exploration of mental and physical health [95]. In some studies (6/51, 12%), various sensors (eg, air pressure, piezoelectric strain, and electric sensors) were combined in single devices to detect a single target health outcome (ie, mastication related to healthy diet). The sensors used EMG, ear canal pressure, and muscle movement biomarkers to differentiate food types. The accuracy of the indicators of chewing strength remains uncertain [38]. Other sensor combinations, including photo, mechanical, and electric sensors, have also been used in single devices. A device that captures signals of body temperature, acceleration stress, and HRV simultaneously provides information about the risk of heart disease and gait disturbances with reliable accuracy and no wearer discomfort. Although the device cannot easily distinguish between walking and running, elaborate calibration effectively provides this capacity [68]. Future research should examine the feasibility of combining sensors and processing of the obtained data.

In the studies included in this review, the sensor type and health outcomes of interest differed according to sensor location within the ear; devices placed in the ear canal were used in almost half of the studies (26/51, 51%). However, ear sensors can have problems related to wearability, small size, battery life, and real-time signal processing [96]. Traditionally, biomarkers have not been measured in the ear but, with further advances in technology, the ear will become more attractive as a location for measurement devices relative to other body parts.

Digital therapeutics is an emerging field of application that involves the use of digital technology for health care [97]. It has been growing steadily with the development of several new programs and apps [98,99]. Interventions targeting obesity and dietary habits have been used for technology-supported and mobile device–based smart group care, the restriction of eating times, and digitally-assisted cognitive behavioral therapy. Wearables were also used in these programs [97,100]. Digital health care services and the development of wearable technology and IoT services will play important roles in the future as parts of public health services (ie, DPH). After the COVID-19 pandemic, the demand for DPH tools such as tracing apps, chatbots providing COVID-19 information, and digital mental health support services has increased sharply. Large-scale data accessibility is expected to facilitate sustainable DPH [28]. Future earable IoT systems have potential uses in DPH because of their advantages for real-time monitoring and analysis.

Wearable technology is widely used in health care to prevent, diagnose, manage, and treat conditions and for patient rehabilitation. IoT could contribute to the development of smart homes [101], smart cities [102], and smart governance [91]. This review suggests the possibility for the further development of earable devices to obtain evidence-based data that inform policies and regulations for smart homes and smart cities and for the provision of medical services for all patient populations [81,91,101,102].

Limitations

This review has some limitations. Even though available standardized terms from 3 databases were included, our search strategy may have missed some articles. This review was exploratory in nature and included a wide range of study designs, leading to the possibility of heterogeneity. By the research design of this review, the research settings and assessment of risk of bias in individual studies were not described in detail during extraction of the characteristics of earable devices. Finally, the subjectivity in data collection might have remained even if a validation process in data extraction and collection was used to mitigate the bias.

Conclusions

Health-related indicators and biomarkers detected using earable devices can be used to monitor health outcomes. Brain status, healthy diet status, and CVD were the most frequently measured outcomes. Combinations of targeted biomarkers were collected using several sensors in some studies. Earable devices can be used for secondary prevention by monitoring health or disease status and also have potential for primary prevention. However, use for tertiary prevention was limited and particularly called for more research. Earable devices can be connected to smartphones or tablets through cloud servers for guaranteed accessibility and compatibility of continuous health monitoring data.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1
A model for the relationships among wearables, earables, and hearables.
[PPTX File , 42 KB - mhealth_v10i11e36696_app1.pptx]

Multimedia Appendix 2
Systematic review methodology.
[DOCX File , 39 KB - mhealth_v10i11e36696_app2.docx]

Multimedia Appendix 3
Data abstraction from selected articles.
[DOCX File , 34 KB - mhealth_v10i11e36696_app3.docx]

Multimedia Appendix 4
Key properties of earable devices and health-related indicators.
[DOCX File , 83 KB - mhealth_v10i11e36696_app4.docx]

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Abbreviations

AMSTAR-2: A Measurement Tool to Assess Systematic Reviews
CNS: central nervous system
CVD: cardiovascular disease
DPH: digital public health
ECG: electrocardiography
EEG: electroencephalography
EMG: electromyography
EPW: ear pulse wave
HR: heart rate
HRV: heart rate variability
IoT: Internet of Things
MPG: mechanical plethysmography
PPG: photoplethysmography
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses

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Review

Trends in Smart Helmets With Multimodal Sensing for Health and Safety: Scoping Review

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Abstract

Background: As a form of the Internet of Things (IoT)–gateways, a smart helmet is one of the core devices that offers distinct functionalities. The development of smart helmets connected to IoT infrastructure helps promote connected health and safety in various fields. In this regard, we present a comprehensive analysis of smart helmet technology and its main characteristics and applications for health and safety.

Objective: This paper reviews the trends in smart helmet technology and provides an overview of the current and future potential deployments of such technology, the development of smart helmets for continuous monitoring of the health status of users, and the surrounding environmental conditions. The research questions were as follows: What are the main purposes and domains of smart helmets for health and safety? How have researchers realized key features and with what types of sensors?

Methods: We selected studies cited in electronic databases such as Google Scholar, Web of Science, ScienceDirect, and EBSCO on smart helmets through a keyword search from January 2010 to December 2021. In total, 1268 papers were identified (Web of Science: 87/1268, 6.86%; EBSCO: 149/1268, 11.75%; ScienceDirect: 248/1268, 19.55%; and Google Scholar: 784/1268, 61.82%), and the number of final studies included after PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) study selection was 57. We also performed a self-assessment of the reviewed articles to determine the quality of the paper. The scoring was based on five criteria: test environment, prototype quality, feasibility test, sensor calibration, and versatility.

Results: Smart helmet research has been considered in industry, sports, first responder, and health tracking scenarios for health and safety purposes. Among 57 studies, most studies with prototype development were industrial applications (18/57, 32%), and the 2 most frequent studies including simulation were industry (23/57, 40%) and sports (23/57, 40%) applications. From our assessment-scoring result, studies tended to focus on sensor calibration results (2.3 out of 3), while the lowest part was a feasibility test (1.6 out of 3). Further classification of the purpose of smart helmets yielded 4 major categories, including activity, physiological and environmental (hazard) risk sensing, as well as risk event alerting.

Conclusions: A summary of existing smart helmet systems is presented with a review of the sensor features used in the prototyping demonstrations. Overall, we aimed to explore new possibilities by examining the latest research, sensor technologies, and application platform perspectives for smart helmets as promising wearable devices. The barriers to users, challenges in the development of smart helmets, and future opportunities for health and safety applications are also discussed. In conclusion, this

paper presents the current status of smart helmet technology, main issues, and prospects for future smart helmet with the objective of making the smart helmet concept a reality.

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KEYWORDS

Internet of Things; IoT; sensor technology; smart helmet; smart sensor; wearable device; mobile phone

Introduction

Background

An Internet of Things (IoT)–smart helmet can be defined as a helmet integrated with electronic sensing, alerting, and communication devices and used not only as protective headgear but also to provide intelligent services for enhancing user capabilities or minimizing the risk of injuries and fatalities. This technology can benefit users through activity [1], physiological [2], and environment [3] monitoring or location sharing [4]. With advances in computing power and microelectronics, health and safety can be further promoted with real-time physiological measurement capabilities and data processing that can provide actionable and important information about an individual and their surrounding environment [5-9]. Specifically, smart helmets, as personal protective equipment, can be used to reduce injuries, ensure safety, especially in hazardous occupations, and make the return of injured people fast and easy. However, because of the recent development of smart helmets, previous publications lack an in-depth review of existing studies on the diversity of smart helmets and possible future innovations for health and safety purposes. Similar to wearable sensors, smart helmets are being increasingly used to address health and safety concerns [10]. Currently, available commercial systems and research are mainly focused on motorcycle helmets and applications for defense personnel, where wearing a smart helmet is mandatory or recommended.

Previous studies have indicated the potential applications of smart helmets in diverse scenarios, such as industry, first responder applications, and health tracking [11]. For instance, the construction industry has adopted the use of smart helmets for health and safety management by monitoring workplace surroundings or the physiological signals of workers [12]. As construction workers are prone to falls and objects falling, most studies considered inertial measurement unit (IMU) sensors to detect accidents [13-16]. A study by Seo et al [17] and Pirkl et al [18] used ultrasonic sensors to quantify space dimension by measuring wave bounding and floor safety by measuring the density of the walls. Other industrial applications include a DAQRI smart helmet that used augmented, mixed reality for user enhancements like object recognition, resource management, and thermal vision [19]. For a motorcyclist, a smart helmet can send a message to the nearest hospital if the rider is involved in an accident [20,21]. Moreover, an alcohol sensor can measure the alcohol level of the rider and lock the ignition system if the level is above a certain threshold [22]. For first responders, a smart helmet can provide a thermal scan of an individual to check for COVID-19 symptoms [23] or injuries such as broken bones [24] or bleeding [25]. An IoT smart helmet can also track the status of the response crew in real time and report back to a central control center [23]. With the development of the Internet of Battlefield Things, smart helmets are becoming more prominent in the military [26]. Furthermore, smart helmets can be used as health trackers to acquire physiological, behavioral, and contextual data for the diagnosis, treatment, and management of chronic diseases and negate the risk of injury such as falls in the older adults [27].

There are several studies on smart helmet technology that focus on specific fields of application. For instance, Fernández-Caramés et al [28] introduced a smart helmet as part of smart clothing and combined it with smart glasses for augmented reality. Similarly, Campero-Jurado et al [29] described the possible integration of artificial intelligence technology with smart helmets to improve the safety of workers. Mardonova et al [30] described the use of wearable sensor technology in the mining industry and other applications to enhance the safety of mining operations and improve wellness among workers. Similarly, Shi et al [26] reviewed wearable device applications for the military and proposed a framework based on body sensor networks.

Objectives

This review presents a comprehensive analysis of smart helmet technology and its main characteristics and applications for health and safety and provides a presentation of the most relevant challenges to its implementation. Thus, our overarching goal is to clarify the main purpose and domain of smart helmet technologies to improve health and safety through sensing, inference, and actuation. This is achieved by addressing the following questions:

1. What are the main purposes and domains of smart helmets for health and safety?
2. How have researchers realized key features (inference and actuation) and with what types of sensors (sensing)?

The remainder of this paper is organized as follows. After selecting studies that contain the required keywords, we assessed smart helmet articles to ensure the quality of the prototype. We then classified and summarized the studies based on their domain, purpose, and sensor use. Finally, we have discussed the findings and reviewed the trends in smart helmet technology, identifying the main current technical limitations and outlining the primary challenges on a broader scale.

Methods

This review was performed according to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines [31]. Accordingly, strict eligibility criteria were applied to identify journal articles and reviews addressing the collection of sensor-based smart helmet information and to

investigate key features of smart helmets with built-in sensor applications.

Study Selection Criteria

The search for appropriate studies was performed using the following electronic databases: Web of Science, ScienceDirect, and Google Scholar. The following combination of search terms was used: “Smart helmet” AND “sensor.” Duplicated studies were removed before starting the selection. An eligibility check was performed on the title, keywords, and abstract of each study. Full-text copies of all potentially relevant papers and papers with insufficient information in the abstract to determine eligibility were obtained. The inclusion and exclusion criteria were as follows:

• Types of methods: studies reporting smart sensing using custom sensors such as infrared (IR), ultrasound, piezoelectric, temperature, and GPS sensors were included. Studies describing internet-based interventions, conceptual technologies, and collision testing for helmet design without a sensor-based component were excluded.

• Types of outcomes: studies reporting results associating prototype and sensor-based data were included. Papers providing descriptions of smart helmets but no experimental outcomes were excluded.

• Language and time frame: English-language full-text articles were included in the review. Considering the trend of technology evolution, only papers published between January 2010 and December 2021 were included.

A study selection, in accordance with the eligibility criteria, was performed independently by 2 of the authors: one with a clinical background and one with a technological background. There were no cases of disagreements between the 2 authors.

Content Analysis and Study Quality Assessment

The extracted information consisted of the following: (1) field, (2) smart helmet purpose, (3) sensors used, and (4) validation. We also performed a self-assessment of quality on reviewed articles based on 5 criteria; that is, test environment, prototype quality, feasibility test, sensor calibration, and versatility of the smart helmet (Textbox 1). Each criterion was scored from 1 to 3, and the sum of scores ranged from 5 to 15, as prior studies used this kind of scoring to provide an overview of the quality of the papers reviewed [32-35]. This idea of *assessment scores* originated from the work of Suri et al [32], AtheroPoint’s artificial intelligence–based Bias—AP(ai)Bias—for detecting a risk of bias in the study selection process. By scoring studies with each attribute, we tried to show the overall trends in smart helmet research. Moreover, the projection of the studies to a common assessment basis provides a unified form for revealing the characteristics that make them advantageous or disadvantageous and can translate these characteristics to interpretable implementations in real-life settings.

Textbox 1. Criteria for quality assessment of reviewed articles.

Test environment

- Daily setting (score 3)
- Controlled setting (score 2)
- Laboratory setting (score 1)

Prototype quality

- Complete prototype (score 3)
- Preliminary prototype (score 2)
- Conceptual prototype (score 1)

Feasibility test

- Evaluation with cross-validation (score 3)
- Accuracy measurement (score 2)
- Only present sensor test data (score 1)

Sensor calibration and testing

- Real test data (score 3)
- Sensor test Data (score 2)
- Only sensor specification data (score 1)

Versatility

- Multiple domains with multiple applications (score 3)
- Single domain with multiple applications (score 2)
- Single domain with specific use (score 1)

Results

Overview

As summarized in the PRISMA flowchart in Figure 1, a total of 87 (6.86%) records were obtained from Web of Science, 149 (11.75%) from EBSCO, 248 (19.55%) from ScienceDirect, and 784 (61.83%) from Google Scholar leading to a total of 1268 journal papers. Across the 4 databases, 535 (42.19%) duplicates were identified and removed. A total of 624 additional records were excluded mainly because they reported on other technologies or other fields or both. Some of the papers were written in languages other than English (n=53, 9.9%), not accessible (n=50, 9.3%), or dealt with the design of the helmet (n=75, 14.0%). An additional 52 papers were excluded because they did not report on suitable smart helmets or did not report on sensors. This elimination resulted in 57 full-text papers remaining to be considered.

To assess the quality of the targeted studies, we ranked the smart helmet prototypes based on the abovementioned scoring criteria. A total of 34 studies provided an actual prototype of the smart helmet and are included in the analysis as illustrated in Figure 2. The raw cutoff mean score was 2.0 with SD 0.5, where higher-than-threshold studies provide a practical and validated smart helmet prototype. The assessment criteria distribution showed that most of the articles focused on sensor calibration while the feasibility test of the prototype was the least scored as presented in Figure 3.

Figure 1. Study selection procedure in flowchart.

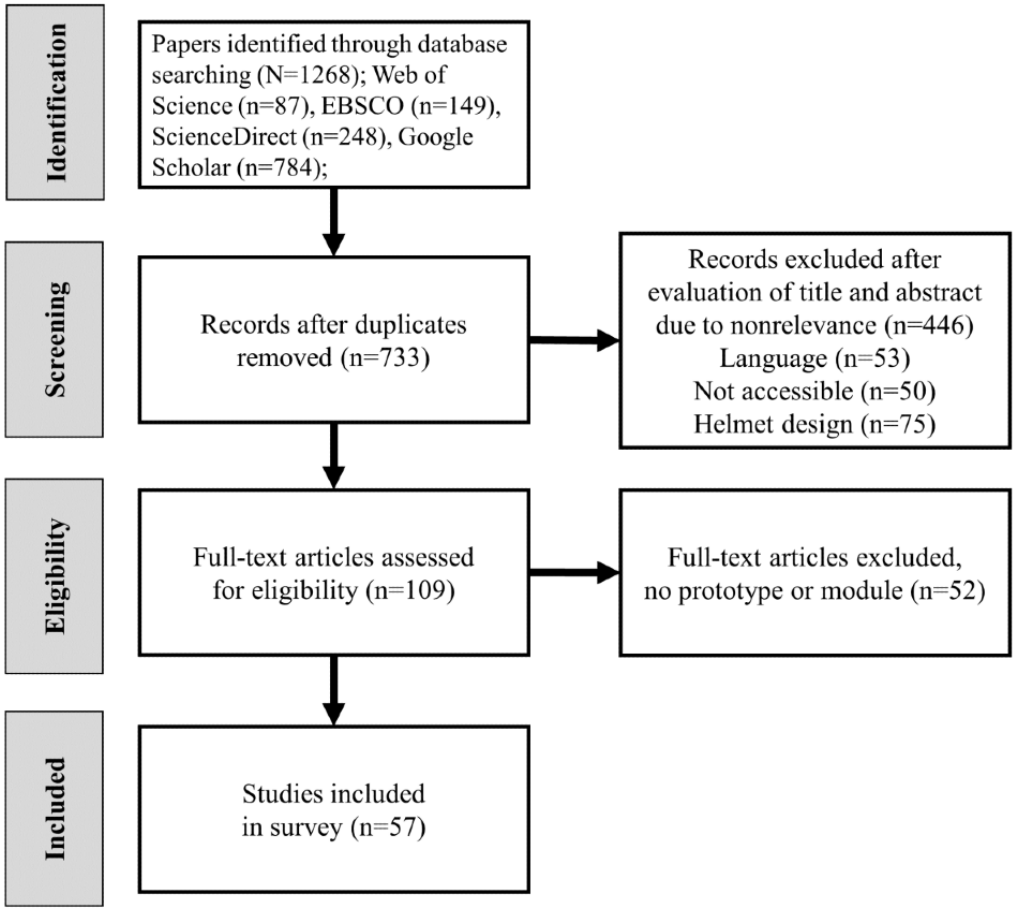


Figure 2. Pareto analysis on smart helmet prototypes.

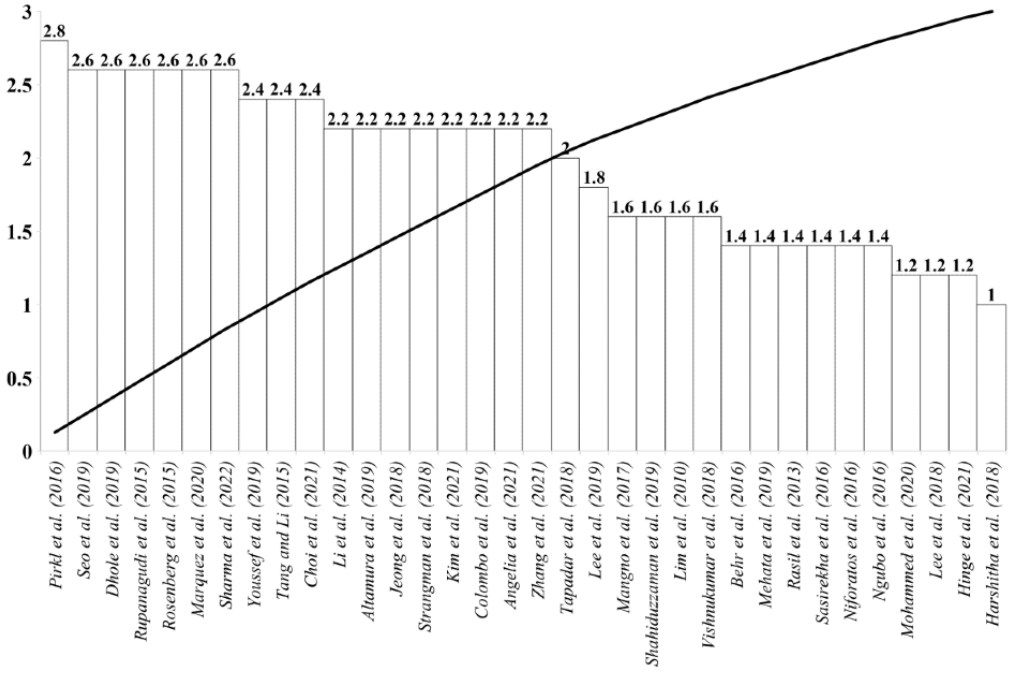
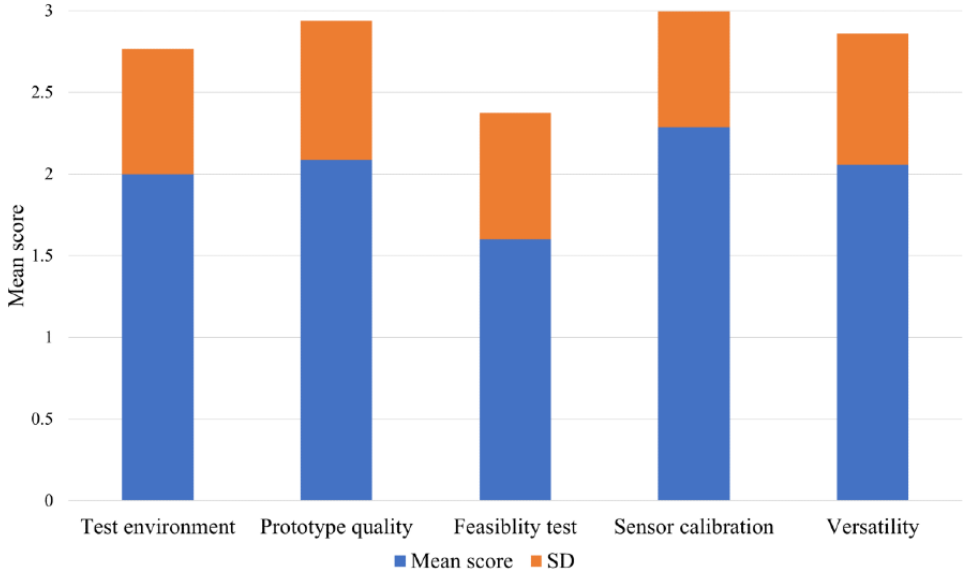


Figure 3. Assessment area score distribution.



Classification of Smart Helmets

Smart helmets can be classified based on their functions, purposes, and fields of use. Previous studies on smart helmets have mainly been focused on sports, industrial safety, assisting first responders, and health tracking. Figure 4 shows the distribution for the 57 selected articles. The numbers of articles that presented smart helmet prototypes for industry, sport, first responder, and health tracking applications were 18 (53%) [13-18,36-47], 7 (21%) [48-54], 4 (12%) [55-58], and 5 (15%) [59-63], respectively. The numbers of articles that included module simulations instead of prototypes for industry, sport, and health tracking applications were 5 (22%) [64-68], 16 (70%) [69-84], and 2 (9%) [85,86], respectively. Figure 5 provides a further classification of smart helmets based on their purposes for health and safety promotion: activity risk sensing (ARS), physiological risk sensing (PRS), environmental risk sensing (ERS), and risk event alerting (REA).

Figure 4. Distribution of articles.

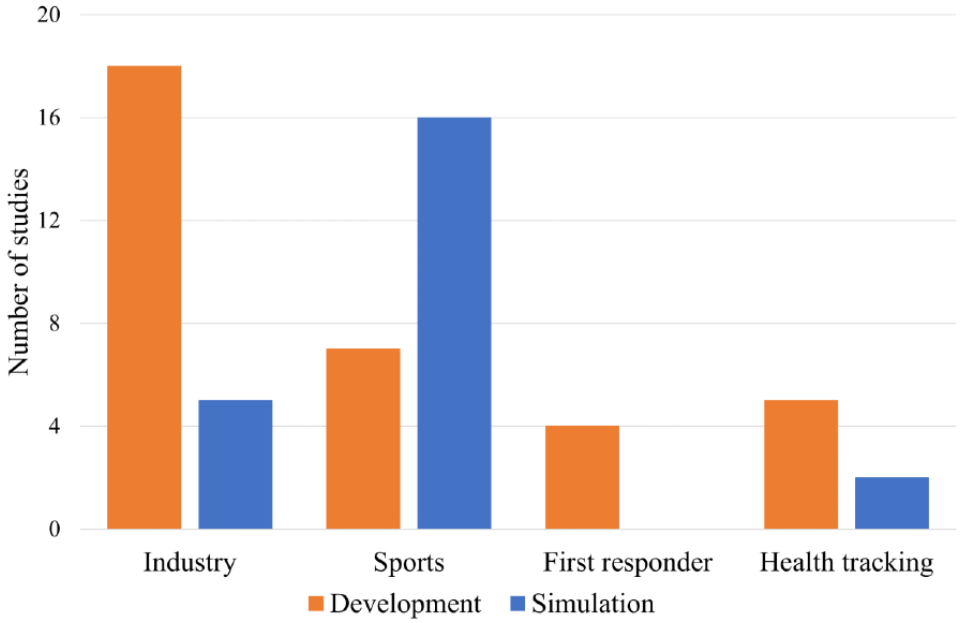
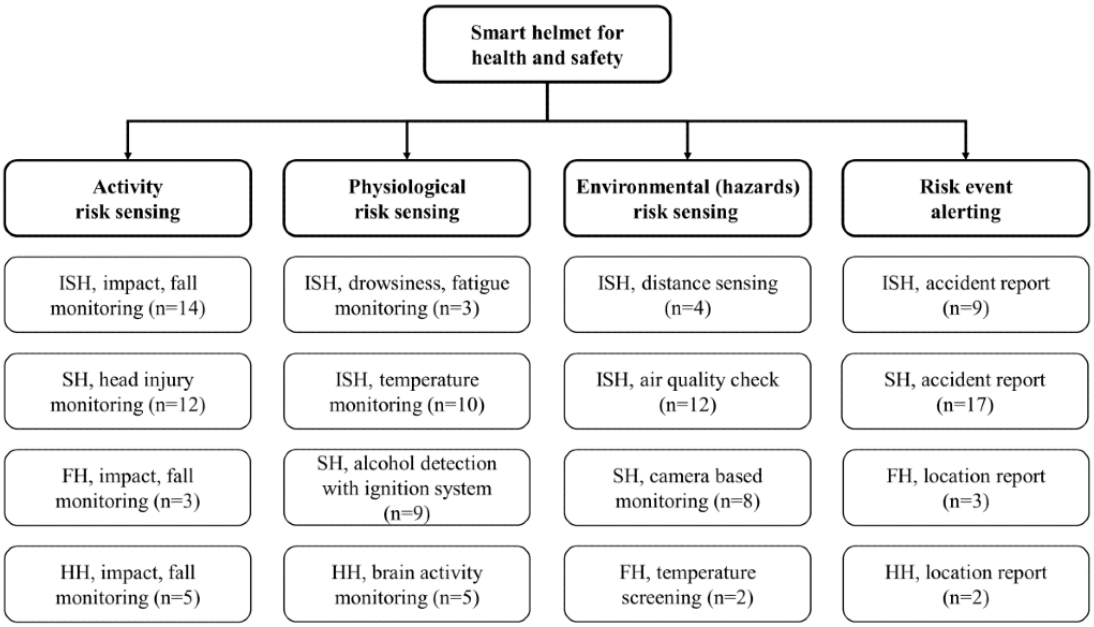


Figure 5. Classification of smart helmets. FH: First responder helmet; HH: health tracking helmet; ISH: industrial safety helmet; SH: sports helmet.



Activity Risk Sensing

As a means of safety, these helmets monitor head motion or impact. Individuals may fall unconscious because of hazardous events and be left without assistance, but sensing via a smart helmet could help mitigate this risk. The sensors used include accelerometers [17,40,49,51,58,60,61,63], gyroscopes [13,60-62], or IMUs [13-16,18,37,44,46,55,57,59]. These sensors can measure 3- to 6-axis bodily motions (eg, acceleration and orientation) and monitor any anomalous events such as sudden spikes of the signal (might indicate fall or hit from a falling object) or become quiet (might indicate no movement or unconscious after an accident) [36,40,55]. The output from these sensors is often integrated with actuation, such as REA systems to enable rapid responses.

Physiological Risk Sensing

With the increasing demand for health monitoring, biosensors are incorporated into helmets to allow individuals, health care providers, or sports coaches to track individual, community, or team health status. For instance, industrial workers or firefighters are at risk of fatigue, overheating, and exposure to hazardous gasses where continuous monitoring can prevent such incidents. There have been attempts to quantify worker fatigue using electroencephalography (EEG) signals [13,34], and to use temperature monitoring to manage overheating [14,43,47]. These helmets have integrated sensors for monitoring body temperature [14,15,39,40,42,43,47,52,54,57-60], heart rate [14,40,42,43,57,58], blood pressure [39,47], electrocardiogram (ECG) [59,60,63], and EEG [13,37,59,60,63] signals.

Environmental (Hazards) Risk Sensing

In addition to the benefits of monitoring the physiological state of an individual, it is also meaningful to monitor the surrounding environment to minimize risk before an incident happens. For coal-mining workers, exposure to hazardous gasses needs to be avoided and gas sensors incorporated into smart helmets for mining operations can be used to notify users of such gasses [15,16,38,39,42,45]. For health care workers, an IR camera integrated with a head-mounted display can provide thermal scanning to check for COVID-19 or other viral and bacterial infections [14,23,87,88]. A camera mounted on the rear of a smart helmet can scan and warn drivers of motor vehicles or objects approaching from behind [50].

Risk Event Alerting

The sharing of sensing output is also an important feature of smart sensing. For example, gas leakage detection in an industrial setting should sound an alarm for the nearby community or the head injury of a user following a collision should be reported to the nearest first-aid point [42,45,47]. Location and position tracking sensors include a GPS, and this output can be transmitted via radio-frequency (RF) transmitters or through the cellular network as a message.

Common Smart Helmet Sensors

Typically, a smart helmet consists of a microcontroller to process sensor data; a liquid-crystal display or organic light-emitting diode panel for notification viewing; a light-emitting diode for warning; and a Wi-Fi, RF, Bluetooth, or cellular networking module to transmit data wirelessly. Different sets of sensors can be used to achieve certain functionalities such as detection and reporting of head collisions, air quality checking, or SOS message transmission. Figure 6 presents frequently used sensors in smart helmets. In terms of activity risk sensing, impact sensors and IMU are widely used to detect head injuries [13-16,18,36,37,40,46,52,55,57-61,63,66,70-73,75-78,80-83], and an IR sensor or force-sensitive resistor (FSR) is used to confirm whether a worker has worn the helmet [36,39,48,49,67-70,73,74,79]. To monitor physiological changes, body temperature, photoplethysmogram, and EEG sensors are adopted [13,37,40,42,43,47,57,58,64,67,68,72,80,84,86]. Alcohol sensors are used to prevent excessive alcohol use while riding a motorcycle [49,52,69,76-78,82]. To analyze external factors that may put users at risk, gas, temperature, and humidity sensors are used [15-17,36,38,39,42,45,64,67,68]. IR cameras can be used for temperature scanning [18,55,56]. Finally, GPS and Global System for Mobile Communication and General Packet Radio Service sensors are adopted to report nearby accidents [51,55,56,62,65,70,75-78,80,82,83]. Multimedia Appendix 1 [13-18,36-63] summarizes 34 original articles that have reported on the development of prototypes of the proposed smart helmets. Each article is categorized according to the application field, study purpose, the sensor used, wireless protocol, validation method, and assessment score.

Figure 6. Major risk sensing and adopted sensors.

Features of Smart Helmet Sensing

Major features of smart helmets were fall detection, health monitoring, accident prevention, alcohol check, location report, and distress alert as shown in Multimedia Appendix 1. The IMU sensor and accelerometer were adopted to detect sudden changes in head position or acceleration in a certain direction [13-16,18,37,44,46,55,57,59]. For health monitoring, various physiological sensors such as temperature [14,15,39,40,42,43,47,52,54,57-60], heart rate [14,40,42,43,57,58], humidity sensors [15,38,42,54], and alcohol sensor [49,51,69,76-78,82] were used for continuous monitoring. That is, specific sensors were used to obtain certain features of smart helmets. Although direct readings of the sensor outputs are sufficient for certain features, researchers have also proposed alternatives or inferred other functionalities. For instance, an IR sensor can be used as a proximity sensor as the time for IR reflection depends on the distance between 2 objects. It can also be used to detect whether the helmet was worn or not [36,40,67-70,73]. An FSR is a simple resistor whose resistance changes when an external force is applied, and it can be used to detect if a helmet is being worn by evaluating the resistance changes [48,49,68,74,79]. To check for abnormal head motions, an accelerometer and a gyroscope are often adopted. However, acceleration change or temporal difference in acceleration can also signify abnormal head motions [49]. Furthermore, if the tilt angle measured from the accelerometer remains unchanged for some time, it may be inferred that the user is unconscious [73]. One study used a brushless direct current fan as a velocity sensor as the speed of a fan is proportional to its velocity [48]. Ultrasound sensors and light detection and ranging are often used to measure distance; however, attenuated reflection signals may indicate the density of the material [18] or ground safety [17]. Table 1 summarizes

how these features are supported by extracting various modalities from sensors.

Table 1. Additional features of smart helmet sensing.

Feature	Type	Sensor	Modality	References
Helmet-wearing check	ARS[a]	IR[b] sensor	Helmet-to-head proximity or contact	[36,40,67-70,73]
Helmet-wearing check	ARS	Force-sensitive resistor	Resistance to change with a given force	[48,49,68,74,79]
Head motion check	ARS	Accelerometer	3-axis velocity threshold, acceleration variation, the temporal difference in acceleration	[36,40,49,51,52,59,63,66,70,72,75-78,80-82]
Head motion check	ARS	Gyroscope	Angular velocity	[13,61,71,73,83]
Head motion check	ARS	IMU[c]	3-axis inertia change	[55,61]
Driver unconsciousness check	ARS	Accelerometer	Tilt-angle measurement	[73]
Alertness check	PRS[d]	EEG[e]	The ratio of alpha and beta band energy spectrum	[13,37]
Speed check	ERS[f]	Brushless direct current fan	Rotor velocity to voltage	[48]
Floor detection	ERS	LiDAR[g]	Received signal strength indication	[17]
Material detection	ERS	Ultrasound sensor	Signal reflection	[18]

[a]ARS: activity risk sensing.

[b]IR: infrared.

[c]IMU: inertial measurement unit.

[d]PRS: physiological risk sensing.

[e]EEG: electroencephalography.

[f]ERS: environmental risk sensing.

[g]LiDAR: light detection and ranging.

Discussion

Principal Findings

In this review, we summarized the published literature on smart helmet technology and the key features of sensors used between 2010 and 2021 (12 years). With the growing demand for smart systems and sensors in the provision of point-of-care, these studies provide possible novel functionalities and propose the potential deployment of smart helmets. Most of these studies have been based in environments in which wearing a helmet is mandatory or suggested, as in occupational health and safety applications, which are widely studied, as shown in Figure 4. Smart helmets can be potentially used in construction [13,17,18,37,39,40,65,66], coal mining [36,38,42,64,68], motorcycle [48-52,69-78,80,82-84], and bicycle riding [54,79], police [56] and firefighting [55,57,58], and health tracking [59-63,85,86] applications. Among the 57 considered articles, there were 4 major domains for smart helmets: ARS, PRS, ERS, and REA, as shown in Figure 5. In addition, the sensors frequently adopted in smart helmets for various purposes were presented in Figure 6. Finally, 34 original articles with proposed prototypes were outlined in Multimedia Appendix 1 and Table 1 according to their key features and validation schemes. In addition, we performed assessment scoring on reviewed articles to show a general tendency of previously done smart helmet research. This paradigm has been adopted in recent artificial intelligence review studies where nonrandomized studies of the effects of the intervention can be potentially biased. In general, the raw cutoff is set to eliminate potentially biased studies, but we skipped this step because of the small number of studies (n=34). The results of assessment scoring revealed that most studies tried to show sensor calibration results or simulations to provide proof of concept. The mean scores of assessment scoring on 5 criteria were 2 out of 3 on the test environment, 2.1 on prototype quality, 1.6 on the feasibility test, 2.3 on sensor calibration, and 2.1 on versatility. Thus, studies of smart helmets lacked feasibility tests for real field use where demonstrations of smart helmets were conducted in controlled laboratory settings. However, worker safety is not only closely related to personal life, but also it can lead to serious accidents such as fire or explosion; for example, a person managing a nuclear power plant is injured. In this concern, smart helmets seem much in demand, but there are a limited number of commercial products in the pilot stage. Therefore, we would like to further discuss further design considerations for personal safety, the general acceptance for deployment in the fields, and potential applications.

Modular Smart Helmet Design

The main purpose of helmets for military, industrial, and sports use is to protect the brain from external impact. Therefore, smart helmet products need to be tested on various aspects like shock absorption, penetration resistance, eyesight, strap strength, flammability, electrical insulation, and lateral rigidity. The detailed physical and performance requirements can be found on global standards such as ISO 3873:1977 Industrial safety helmets [89], EN 960:2006 Headforms for use in the testing of

protective helmets [90], Snell testing [91], and CE (Conformitè Europëenne) product certification. Thus, in the case of smart helmets that are researched and sold, a sensor or module attached to a helmet should meet these international standards. However, designing a modular structure that can be easily detachable may not degrade physical performance and be able to provide smart features. Some representative cases are as follows; LifeBand from SMARTCAP [92] operates with an EEG measurement module that can estimate the condition of workers in real time attached to the helmet strap, and a smart EEG module [93] that can monitor workers' health status, drowsiness, and poor concentration through an accelerometer, a heart rate sensor, and an EEG sensor from HHS (Health and Happiness System Co. Ltd) is easily attachable on the forehead part inside of standard industrial safety helmets.

The smart sensing module can be configured with various sensor measurements, such as user physiological signals, environmental monitoring, and alerting for location reports. That is, it is possible to design a modular smart helmet that allows users to freely add features which are not available elsewhere, such as improved safety by sensing 360° vision for motorcycle helmets [94] or thermal warning for firefighter helmets [57]. Measurements from modular sensors and linking to backend applications allow direct personalized real-time data recording and interpretation, which enables the creation of applications and services to improve health and health care based on modern IoT paradigms [95,96]. When a modular smart helmet is used in group sensing, different individuals may be equipped with different sets of sensors to improve the quality of environmental sensing with collaborative sensing. Recently, in ECE (Economic Commission for Europe) 22.06 [97], the revised European helmet safety standard that has been in force since January 22, 2022, the crash test, which measures the strength by applying an impact to the helmet from various angles, has been strengthened compared with the previous regulations. Accordingly, the overall helmet shell material could be modified or get thicker which leads to consideration of weight and user comfort.

Design Considerations

Although the reviewed articles described potential applications and the demand for intelligent systems, they provided little evidence related to the usability and practicality of the proposed device. However, additional metrics such as smart helmet versatility, power consumption, and durability should be determined to examine the usefulness of the system, as well as comfort and ease of use for different population characteristics [98,99]. Without practical applications, user acceptance of smart helmets will not develop [100,101], and consequently, this technology will remain a proof of concept. Furthermore, the weight of smart helmets should be considered to avoid the possibility of neck pain, which has been discussed in the cases of motorcycle helmets and helicopter pilots wearing night glasses [102-104]. If the systems within smart helmets were to become more complicated, such helmets could become more uncomfortable, leading users to be reluctant to wear them. Detailed surveys on usability, such as that in Niforatos et al [53], Zhang [57], and Jeong et al [67], and performance evaluations from daily life trials need to be conducted to ascertain smart helmet usability and reduce the potential reluctance of users by incorporating simple protocols for the number of sensors and user specificity, comfort, including weight, and fashion consideration for the general population.

Communication technologies allow smart helmets to "talk" to each other and to exchange information detected by onboard sensors. To protect and promote health and safety, real-time monitoring of individual data are important in terms of requiring fast responses to incidents and hazards. Connected smart helmets can be implemented with several communication protocols such as Bluetooth, Wi-Fi, Zigbee, and cellular networks. Among reviewed articles, the most widely used protocol was Bluetooth as a representative personal area networking protocol, because a smart helmet does not require wide-area or cellular network communications (eg, LTE and 5G) and can benefit from low energy consumption in the scenarios under consideration [64,80]. The data then can be transmitted to local IoT gateways (eg, dedicated stationary routers or smartphones as mobile routers) to offer data communications. Smartphones could serve as personal mobile gateways that do not have connectivity distance limitations and they are also used to preprocess the data acquired through smart helmets. A low-energy version of Bluetooth or Bluetooth low energy is also suitable for a connectivity feature. When mobile phones are not used as gateways, it is required to install local IoT gateways such as Bluetooth low energy beacons and RF identification in local workplaces which might increase overall management costs [105]. There are extreme work environments where wide-area network communications are not feasible. For example, coal miners lack wide-area network coverage, and thus, existing prototypes usually adopted Zigbee because of the continuously changing working environment and the confined space that causes interferences in communication [106]. A Zigbee unit can be connected to a local area network that supports midrange wireless connectivity and can share information among multiple devices at the same time. Multihop connectivity with Zigbee can enhance data connectivity in extreme environments. In contrast, smart helmets for motorcyclists typically use wide-area network communications, which can be used to send urgent help alerts whenever injuries are detected (eg, sharing location information). Overall, connected helmets assure health and safety by offering continuous risk sensing and real-time incident response. Critical system design requires low-energy usage for long-term use and reliable network connectivity for data exchanges with a suitable network architecture that meets situational user needs.

Another major challenge in the development of smart helmets is personal information collection and privacy infringement. With the advancement of the IoT, real-time monitoring data are shared and analyzed to find factors related to events. Although this monitoring is supposed to assist users, some aspects of personal privacy are violated [107-111]. Prior studies have shown that privacy concerns related to wearable cameras are often influenced by the social, behavioral, and environmental contexts of users [112]. Wearable camera users are often conscious of bystander privacy, and likewise, bystanders are concerned about potential privacy violations (eg, the subtleness and ease of recording) [113]. Advanced data processing may

also have privacy implications. However, the current studies utilizing wearable optical cameras for image transmission [55,56], resource management [65], and facial recognition [114] lack privacy considerations. Furthermore, personal physiological data or location information can be misused, possibly associated with poor data management policies. In such scenarios, health monitoring results may encourage the tracking of work performance (ie, using the data for a secondary purpose without explicit consent). This practice may influence the performance review of workers and cause monitoring to become surveillance (beyond health monitoring). Beyond secondary use, the security of the devices themselves can also be problematic as the low computing power within smart helmet systems may make them vulnerable to unauthenticated access [115,116]. As smart helmet technology is still in its infancy, such implications are not yet fully understood and should be considered as part of future research and implementation.

Emerging Applications of Smart Helmets

A recent example of a promising smart helmet is a helmet with a thermal camera to assist in monitoring the COVID-19 outbreak [14,23,87,88]. This KC N901 can measure the body temperatures of people in a crowd with an accuracy of 0.3 °C using an IR camera, as well as scan the QR codes of individuals, recognize license plates, and recognize people using an optical camera with facial recognition functionality [114]. It can detect a person with a high temperature and transmit the location and identity of that person. According to the manufacturer data, the helmet weighs around 1 kg, can measure the temperatures of 200 people in a minute, and has a battery life of 5 hours in temperature scan mode, thereby showing promise as a mobile monitoring system. However, helmets with thermal imaging also need to be able to determine the causes of increased temperature to avoid false positives and unnecessary intervention or contact tracing, which often occurs in menopausal women, ill individuals, postexercise, and pregnant women. The latter factor is not only important in terms of individual privacy but can also be applied to provide fetal health indicators [117]. Another emerging application of smart helmets is related to electric scooters. Since the introduction of urban rental programs, major injuries associated with electric scooters have included head injuries, as users rarely wear helmets while riding scooters [118,119]. This recently introduced mode of transportation continues to expand because of its usability and low cost, but there have been little to no efforts to establish safety regulations. Mitchell et al [120] proposed a correlation between wearing a helmet and decreased risk of head injury in cases of alcohol consumption. Smart helmets may help encourage users to wear helmets by incorporating electric scooter ignition-lock systems with helmet-wearing checks [48,49,69,70,73,74,79], alcohol checks [49,52,69,76-78,82], and SOS signal sending capabilities [51,70,75-78,80,82,83].

Conclusions

This paper comprehensively reviewed the recent trends in smart helmet technology. The primary uses of smart helmets for health and safety were explored, and the most relevant applications were described, as well as the sensors adopted to enable key features. Furthermore, the most relevant examples of smart helmet applications were detailed, showing their potential uses. The current focus on smart helmets are industrial safety helmets and motorcyclist helmets, and there are growing application fields for first responders and general health tracking where health and safety matter. Smart helmets play key roles in sensing capabilities, actuations, and distress alerts. Finally, the main barriers, challenges, and recommendations for the deployment of smart helmets were discussed. In summary, this paper presents the current status of smart helmet technology, main issues, and prospects for future smart helmet designers and developers with the objective of making the smart helmet concept a reality.

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Authors' Contributions

PL and HK wrote the manuscript. PL performed a database search for study selection, PL and HK reviewed and confirmed data for Multimedia Appendix 1, and PL wrote data for Table 1. MSZ, AK, HFJ, LH, UL, and YJ contributed to the critical revision of the paper, and all authors reviewed the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Summary of original articles.
[DOCX File , 24 KB - mhealth_v10i11e40797_app1.docx]

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Abbreviations

ARS: activity risk sensing
ECG: electrocardiogram
EEG: electroencephalogram
ERS: environmental risk sensing
FSR: force sensing resistor
IMU: inertial measurement units
IoT: Internet of Things

IR: infrared
ISH: industrial safety helmet
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PRS: physiological risk sensing
REA: risk event alerting
RF: radio frequency

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Original Paper

First-time Mothers' Understanding and Use of a Pregnancy and Parenting Mobile App (The Baby Buddy App): Qualitative Study Using Appreciative Inquiry

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Abstract

Background: Internationally, there is increasing emphasis on early support for pregnant women to optimize the health and development of mothers and newborns. To increase intervention reach, digital and app-based interventions have been advocated. There are growing numbers of pregnancy health care apps with great variation in style, function, and objectives, but evidence about impact on pregnancy well-being and behavior change following app interaction is lacking. This paper reports on the qualitative arm of the independent multicomponent study exploring the use and outcomes of first-time mothers using the Baby Buddy app, a pregnancy and parenting support app, available in the National Health Service App Library and developed by a UK child health and well-being charity, Best Beginnings.

Objective: This study aims to understand when, why, and how first-time mothers use the Baby Buddy app and the perceived benefits and challenges.

Methods: This paper reports on the qualitative arm of an independent, longitudinal, mixed methods study. An Appreciative Inquiry qualitative approach was used with semistructured interviews (17/60, 28%) conducted with new mothers, either by telephone or in a focus group setting. First-time mothers were recruited from 3 study sites from across the United Kingdom. Consistent with the Appreciative Inquiry approach, mothers were prompted to discuss what worked well and what could have

been better regarding their interactions with the app during pregnancy. Thematic analysis was used, and findings are presented as themes with perceived benefits and challenges.

Results: The main benefit, or what worked well, for first-time mothers when using the app was being able to access new information, which they felt was reliable and easy to find. This led to a feeling of increased confidence in the information they accessed, thus supporting family and professional communication. The main challenge was the preference for face-to-face information with a health care professional, particularly around specific issues that they wished to discuss in depth. What could have been improved included that there were some topics that some mothers would have preferred in more detail, but in other areas, they felt well-informed and thus did not feel a need to seek additional information via an app.

Conclusions: Although this study included a small sample, it elicited rich data and insights into first-time mothers' app interactions. The findings suggest that easily accessible pregnancy information, which is perceived as reliable, can support first-time mothers in communicating with health care professionals. Face-to-face contact with professionals was preferred, particularly to discuss specific and personalized needs. Further studies on maternal and professional digital support preferences after the COVID-19 global pandemic and how they facilitate antenatal education and informed decision-making are recommended, particularly because digital solutions remain as a key element in pregnancy and early parenting care.

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KEYWORDS

pregnancy; antenatal support; antenatal education; communication; digital; pregnancy apps; mobile phone

Introduction

Background

The widespread accessibility and ease of communication have underpinned the development of *mobile apps*, which have led to a fundamental change in the methods that people use to access information [1]. OFCOM [2] described apps that present information in a "streamlined way that allowed them to access details they needed quickly." In 2021, the estimated number of global smartphone users was 6.4 billion, 73.9% increase from 2016 and growth rate that will mean that, by 2023, more than half the people in the world will own a smartphone [3]. In 2020, 429 pregnancy apps were identified in the Apple App Store and 1006 in the Android equivalent platform, Google Play Store [4]

Previous literature on the design, content, and application of pregnancy apps highlights that although there are high number of apps targeting pregnancy, quality and usability are highly varied, as are the approaches and outcome measures used to evaluate their impact [5]. When the complexity of pregnancy is considered in the context of app design and interaction, it has been observed that most apps use a shallow functionality with static information framed toward a medical view of pregnancy care [6]. As pregnancy presents physical, informational, emotional, and social needs, designers need to consider how to provide support beyond static information or direction to medical professionals. The five common *types* of pregnancy app content have been identified [6] and include the following: (1) reference encyclopedias, (2) guides tied to pregnancy timelines or daily information, (3) tracker logs or countdowns, (4) heads-up dashboards, and (5) text or photograph journal functions. Following analysis of identified pregnancy apps in which self-care, psychosocial peer support, and partner or spouse support were largely absent, Peyton and Wisniewski [6] suggested that app designers consider the social experience of pregnancy beyond the medical and corporeal context.

In general, women seek to use perinatal health apps in a *mix and match* approach, along with a wide range of other sources including friends, family, and health care professionals (HCPs) [7]. They seek information with a fine balance between awareness and information seeking, with the risk of increasing anxiety and confusion [7]. By accessing apps and digital information during pregnancy, women may be seeking to understand *normality*, to help them to check if their experiences or symptoms are to be expected or something they should take action on [8]. Pregnant women often seek the experiences of others to support their decision-making or to make them feel more informed when raising discussions with professionals [8].

The national child health and well-being charity, Best Beginnings, launched the Baby Buddy app in November 2014 [8]. The charity describes the Baby Buddy app as "an electronically delivered health intervention" that is intended to support and guide women through pregnancy (antenatal period) and the first 6 months of their child's life (postnatal period). The app was co-designed with mothers to inform and empower women of all ages and from wide sociodemographic backgrounds, so that all expectant parents can search for and benefit from high-quality information and support during pregnancy. Best Beginnings worked closely with HCPs to ensure that the Baby Buddy app provided evidence-based information [8].

Best Beginnings has taken a universal proportionalism approach in designing the app, and, as a child health charity, is committed to embracing the growing digital health space to support young families. The content of the Baby Buddy app is written so that it can be understood by anyone with a reading age of ≥11 years with a read aloud element available and can be downloaded free of charge from the Apple App Store and Google Play Store by anyone with a suitable smartphone. The app uses a blend of the 5 common types of content identified by Peyton and Wisniewski [6], but, in addition, offers a large amount of professional and peer-voiced video content across medical, social, and emotional

pregnancy and parenthood experiences. The app also allows for personalization at set up including the names of partners or supporters involved in the parent journey. Although the Baby Buddy app was developed to target young mothers, it was also accessible to a wide range of mothers and families. This was evident from the demographic characteristics captured in the Baby Buddy app downloads [9]. This study is one of the first to evaluate a United Kingdom–based pregnancy app that provides dynamic information and behavior change content, which has been widely embedded in the National Health Service (NHS) maternity services, and to further understand the perceived benefits and challenges of its use.

Study Objective

An independent, longitudinal, mixed method study of the Baby Buddy app was commissioned by Best Beginnings, funded by the Big Lottery, United Kingdom [10].

This observational study assessed the effectiveness of the Baby Buddy app in improving maternal self-efficacy and mental well-being [10,11]. It also involved a qualitative arm that aimed to understand when, why, and how first-time mothers use the Baby Buddy app and the perceived benefits and challenges [10]. This paper reports on the qualitative arm of the study.

Methods

Overview

Appreciative Inquiry (AI) was chosen to underpin the mixed methods to add depth to the quantitative findings [12]. AI is an emerging research methodology that has theoretical and philosophical underpinnings in action research and organizational change [13] and has been used effectively within a variety of complex structures including health and social care settings. It was useful because it focused on the positive, that is, *what works well*, before moving on to *what could be improved.* It involves the systematic discovery of what is most effective [12,14].

Sample and Recruitment

Recruitment for the qualitative arm was from three maternity units participating in the main BaBBLeS study [10,11] (located in the Northwest, Southeast, and Midlands, England). The inclusion and exclusion criteria are listed in Textbox 1. Each woman received a participant information booklet that combined the study invitation letter and information booklet.

Women who participated in the longitudinal study [10] were also invited to a telephone interview or focus group, and additional informed consent was obtained. Overall, 28% (17/60) of the first-time mothers participated in the qualitative study via telephone interviews (9/17, 53%) or a focus group (8/17, 47%) across the 3 sites, with women ranging from 12 to 37 weeks (3-9 months) of the postnatal period.

Textbox 1. Inclusion and exclusion criteria for participants of the main BaBBLeS study, from which this sample was drawn [15,16].

Inclusion criteria

- Aged ≥16 years
- No previous live child
- Between 12 weeks and 16 weeks and 6 days of gestation

Exclusion criteria

- Aged <16 years
- Already has ≥1 child
- Before 11 weeks and 6 days or after 17 weeks of gestation

Data Collection Tools

One-to-one interviews or focus group interviews were offered and conducted in the postnatal period. A total of 60 women agreed to be contacted for an interview across the recruitment sites. Of these 60 women, 2 (3%) women declined, 9 (15%) were interviewed over the telephone, and 8 (13%) attended the focus group. A breakdown of this sample is presented in Table 1. The focus group was *baby friendly* to accommodate additional needs including a sensory playroom. A flexible interview style with prompts was developed by the research team, and telephone interviews were offered, as these are less demanding in terms of the participants' time [17]. Interviews were conducted by experienced health researchers, including registered midwives.

Telephone interviews were flexible, which was particularly important when considering that participants were first-time mothers and were interviewed by midwives who were best placed to discuss and question any concerns the participant was having. The interviews were audio-recorded, anonymized, and transcribed verbatim. To maintain consistency and collect comparable data, the interview schedule for the telephone interviews was developed by the research team alongside the schedule used for the focus groups. Drawing on the AI approach, the interviews specifically explored when, why, and how first-time mothers use the Baby Buddy app and the perceived benefits and challenges.

Using the same principles, focus groups were conducted by experienced health researchers, including registered midwives, over a 2-hour period during which the first-time mothers were

encouraged to work in groups and discuss among themselves. Consistent with the AI approach [12], comment cards, sticky notes, and colored pens were used to discuss *what worked well* and *what could have been better*. In practice, this meant writing or drawing bullet points to help them to explain their thoughts. Visual prompts included laminated screenshots of the Baby Buddy app's key features and sections. The Baby Buddy app was also made available on electronic devices, in case they wished to remind themselves of any areas within the app.

Table 1. Breakdown of the qualitative sample by site and level of participation (N=60).

Sites	App users who had agreed to be contacted, n (%)	Refusals or noncontactable users, n (%)[a]	Users who were interviewed, n (%)[b]	Users who attended the focus group, n (%)[c]	Total number of users who were interviewed or attended the focus group, n (%)[d]
Northwest	10 (17)	8 (13)	2 (3)	0 (0)	2 (3)
Midlands	38 (63)	26 (43)	4 (7)	8 (13)	12 (20)
Southeast	12 (20)	9 (15)	3 (5)	0 (0)	3 (5)

[a]Total=43/60, 72%.

[b]Total=9/60, 15%.

[c]Total=8/60, 13%.

[d]Total=17/60, 28%.

Data Analysis

An inductive thematic analysis was conducted based on the in-depth data collated. The thematic analysis was guided by a commonly practiced process described by Braun and Clarke [18]. Principally, this method involves manually sifting through the transcription data, and the codes obtained from that data were related to the study objectives and the AI approach. Transcriptions were read and then reread to ensure in-depth understanding of the meaning behind the written text, and then, relevant phrases were grouped, framed into grids and tables, categorized into themes, and regrouped into *benefits* or *challenges*. Transcripts were reviewed independently by 2 members of the team, with grouping discussed and final themes agreed upon. Once all the relevant text was coded into themes and substantiated with primary evidence, they were recorded in a finalized matrix (refer to sample matrix, *benefits*).

Ethics Approval and Governance

Ethics approval was obtained from the West Midlands - South Birmingham research ethics committee (reference number 16/WM/002) via the web-based Integrated Research Application System. Ethics approval was also sought from and approved by the research ethics committee at the Faculty of Health and Life Sciences, Coventry University (reference P45795), where the *medium to high risk* procedure was adhered to. All participants were anonymized with unique participant information numbers, and transcription was undertaken to ensure total anonymity.

Results

Overview

Consistent with the AI approach, the findings are presented under 2 subheadings, which reflect the structure of the focus group and interviews, where the questions were posed according to these main questions. In terms of discovering when, why, and how first-time mothers interacted with the app, *what worked well* was described to be linked to themes around accessibility of information, including daily pop-ups and a need to seek knowledge on certain aspects of pregnancy and childbirth. Themes around *what could be improved* were about individual preferences regarding app function and content. The perceived benefits were described in terms of access to information considered reliability, and increased sense of confidence to engage in further discussion with HCP and partners. First-time mothers also expressed a desire for great face-to-face engagement with HCPs or peers as a need that the app will not be able to address.

Benefits

What Worked Well?

In describing what worked well, mothers discussed how they used the app to increase their knowledge and understanding of pregnancy topics and app, and some had been guided to do so by HCPs. Although some mothers would use this app along with a range of other sources to seek information about specific topics, the app would prompt them to discover topics that they had not yet considered. There were 4 themes that emerged from the mothers' accounts of what they thought worked well in using the app.

New Information

Throughout the interviews and focus groups, first-time mothers spoke about how they liked acquiring the information they received from the Baby Buddy app and how this made them feel that they had increased their knowledge. They suggested that it was just the right amount of information, topics were concise and easy to understand, and they were able to recall the details they had learned in the focus group and interviews:

> *I like the information about what size it was and what to think about in terms of my health, and how the baby was growing and getting ready.* [P6]

The first-time mothers also discussed the fact that the information on the Baby Buddy app gave them more information about their pregnancy, particularly when engaging with HCPs. This was evident, specifically when accessing key words that they may have been unfamiliar with:

> *So sometimes my midwife would say certain things, and I would like, if it was something medical, go and look at what was going on, and what words meant, and also like for areas, like GPs and different...I'd go and look for information there...* [P33]

The information provided by the Baby Buddy app continued from pregnancy to postnatal period and may have increased their knowledge. First-time mothers also suggested that it was nice to still have notifications regarding their baby's development up to a month after childbirth. Breastfeeding was a particular feature from which first-time mothers felt that they had learned a lot:

> *Gosh there's loads, I think I learned that you can restart your milk supply, and different ways of feeding her so, I struggled a little bit at first because she was taking too much too quickly, but I read that if I leant back a little bit it would slow the flow down.* [P102]

> *From the community, the community one helped quite a lot, when the baby was first born I was told to look at it for like breast feeding bits and stuff, by my midwife and the breast feeding team...that was useful.* [P103]

Quotes demonstrate how first-time mothers were not only actively using the information they had found to support their decisions in the postnatal period but also how HCPs and first-time mothers were interacting via the Baby Buddy app, which may have helped to keep the lines of communication open. First-time mothers also learned about the size and development of their child throughout pregnancy via the Baby Buddy app, which seemed to support engagement with the app and may improve first-time mothers' confidence and feeling of being in control:

> *How much is your baby, for example at 36, you see a picture and your baby, what is doing your baby, with the eyes, the mouth. For vomiting, it tells you when your vomiting will stop, or what you feel when your baby is coming in the last few months.* [P104]

> *Probably more about the fetus's growth, yes what it was actually doing at certain points, as opposed to the birth, because I think a lot of my friends already had children and I've done a lot of work with mothers and babies in my job, I think I was quite aware of certain stories and options, yes but it was definitely the fetus's growth...Which is really exciting to know especially in a first pregnancy isn't it.* [P105]

Overall, the data suggest that participants were using the Baby Buddy app both during the antenatal and postnatal periods to access knowledge and inform decision-making during their journey as a first-time mother.

Reliability

The themes developed from the extracted quotes indicate that first-time mothers felt one of the clear benefits was that the information in the Baby Buddy app was provided by professional sources, which conveyed reliability, as described in these extracts:

> *And I think that the Baby Buddy one because you know that it's been tried and tested by midwives it's not just generic information, every day you're getting something to think about.* [P58]

> *Yes, because you feel confident knowing that it's tried and tested by midwives, in the videos you have the Midwives perspective, I liked that.* [P66]

When first-time mothers compared the Baby Buddy app with other web-based sources of information, such as other maternity apps and sources such as Google, they felt that these may not be as reliable. After watching the film footage of midwives providing information on topics such as breastfeeding, first-time mothers described feeling reassured that they were receiving reliable information. Mothers seemed to trust the information they were receiving, which helped to reassure them:

> *...And at the end of the week it would say the measurements of the child and what kinds of things you should be going through, so it really helped you in the pregnancy just to know what was happening, instead of like panicking about things, so like that's normal...* [P4]

These comments suggest that the Baby Buddy app acted as a source of comfort for some first-time mothers, helping them to stay calm and positive about their pregnancy. Participants appreciated the videos with accounts of experiencing motherhood:

> *Thinking about it I did watch some of the films with the mums talking, about their experiences, I did watch those as well, a few of them, just interesting really, I don't think I necessarily got anything I didn't know from it, but it's nice to see, with other mums.* [P14]

The Baby Buddy app can be used to set reminders for appointments, dates to remember, and exercise tool that participants reported using:

> *You could use it to remind yourself to do things, like your pelvic floor exercises.* [P29]

> *Yes, and if you have appointment for my baby or my appointment, so I go to the application and I know.* [P30]

In addition to the app providing information, it also included capabilities that allowed users to add information to the app, such as appointments with midwives. This feature of the app encourages long-term engagement by providing first-time mothers the opportunity to use the app throughout pregnancy and after childbirth. This also suggests that the Baby Buddy app was being used as an organizational tool for first-time mothers, keeping the lines of communication open between them and their HCP.

Using the Baby Buddy App—Ease of Access

While exploring when, how, and why first-time mothers used the Baby Buddy app, mothers agreed that, once they had downloaded it, information was easily accessible. They were able to track their daily progress, read daily updates via pop-ups, and find information related to specific topics with ease. They particularly liked the daily pop-ups, which were useful for

women who worked and did not have time to search through information regarding their pregnancy, as described in the following quote:

> *...The updates would come, and they didn't like override, some apps pregnancy things coming all the time, this one just gave you one simple answer a day, so nice and easy and not too much...* [P26]

A steady flow of alerts and pop-ups provided by the Baby Buddy app ensured that women had easy accessibility and readily available information throughout their pregnancy, regardless of where they were. When more detail about a particular topic was required, it could be accessed via the app at a time that suited women:

> *...Because you're getting information every day, it will provide you with links, the app was the foundational platform for looking up more stuff, it would give you like a summary of what to expect, so one thing I liked about the app was, you didn't necessarily have to wait to say 7 months pregnant to tell you about pain relief options, it would make suggestions about that early on, so that when I did go to my antenatal classes where they teach you about that stuff I kind of had an idea and then you knew you could ask more questions.* [P36]

In turn, the alerts and pop-ups led to first-time mothers watching films about specific topics and accessing their customized character or *avatars* (where the appearance, such as hair, skin tone, clothes, and body shape, can be altered to resemble themselves or designed to their preference to guide them through the app content). They also particularly enjoyed videos about breastfeeding, which provided another layer of depth of information:

> *[Talking about breastfeeding and latching] Yes, people can tell you how to do it, but actually seeing on the video it being done was much clearer.* [P65]

In particular, some participants also used the Baby Buddy app to find information about pregnancy-related problems. A woman told us that as soon as she was diagnosed with pre-eclampsia, she used the app for information, which helped her as explained in the following quotes:

> *...The videos I watched were mostly to do with pregnancy, it was actually like really helpful, cos I ended up really ill with the pregnancy, that's why I've got him now, I shouldn't have had him, he shouldn't have been here, he was 5 weeks early, I had pre-eclampsia...yes, so that app did help me, it guided me a little bit.* [P3]

> *Yes I mean, some of the things that obviously I'm a first time mum, so, no matter how confident you feel going into it, once you've given birth its looking for answers to questions that you don't realize you're going to have beforehand if you know what I mean?* [P2]

In addition to being able to access daily information, films, and updates and personalize avatars, the first-time mothers expressed approval for the Baby Buddy app's sharing capability, which allowed them to share *tailor-made* information with partners and their families and friends:

> *I like the fact that the app allows you to put your husband's name in, so it says you can talk to [person's name is removed] about this, and he could have downloaded the app, I thought it was really nice.* [P59]

> *...And it refers about your husband or partner by name if you put that information in, I really like that. I would definitely recommend it to other people, my sister's just got pregnant and I recommended it to her.* [P60]

These findings indicate that the Baby Buddy app's prompts, short films, and easily accessible information may be particular features that encouraged women's engagement with the app. The sharing capability of the app also ensured that women could provide information to their friends and partners, which may have further improved app engagement.

Increased Confidence

A further clear benefit was that the more the mothers felt the information they were accessing within the app was reliable, the more they used it to support their pregnancy and postnatal care. First-time mothers felt that being equipped with the knowledge they had accrued from the Baby Buddy app gave them more confidence to plan their care with an HCP:

> *I think I used it to make choices, I used it together with parent-craft classes, I used them together because I liked that you had the video of the midwife explaining different types of pain relief options, and you had the script that you could read about the different options, so it just meant you could really think about it, one of the things I did was I downloaded the NHS birth-plan template and wrote mine out in pencil so that when went to the actual classes, I could ask questions, I could change my plan, it gave you confidence that you weren't going off to something with nothing.* [P37]

Participants from the focus groups also reported that they would use the information from the Baby Buddy app to support their discussions around choice with partners and family members and that they were feeling knowledgeable; therefore, they had the confidence to do so. This may have provided women with more control over their choices and decisions, which, in turn, empowered them to feel more confident about the care they received and the care they provided to their baby:

> *I just thought it was a good platform, because as a new mum you know you're pregnant but you don't know what to expect, so it's always nice to have this foundational knowledge to make you feel confident about decisions that you are making. It wasn't complicated to use.* [P64]

Challenges—What Could Be Better?

An Intervention That Supports Help-Seeking Behavior

Although first-time mothers valued and trusted the information provided by the app, they expressed a preference for face-to-face support from their HCPs. When they needed specific information about breastfeeding or general advice for their child, they would often seek advice from an HCP in preference to accessing the Baby Buddy app's features:

> *But if we think we're doing something wrong then I tend to ring the doctors, or the health visitor...because we're first-time parents and we don't want to do anything wrong, and we don't want to go by the book, like, in case it's not the right decision, I think it depends on your baby's development as well I think.* [P80]

However, data also highlighted that, although first-time mothers enjoyed interacting with the Baby Buddy app, they still preferred reassurance from an HCP. This could be because they preferred face-to-face contact and may have needed further reassurance about the decisions they were making.

First-time mothers also spoke about their preference for antenatal classes toward the latter half of their pregnancy. A participant described that the amount of Baby Buddy app use diminished once antenatal classes were attended:

> *...Towards the end when I started NCT classes I used it less, but it was definitely very helpful in the first 6 or 7 months I'd say.* [P6]

Antenatal classes offer the opportunity for facilitated learning and social interaction with peers, which are not available to women through the Baby Buddy app.

Where the Need for App Improvements Was Identified

Although first-time mothers spoke positively about the daily information, knowledge, and support they received via the Baby Buddy app, there were particular areas throughout pregnancy and after childbirth, in which participants would have liked more detail, including pregnancy and labor progress, birth plans, checklist of items to have ready for giving birth, and long support after birth:

> *The thing I was sad about with the Baby Buddy app was that it finished...it would be nice if it followed you for one year after you've had your baby, because it's a really useful simple app.* [P66]

First-time mothers suggested that expanding the detailed information for the week-by-week pregnancy journey will be beneficial, specifically further information about their child's development and what to expect:

> *The only things that I would have liked more of was like the week by week update, as they're growing, the fetus, a bit more detail in it.* [P92]

First-time mothers also suggested additional features for the Baby Buddy app such as tools to make decisions about labor, contraction counter, and accessible birthing plan template. Nevertheless, in more than two-thirds of interviews, the mothers did not think that anything needed improvement in the Baby Buddy app. Some first-time mothers reported downloading the Baby Buddy app, but did not actively use its features. This may be owing to individual differences between first-time mothers who participated in this study. This includes language considerations, because some mothers struggled to fully interpret or understand the information, as there was no option apart from English language:

> *If you could put in this application the Greek language, or different languages, you know, because sometimes I can't read it, I can't understand it, sometimes I need to copy paste and translate. So put in more languages. I have friends from Poland, and they use this application and they tell me to translate for them, and I may be working or something like that.* [P96]

Mothers in this study may also not have used the Baby Buddy app after downloading it because of their existing knowledge and beliefs. This was particularly evident when they were asked whether the information and films on breastfeeding had helped to guide their decisions around the topic area:

> *I always knew that breastfeeding was what I wanted to do, but it set my mind in that mindset, this is what I'm going to do, I was determined to do it.* [P97]

Discussion

Principal Findings

This is one of the first qualitative studies aiming to understand when, why, and how first-time mothers use the Baby Buddy app and the perceived benefits and challenges. By taking an AI approach, the questions about what worked well and what could be improved were explored with app users who were able to relate a range of experiences they had with using the app throughout their pregnancy to postnatal journey.

First-time mothers who participated in the qualitative arm of the study found that the Baby Buddy app worked well owing to its accessibility and that the information was concise and easy to find. This made them feel that they had gained knowledge, and they felt that the information was reliable owing to its association with HCPs in the film and written content. They liked that although the information was linear, different aspects could be accessed as and when needed. They particularly liked the personalized daily updates about the progress of their pregnancy and child development. This had a snowball effect in that it reassured these mothers that the information they were receiving was correct. This appeared to increase their confidence in using the app and encouraged them to continue using it throughout pregnancy and postbirth care with the HCP. These mothers were particularly reassured by the reliability of the sources of the videos in Baby Buddy that featured midwives. This gave them the confidence to ask more detailed questions to their HCPs, knowing that they could always refer to the Baby Buddy app if necessary. Time pressure is a known key barrier to effective discussion about the content of leaflets [19]; the Baby Buddy app offers women the opportunity to browse and explore information according to their own needs and interest.

This mitigates the selectivity of HCPs and may contribute to a sense of increased confidence in discussing birth options.

Our findings align with other studies that have explored how women use digital information to enhance their candidacy for appropriate use and escalation of concerns to an HCP [20]. Similarly, we found that women were more confident in discussing issues with HCPs when they felt that they had some knowledge as a starting point. Candidacy in the context of maternity care has been described as a dynamic and continuous process subject to redefinition through interactions [21]. Eligibility for health care is determined by the individual and health services, and there may be increased barriers for a more vulnerable population [21]. The concept of empowerment is one that is frequently referred to within maternity services, and the external attributes of this concept include access and control over resources, such as reliable knowledge and information [22]. The nurturing of candidacy and empowerment within the maternity population is a critical part of the transition to parenthood; the consequences can influence satisfaction with birth experiences, contribution to overall health of families, and development of self-advocacy [22]. An interesting novel observation emerging from our findings was that women reported using the information from the app to support conversations with family members about birth and feeding choices. The influence of people in their immediate social sphere are known to have significant influence on mothers' decision-making [23]. The participants were recruited from the BaBBLeS cohort study [10,11], which had change in self-efficacy as the primary outcome. Although the study reported no significant difference in change in self-efficacy scores from pregnancy to 3 months after birth in app users, it is worth noting that average baseline self-efficacy (measured using the Tool to Measure Parenting Self-Efficacy) was high. Mobile health (mHealth) adoption and engagement in users with high baseline self-efficacy have been reported in other studies in mHealth [15]. In our findings, women described how access to reliable digital information had provided "a foundational knowledge to make you feel confident about decisions you are making." Self-efficacy theory [16] implies that the antecedents of self-efficacy include mastery and vicarious experience, both of which can be observed from the participants' experiences of using the app. This aligns with previous studies in which women who engaged in web-based forums demonstrated increased health literacy and further confidence in raising questions with health care providers [13,24].

It should be noted that the first-time mothers who were interviewed were often using multiple sources to access information, including other maternity apps or web pages. They used a *pick and choose* technology consumer style approach to decide the particular type of information that they used from different apps. This is in agreement with an investigation into mHealth activities of pregnant women who are disadvantaged in the United States, which discovered that a high number of women (97%) engaged in pregnancy health information through a combination of websites and apps [25]. This is further evidence that women turn to a wide range of both web-based and offline resources for informational needs during pregnancy [7]. This again highlights the need for reliable and consistent information in mHealth interventions during pregnancy, as confusion and contradicting or false information can undermine the relationship with the HCP, lead to erosion of candidacy, and have negative impacts. Although first-time mothers appreciated the information they received, many preferred in-practice supports via HCPs, such as their midwife. Although they felt that the Baby Buddy app was reliable, as first-time mothers, they wanted to seek face-to-face advice from an HCP to support their decision-making. This highlights the central importance of *a face* within the health system [26].

All data for this study were collected before the 2020 COVID-19 pandemic, when, to limit contact with pregnant women, antenatal care provision was conducted remotely. Feedback to evaluate a virtual antenatal clinic implemented at this time in the United Kingdom reported that 86% of service users were highly satisfied with the virtual clinic. Notably, there were no differences by demographics of either age or ethnicity, but 56% of the people still preferred face-to-face clinics [27]. HCPs also reported high level of approval for long-term use of virtual clinics, with 78% rating their experience as the same or better than face-to-face clinics [27]. Although the COVID-19 pandemic has pushed digital and remote solutions to the fore and they were received well as a suitable crisis contingency, time will tell how much of reduction in face-to face contact is acceptable to women outside the context of a global pandemic. Although virtual clinics offer feasible advantages to women in terms of reducing travel, time away from work, and childcare challenges, this must be considered in the context of those for whom digital exclusion is a reality, who experience language and context difficulties in virtual encounters, and who may need face-to-face appointments to build a relationship of trust with their care team. As England rolls out a Midwifery Continuity of Carer model, with personalized and relationship-based care at its core [28], the place of digital and virtual care is already being considered alongside maternity digital transformation. A key aspect of the application of mHealth to support midwifery tasks has the potential to lead to efficiencies that free up time for relationship-building in face-to-face contact.

One of the barriers was that some mothers made a conscious decision not to engage in some of the more "nerve wracking" topics of information, such as labor or care after birth. The extent to which users of web-based content can exert this avoidance selectivity should be considered by HCPs when discussing any web-based resource use. This may also help to increase discussion around any fears, worries, or concerns they may have; highlight mental health issues; and seek further support if needed. It has previously been shown that people who do not engage in pregnancy health apps had scored higher on the State Trait Anxiety Index than those who engaged [5]. In the main cohort study from which the sample for this study was drawn, low levels of self-reported social support were associated with poor mental well-being scores [29]. In addition to this, a negative association was seen between self-reported social support and socioeconomic status [29]. An investigation into how women narrate anxiety and depression during pregnancy found that women are highly conscious of the socially constructed imperative to be happy and positive to maintain the

perception of a *good mother* [30]. Women distanced themselves from the language of distress and wished to appear in control of their emotions [30]. This included using discursive strategies such as distancing from the depressed self, using codes to discuss issues around distress, and seeking to portray balance and control of emotions to maintain the *happiness imperative* [30]. Future app design and studies on the human-computer interaction in a pregnancy context should explore this issue in more depth to understand how information can be presented to avoid increasing anxiety, feelings of social exclusion, or perpetuation of societal ideal imagery.

At the time this study was conducted, the Baby Buddy app lacked social engagement within its features. First-time mothers felt that during the latter half of pregnancy, antenatal classes were more engaging and thus provided the opportunity to speak to other first-time mothers about their decisions and worries in addition to HCPs. Having access to peer support via social groups, shared discussion and perspectives may increase the likelihood of mothers feeling "safer" to interact about these topics. A recommendation for the future use of any app will include conspicuous information about where to find group support sessions with other first-time mothers. Although the Baby Buddy app potentially has this feature, this study found that many mothers were not aware, and thus, it was undiscovered. In addition, an interactive web-based group discussion feature to keep first-time mothers engaged throughout later stages of pregnancy and after birth may be particularly valuable to women during COVID-19 recovery but will need additional resources for content moderation. Further studies on women's preference for group antenatal education via digital platforms, face-to-face mode, or a combination of both is also required for future service design, including full evaluation of innovations emerging from the pandemic [31]. It is worth noting that since this study was conducted, the Baby Buddy app has been developed further with additional content including increased information on local services, information for fathers, and access to a maternity helpline.

Although this study interviewed only 17 women, the team gathered many rich and in-depth views and perspectives from first-time mothers. The extent to which these findings will apply to second-time or third-time mothers is difficult to infer. Although other studies have also found first-time mothers to be more frequent app users [5], they may have different needs and expectations, given previous experience with maternity services. The cohort study from which our sample was drawn [10] was typical of a UK pregnancy and digital health research demographic in that it was predominantly White, well-educated, and older women who volunteered for the study, despite the recruitment sites representing a broad demographic. Strategies to ensure engagement of broad ethnic, socioeconomic, and maternal age groups will provide great understanding of the transferability of the findings. Studies focusing on specific demographic groups and their interaction with digital services and interventions is required to produce a truly equitable future maternity service, which undoubtedly will comprise a combination of digital and face-to-face delivery of care. Similar studies exploring the experiences of fathers and other parenting dyads in their perinatal mHealth needs will be of value, including the need for inclusion of lesbian, gay, bisexual, transgender, queer, and other communities in the perinatal digital space.

Conclusions

This paper adds to current literature on pregnancy app interaction and explores how women have engaged with a specific NHS-approved app that was co-designed with service users and has sought professional validation of content for reliability. The obtained insight builds on the understanding of how mHealth and digital interventions can contribute to women's sense of empowerment through access to information that can be used to negotiate health care choices, both with health professionals and within families. Before the COVID-19 pandemic, first-time mothers preferred in-practice support from their HCPs and engaged less with the app as they developed peer support in later pregnancy from antenatal groups. Further studies are required to determine how these preferences evolve after the pandemic. Although the Baby Buddy app was useful, multiple sources of web-based information was sought by first-time mothers when it was not available in the app.

Findings presented in this paper can support the design and development of interventions aimed to encourage first-time mothers' engagement with digital health management tools. In addition, these findings can lead to further understanding of mHealth behavior during pregnancy and the relationship between digital technology and human interaction.

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Conflicts of Interest

None declared.

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Abbreviations

AI: Appreciative Inquiry
HCP: health care professional
mHealth: mobile health
NHS: National Health Service

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Original Paper

Shortening the Time Interval for the Referral of Patients With Soft Tissue Sarcoma to Expert Centers Using Mobile Health: Retrospective Study

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Abstract

Background: According to guidelines, all patients with sarcoma must be managed from initial diagnosis at expert sarcoma centers. However, in everyday practice, the time interval to an expert center visit can be long, which delays presentation to an expert multidisciplinary tumor board and increases the risk of inappropriate management, negatively affecting local tumor control and prognosis. The advent of mobile health offers an easy way to facilitate communication and cooperation between general health care providers (eg, general practitioners and radiologists) and sarcomas experts. We developed a mobile app (Sar'Connect) based on the algorithm designed by radiologists from the French Sarcoma Group. Through a small number of easy-to-answer questions, Sar'Connect provides personalized advice for the management of patients and contact information for the closest expert center.

Objective: This retrospective study is the first to assess this mobile app's potential benefits in reducing the time interval for patient referral to an expert center according to the initial clinical characteristics of the soft tissue tumor.

Methods: From May to December 2021, we extracted tumor mass data for 78 patients discussed by the multidisciplinary tumor boards at 3 centers of the French Sarcoma Group. We applied the Sar'Connect algorithm to these data and estimated the time interval between the first medical description of the soft tissue mass and the referral to expert center. We then compared this estimated time interval with the observed time interval.

Results: We found that the use of Sar'Connect could potentially shorten the time interval to an expert center by approximately 7.5 months (P<.001). Moreover, for half (31/60, 52%) of the patients with a malignant soft tissue tumor, Sar'Connect could have avoided inappropriate management outside of the reference center. We did not identify a significant determinant for shortening the time interval for referral.

Conclusions: Overall, promoting the use of a simple mobile app is an innovative and straightforward means to potentially accelerate both the referral and management of patients with soft tissue sarcoma at expert centers.

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KEYWORDS

sarcoma; apps; mHealth; mobile health; health app; mobile app; referral; consultation; care coordination; tumor; cancer; oncology; soft tissue; connective tissue; prognosis; communication; interprofessional; patient management; physician; doctor; health care provider; specialist; general practitioner; GP

Introduction

Sarcomas are malignant mesenchymal tumors that can arise from any soft tissue or bone. Soft tissue sarcoma (STS) represents less than 1% of adult cancers and is characterized by important heterogeneity in clinical presentation, histological subtypes, and aggressiveness [1]. In general, the diagnosis and management of sarcomas and soft tissue intermediate malignancies can be inappropriate at nonexpert centers [2]. In France, only 40% to 50% of patients with sarcoma are treated according to clinical guidelines [3], even though following these guidelines is an independent prognostic factor for both disease-free and overall survival [4]. Nevertheless, a considerable proportion of patients with sarcoma, particularly those with smaller soft tissue tumors (STTs), undergo inappropriate surgery (eg, "whoops" surgery) [5-7] outside of an expert center, sometimes without any prior imaging being conducted. Such initial inappropriate surgical procedures lead to the worst local tumor control and poor survival [8,9]. Blay et al [10] report that surgery at an expert center significatively improves overall survival with a hazard ratio of 0.68 compared to surgery outside an expert center. Furthermore, other treatments may become necessary after R1/R2 resection, such as re-excision, with the risk of higher rates of mutilating surgical procedures or the use of adjuvant radiotherapy or chemotherapy leading to more side effects [11-13]. Despite the addition of these treatments, previous studies have shown that unplanned surgery is always associated with poor outcomes [14,15].

The reasons for "whoops" surgery include difficulty in clinically discriminating benign from malignant soft tissue masses [16]. Indeed, sarcomas can mimic lipoma, benign neurogenic tumor, certain infections, and thrombosis, among others [17-21]. Regardless, certain criteria suggestive of STS, including a size over 5 cm, tumor depth, recent growth, and pain, should lead to magnetic resonance imaging (MRI) assessment [20,22,23]. A suspicious tumor can present an inhomogeneous density distribution due to complex pathological changes, including bleeding, necrosis, walls, and calcification, as opposed to the usual simple structure and more homogenous density distribution of a benign STT [24]. As such, the French Sarcoma Group (FSG) expert radiologist team developed an algorithm to guide radiologists in identifying benign versus nonbenign STTs based on the first imaging results [25].

Another reason that could explain this disparity in the management of patients with sarcoma is the social and geographical factors of an area that can substantially delay reach to expert centers, especially for mountainous and precarious districts [4]. However, the development of the FSG across the country helped to reduce the risk of nonoptimal management by proposing an app to help identify and contact the closest expert center—thus promoting a more homogeneous management for patients with sarcoma [25].

Shortening the time interval for referral to an expert center for patients with STS is challenging. To reach most health care providers and raise their awareness, we developed, with the help of Chlorophyll Vision, a mobile app called Sar'Connect in 2021, which aims to increase the rate of early detection of STS and facilitate patient referral to expert centers based on the FSG radiological algorithm and geolocation of health professionals [26]. The FSG radiological algorithm was adapted into a list of 3 to 6 short-answer questions based on clinical and radiologic anonymized information. After answering these questions, users receive 1 of the 3 available pieces of advice for orientation: direct referral to an expert center, necessary complementary imaging, or possible nonexpert center management (Figure S1 in Multimedia Appendix 1). To our knowledge, this is the first time that this kind of app was developed for the management of sarcoma. This study is also the first to assess the potential benefits of Sar'Connect, which has been available since April 2021, for the referral and management of patients with STTs [26].

Methods

Study Design and Recruitment

In this retrospective in silico study, data were collected from 3 different FSG expert centers from May to December 2021: "Centre Oscar Lambret" (Lille), "Institut de Cancérologie de l'Ouest" (Nantes), and "Institut de Cancérologie de Strasbourg Europe" (Strasbourg).

Ethics Approval

Patient data reported in a multidisciplinary tumoral board (MTB) from an FSG expert center were saved in the NetSarc+ database, which centrally reviewed them. Patients were warned of this process before discussion in MTB and were free to refuse the use of their data. The NetSarc+ data collection and further analysis were approved by the ethics committees as required by the applicable national legislation: approval by the "Comité consultatif sur le traitement de l'information en matière de recherche dans le domaine de la santé" on September 16, 2010 (authorization number 10.403), and approval by the "Comité National Informatique et Liberté" on the July 15, 2013 (authorization number 910390, Decision DR-2013-383). No information used in the study or the app was saved.

Patients

Using a structured questionnaire, we collected data for patients with soft tissue masses discussed by an MTB from an FSG expert center. Patient eligibility was as follows: (1) all consecutive cases of histopathological diagnosis confirmed by expert pathologist from "Réseau de Référence en Pathologie des Sarcomes" and (2) cases discussed at the time of initial diagnosis. We excluded patients with primary bone tumors and those with carcinoma, melanoma, or hematological malignancies. In the case of Ewing sarcoma, osteosarcoma, or chondrosarcoma, patients were only included if the tumor was extraskeletal and diagnosis was performed based on the biopsy of a STT. The data collected included histology; date and medical decisions following the first description of the STT; date and conclusion from the first MTB; and tumor characteristics (largest diameter, localization, and, if available, the type and conclusions of radiological exams). We defined 2 groups: benign tumors and malignant tumors (including sarcomas and intermediate tumors). Statistical analyses were performed for each group, both combined and separately.

Assessments

Calculation of the interval was based on the following 2 dates: (1) the date of the first medical description of the soft tissue mass, as mentioned in the medical files; and (2) the date of the first consultation or discussion in the MTB at the expert center.

The mobile app was used retrospectively with the medical information available during the first medical description of the STT. To run the app, the data needed are the size of the mass in millimeters; its depth (superficial or deep); its radiological features (lipid composition, homogeneity, or heterogeneity); and its clinical characteristics (growth, pain, hardness, and shrinkage of the mass). No data are stored, and all data are completely anonymous to protect medical privacy. According to this information, 3 outcomes are possible: (1) advice for direct referral to an expert center, (2) advice to undergo a complementary radiological exam (especially MRI), and (3) informed of the possibility to manage this mass at a local center. To match these 3 possible outcomes of Sar'Connect, an estimated time interval before referral to an MTB was associated with each of them, as follows. To simulate an acceptable and conservative time interval for each outcome, we assigned a 1-month interval for direct referral to an expert center and a 2-month interval if a complementary radiological exam was advised by the algorithm prior to referral. When the algorithm suggested possible nonexpert center management, an interval of 0 months was assigned in the case of benign tumors and an interval equal to the real-life observed time to referral was assigned in the case of nonbenign tumors. All estimated time intervals were assigned according to local practice.

Study Objectives

The primary objective was to compare the real-life observed time to referral to an expert center (calculated between the first medical description of the STT and the date of the MTB) with the time estimated retrospectively according to the recommendations of the algorithm. Secondary objectives included identifying the determinants of the time interval. We also assessed the potential rate of benign tumors being referred to an expert center after the use of Sar'Connect.

Statistical Analysis

To obtain complete data for at least 40 patients, a sample of 60 patients was required for this study. This sample size was estimated to provide at least 90% power for an expected difference of 8 months in favor of Sar'Connect. This difference value and sample size were chosen according to a previous exploratory unpublished retrospective analysis conducted with the same methodology as the one described in this study and based on records from the MTB of Strasbourg's expert center. According to our local practice, this delay was substantial for this situation. Patient characteristics are described using numbers and proportions for categorical variables and using the mean, SD, median, and IQR for continuous variables.

We compared the actual observed time with the estimated time to an expert center using 2-tailed Student *t* test for matching. Sensitivity analysis was conducted based on the change in the initial time interval from 1 to 3 months in cases of immediate referral to an expert center and from 2 to 6 months when an additional imaging procedure was needed. The results are presented as differential means with their CIs and *P* values. All tests were performed with a 2-sided α risk of 5%. Statistical analyses were performed with R statistical software (version 4.1.2; R Foundation for Statistical Computing).

To identify the determinants of the time interval to referral, a Pearson test was performed on the following putative determinants: distance between the patient's home address and the nearest expert center, age, number of clinical signs, tumor size and depth, and prior imaging procedure. All tests were performed first on the whole cohort and then on patients with malignant tumors.

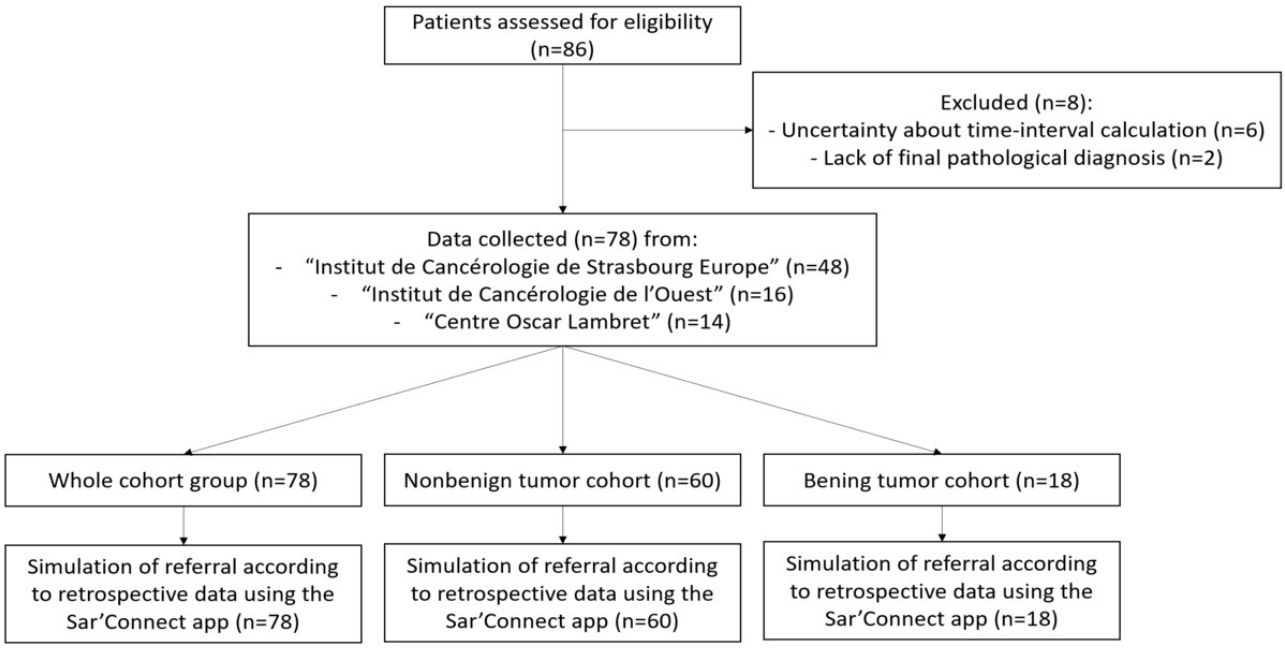
For exploratory analyses, a Bayesian-based method was performed to describe the predictive impact of selected variables using Markov chain Monte Carlo methods. Statistical significance was established when the 95% credibility interval did not contain 0. The results are presented as the median and 95% credibility interval.

Results

Patient Inclusion

In total, 86 patients were included from May to December 2021 (Figure 1). Among them, 8 were excluded from the study: 2 because of the lack of a final pathological diagnosis and 6 because of uncertainty about the time-interval calculation. For the remaining 78 patients, 18 had a benign tumor and 60 a malignant tumor. Main data are summed in Figure S2 in Multimedia Appendix 1.

Figure 1. Flowchart of patient enrollment.



Patients With Nonbenign STT

General Patient Characteristics

We collected data for 60 patients diagnosed with sarcoma or a locally malignant tumor (Table 1). Of the 60 patients in the cohort, 33 (55%) were women. The median age was 60.5 (IQR 21-92) years, with only 6 (10%) aged >30 years. According to medical histories, 10 (17%) patients had a history of 1 or more cancers, including 3 cases of prostate cancer, 2 cases of breast cancer, 3 cases of skin basal cell carcinoma, 2 cases of colorectal cancer, 1 case of endometrial cancer, and 1 case of T-cell lymphoma. There was 1 (2%) patient who had a genetic predisposition toward sarcoma due to neurofibromatosis 1.

The median distance between the patient's hometown and the nearest expert center was 69 (IQR 1-1103) km. Only 1 patient was not referred to the nearest expert center owing to personal choice.

The histological subtype distribution was as expected. Of the 60 patients, 15 (25%) were diagnosed with liposarcoma, including 7 (12%) cases of atypical lipomatous tumors/well-differentiated liposarcoma; 9 (15%) had leiomyosarcoma; 6 (10%) had undifferentiated pleomorphic sarcoma; and 6 (5%) had desmoid-type fibromatosis. Additionally, 15 (25%) cases were grouped as "other histological subtypes" (including extraskeletal Ewing sarcoma, extraskeletal osteosarcoma, gastrointestinal stromal tumor, perivascular epithelioid cell tumor, giant cell tumor, synovial sarcoma, angiosarcoma, and clear-cell sarcoma).

The median tumor size was 90 (IQR 10-450) mm; 10 tumors were not palpable. Regarding location, 26 (43%) tumors were in the limbs, and 25 (42%) were in the trunk (including the pelvis, mediastinum, retroperitoneum, and paratesticular spermatic cord); 9 (15%) patients had a tumor of the thoracic or abdominal wall. Initial clinical signs reported by patients were tumor growth (n=40, 67%), pain (n=25, 42%), and STT stiffness (n=9, 15%).

Radiological exam data showed a median tumor size of 102 (IQR 11-320) mm. Out of 57 tumors, tumor size was over 50 mm in 44 (77%) patients and less than 30 mm in only 4 (7%). Out of 54 tumors, only 10 (19%) cases were superficial and 44 (81%) were at least partially deep. Of the 60 patients, 11 (18%) did not undergo any imaging prior to MTB presentation.

Table 1. Patient and tumor characteristics of the nonbenign tumor cohort (N=60).

Population characteristic	Value
Age (years)	
Median (IQR)	60.5 (21-92)
<30, n (%)	6 (10)
30-60, n (%)	24 (40)
≥60, n (%)	30 (50)
Sex	
Female	33 (55)
Male	27 (45)
Geographical data	
Distance between the patient and nearest expert center (km), median (IQR)	69 (1-1103)
Medical history, n (%)	
Other cancers[a]	10 (17)
Familial history of cancer	3 (5)
Genetic predisposition (neurofibromatosis 1)	1 (2)
Histology[b], n (%)	
Liposarcoma	15 (25)
Leiomyosarcoma	9 (15)
Undifferentiated pleomorphic sarcoma	6 (10)
Myxofibrosarcoma	4 (7)
Desmoid tumor	3 (5)
Dermatofibrosarcoma	2 (3)
Solitary fibrous tumor	2 (3)
Malignant peripheral nerve sheet tumor	2 (3)
Rhabdomyosarcoma	2 (3)
Other	15 (25)
Tumor size (mm; N=57)[c]	
Clinical evaluation, median (IQR)	90 (10-450)
Radiological evaluation, median (IQR)	102 (11-320)
<30, n (%)	4 (7)
30-50, n (%)	9 (16)
≥50, n (%)	44 (77)
Clinical manifestation[d], n (%)	
Pain	25 (42)
Progression of the tumor	40 (67)
Hardness	9 (15)
Shrinkage of the tumor	1 (2)
Recurrence	0 (0)
Location[e], n (%)	
Limb	26 (43)
Trunk	25 (42)
Abdominal or thoracic wall	9 (15)

Population characteristic	Value
Depth on radiological exam (N=54)[f], n (%)	
Superficial tumor	10 (19)
Deep tumor or both superficial and deep	44 (81)

[a]Patients could present more than 1 type of other cancer; other cancers included 3 patients with prostate cancer, 2 patients with breast cancer, 3 patients with epidermal carcinoma of the skin, 2 patients with colorectal cancer, 2 patients with endometrial cancer, and 1 patient with T-cell lymphoma.

[b]Other histological subtypes include other soft tissue sarcomas, gastrointestinal stromal tumors, and extraskeletal Ewing sarcoma or osteosarcoma.

[c]Missing data (n=3).

[d]Patients could have more than 1 symptom.

[e]Trunk localization included the peritoneum, mediastinum, retroperitoneum, and paratesticular spermatic cord.

[f]Including 10 nonpalpable soft tissue tumors; missing data (n=6).

Impact on Patient Referral and Appropriate Care

We assessed the decision for patient management according to the first descriptive data (Table 2).

Of the 60 patients, 27 (45%) were referred to an expert center for initial management, including 18 (30%) who underwent imaging before their referral. For 34 (92%) out of 37 patients, imaging diagnosed an atypical or suspicious aspect of the STT compatible with sarcoma. Despite these conclusions, half (17/34, 50%) of the cases were managed at a nonexpert center.

Out of 60 cases, 22 (37%) were managed at a nonexpert center for biopsy (n=9, 15%) or surgery (n=13, 22%) after the discovery of the STT. Follow-up was the only decision for 11 (18%) cases.

Retrospective simulated outcomes for referral from using the Sar'Connect app with the initial data would have recommended a direct referral to the nearest expert center for 46 (77%) patients and complementary imaging (ultrasound echography or MRI) for 13 (22%) patients. The mobile app algorithm suggested a major change in care for 31 (52%) patients versus real-life outcomes; 30 (50%) patients would have an estimated adequate referral with the use of Sar'Connect, whereas 1 (2%) patient with a superficial dermatofibrosarcoma less than 1 cm in size would not have been referred to an expert center.

Table 2. Patient follow-up and management in the nonbenign tumor cohort (N=60).

Details on the first management of soft tissue tumors	n (%)
Radiological exam[a]	
Ultrasound echography	22 (37)
MRI[b]	34 (57)
Computed tomography	24 (40)
None	11 (18)
Results of radiological exams[c] **(N=37)**	
Atypical or suspicious aspect of soft tissue tumor	34 (92)
Homogeneous adipose or typical aspect of "pseudotumor"	3 (8)
Real-life management after discovery of the mass	
Follow-up without radiological exams	5 (8)
Follow-up with periodic radiological exams	6 (10)
Biopsy at a nonexpert center	9 (15)
Surgery outside of an expert center	13 (22)
Referral to an expert center	27 (45)
Simulated outcomes of Sar'Connect according to first encounter data	
Referral to an expert center	46 (77)
Imaging (MRI or echography)	13 (22)
Referral to a nonexpert center	1 (2)
Potential difference of management between real-life observed outcome and Sar'Connect advice[d]	
Difference	31 (52)
No difference	29 (48)

[a]Patients could have more than one type of radiological exam.

[b]MRI: magnetic resonance imaging.

[c]37 patients with radiologist conclusion available (11 patients without radiological exam); the suspicious aspect of the soft tissue tumor could contain heterogeneity tissue, anarchic vasculature, enhancement, or thick wall. Pseudotumor included synovial or rheumatism degeneration, vascular or lymphatic malformation, elastofibroma, Morton neuroma, hemangioma, schwannoma, and glomus tumor.

[d]Difference in decision was based on groups: optimal decision (a sarcoma referred to expert center) and nonoptimal decision (nonbenign soft tissue tumor referred to a nonexpert center or under watchful waiting only).

Patients Diagnosed With Benign Tumors

Of the 60 patients, 18 (30%) were diagnosed with benign tumors. Their characteristics are reported in Table S1 in Multimedia Appendix 1.

Of the 18 patients, 11 (61%) were referred to an expert center, and all (n=18, 100%) had prior imaging. MRI was performed for 14 (78%) patients, with an atypical or suspicious STT described in most (n=11, 61%) cases. Additionally, 3 (6%) patients were not initially referred to an MTB after imaging, and 1 (6%) patient underwent surgery at a nonexpert center before being referred to an MTB. Using Sar'Connect, 13 (72%) patients would have been directly referred to the expert center, and only 2 (11%) cases would have been recommended for possible management at a nonexpert center. Overall, we found a potential difference in management between the real-life outcome and Sar'Connect simulation in 9 (50%) cases. The mobile app suggested more appropriate management for 4 (22%) patients and referred 5 (28%) with benign tumors to an MTB (Table S2 in Multimedia Appendix 1).

The benign tumor group was not large enough to allow for comparisons with the nonbenign STT group. Nevertheless, variables that appeared to be numerically different included a higher median clinical and radiological size of the tumor (60 and 40 mm in the benign group versus 90 and 120 mm in the nonbenign STT group, respectively) and the absence of a painful STT in all (18/18, 100%) patients with benign tumors compared to 25 (42%) out of 60 patients in the nonbenign population.

Impact on the Time Interval to Appropriate Management

Analyses were conducted on the whole cohort (78 patients), including patients with benign and nonbenign STTs. With a mean time interval of 9.14 (IQR 1-85) months in real life versus 1.4 (IQR 0-10) months estimated with Sar'Connect, we found a potentially clinically meaningful reduction in this time interval of 7.7 months (P<.001). To validate this difference, we repeated

the analysis with a less optimistic estimated time interval for each Sar'Connect result. Hence, we assigned a 3-month time interval in cases of advice for direct referral and a 6-month time interval in cases of radiological exam requirement. This sensitivity analysis found a mean application time interval of 3.6 months and a potential estimated reduction of 5.4 months in favor of the mobile device algorithm (P=.002; Table 3). Two values were considered extreme data (designed as time higher than 2.5 times the SD), and statistical analysis excluding these data confirmed a simulated 6-month difference (P<.001).

We repeated the same analyses in the nonbenign STT population (Table 4) and, again, retrospectively using Sar'Connect to guide patient referral, which resulted in an estimated potential benefit of 6.5 months (P<.001). Although the difference was smaller, real-life outcomes occurred in a significant number of 13 (22%) patients who underwent surgery (with or without prior imaging) or biopsy (n=9) at a nonexpert center.

Table 3. Time interval before patient referral to an expert center in the whole cohort (N=78).

Time interval for patient referral to an expert center	Months	*P* value
Real-life observed results, mean (IQR)		
Time interval after radiological exam	9.14 (1-85)	
Time interval after biopsy of the tumor at a nonexpert center	8.11 (2-36)	
Time interval after surgery outside of an expert center	7.18 (2-28)	
Time interval for the whole cohort	9.0 (1-85)	
According to simulation by Sar'Connect		
Time interval, mean (IQR)	1.4 (0-10)	
Difference with real-life observed results, mean (95% CI)[a]	7.7069 (4.3677-11.046)	<.001
Sensitivity test following Sar'Connect[b]		
Time interval, mean (IQR)	3.63 (0-10)	
Difference with real-life observed results, mean (95% CI)[a]	5.37 (2.0293-8.7178)	.002

[a]Mean difference calculated with 2-tailed Student *t* test for matched data.

[b]Results of the mobile app in sensitivity analysis by replacing the 1-month time interval with a 3-month interval and the 2-month time interval with a 6-month interval.

Table 4. Time interval before patient referral to an expert center in the nonbenign tumor cohort (N=60).

Time interval for patient referral to an expert center	Months	*P* value
Real-life observed results, mean (IQR)		
Time interval after radiological exam	12 (2-28)	
Time interval after biopsy of the tumor at a nonexpert center	8 (3-36)	
Time interval after surgery outside of an expert center	9 (2-29)	
Time interval for the whole cohort	7.9 (1-84)	
According to simulation by Sar'Connect		
Time interval, mean (IQR)	1.4 (0-2)	
Difference with real-life observed results, mean (95% CI)[a]	6.476 (3.0695-9.883)	<.001

[a]Mean difference calculated with 2-tailed Student *t* test for matched data.

Exploratory Analyses

We sought to identify the determinants of the referral time interval in real life and found no statistical correlations with the time interval in standard or Bayesian analysis (Tables S3 and S4 in Multimedia Appendix 1).

Discussion

Principal Findings

To our knowledge, this study is the first to assess the benefice of an app for the early management of sarcoma. Sar'Connect shortened the estimated time interval to an expert center by 7.5 months and could reduce the percentage of misorientation for patient with sarcoma.

Since the beginning of the 21st century, new technologies have contributed to improving communication and data sharing and

have been developed for medical purposes. Mobile health (mHealth) was conceptualized to define the use of mobile devices in the practice of medicine and public health [27]. In 2013, 97,000 mHealth apps were released, and more than 50% of those who owned a smartphone were mHealth app users [28,29]. Moreover, this development will continue to grow because more than 90% of the population owns a mobile phone [30]. To standardize the use of mHealth apps, some countries, such as France and Belgium, have defined guidelines of good practice for health apps and smart devices, which were widely used during the COVID-19 pandemic [31-33].

In general, professional expertise and education can benefit from mHealth apps [34-36]. Before treatment occurs, it is important that health professionals be aware of the pitfalls of misdiagnosed rare tumors such as sarcomas [14]. The Sar'Connect app was developed to improve sarcoma awareness and facilitate early patient referral to expert centers, even at locations far from these centers. This app is part of the French effort to promote the early and optimal management of patients with sarcoma within the French network [1].

Prior to this study, we explored the potential benefits of Sar'Connect in a retrospective local database of patients' files discussed before 2015 at the Strasbourg center to estimate the number of patients needed for analysis. By using the same methodology as used for this cohort, we found a difference of more than 8 months. The difference between this result and recent results may be explained by the difficulty of obtaining a precise date for the first medical description of an STT. In our study, we performed an analysis without outlier values (described as values over 1.5 times the IQR plus the third quartile or under the first quartile minus 1.5 times the IQR) to reduce this difference; 2 data points were considered extreme, and analysis excluding them did not impact the final result. The smaller potential benefits observed in this study may also be explained by geographic differences among centers and improvement in sarcoma management due to FSG awareness campaigns. Indeed, since 2010 and owing to the first French national cancer plan (2003-2009), the FSG has promoted clinical guidelines for the management of sarcoma as well as supported research [37-39]. Based on the work by Fayet et al [3], the FSG has recently emphasized the impact of the heterogeneity of referrals of patients with sarcoma to expert centers in France. In our study, patients with benign STT whose case were presented to an MTB tended to be closer to an expert center, facilitating referral. We developed Sar'Connect to improve the management of patients with sarcoma regardless of geographic disparities. By reducing diagnostic errancy and the risk of suboptimal diagnosis, treatment, and follow-up, patients living far away from expert centers should benefit the most from this mobile app [40].

Our study may be limited by population bias, as all patient data were obtained from sarcoma MTBs, and benign tumors were underrepresented. However, we primarily aimed to show that using this mHealth app may be able to reduce the estimated time interval to MTB referral for malignant tumors, which was successfully demonstrated by a reduction of more than 6 months, even when using sensitivity analyses with longer estimated time intervals. Additionally, out of 60 patients, we found a potential improvement in referral—27 (45%) patients with sarcoma immediately referred to a sarcoma MTB versus 46 (77%) patients if Sar'Connect was used. Other intrinsic characteristics will be determined by assessing the real-life use of our app.

The study was not designed to explore a potential increase in "false-positive" outcomes and the orientation of a benign tumor to a sarcoma MTB. As the app aims to avoid the misdiagnosis of malignant tumors, it was an acceptable outcome that some clinically benign STTs would be referred to an expert center according to the algorithm. Moreover, as all patients included in the analysis were ultimately referred to a sarcoma MTB and Sar'Connect only recommended immediate referral for 13 (72%) patients, we hope that the rise in suboptimal references will not be significant.

Reducing the time interval and avoiding nonoptimal initial surgeries are critical for the management of patients with sarcoma. Using real-life data from MTB databases compared to the Sar'Connect recommendations is relevant for exploring the benefits of such an mHealth app. Although our study was not designed to show any survival benefit, substantial data in the literature emphasize how critical the time interval is for the optimal management of patients with sarcoma [8,14,40-44].

mHealth app development is increasingly important, notably in oncology, and the opportunities offered by mHealth enable a wide range of issues to be addressed. For example, digital versions of patient reported outcomes (PROs), or e-PROs, are highly valuable tools in clinical research, and these data are easy to collect owing to their app. Indeed, in a lung cancer population, the use of PROs for symptoms combined with a clinically based algorithm led to an earlier diagnosis of relapse, with a median overall survival improvement of 6 months [45,46]. In palliative care, telemedicine and mHealth also improve symptom management for patients and families [47].

Other apps exist to promote the management of STT. For example, Sarculator predicts overall survival and metastatic risk in patients who undergo surgical resection because of validated nomograms [48]. Another example is Persarc, a recent mHealth app that helps experts debate STS cases through a mobile device [49]. Sar'Connect was inspired by these pioneering mHealth apps. All of these apps are already available and can easily be distributed to health professionals. Our study and those published for other apps show that a simple and user-friendly mHealth app can improve the management of patients with STS to improve the prognosis of this rare tumor.

Conclusion

This study showed a potential benefit of more than 7 months reduction when referring patients with sarcoma to expert centers using the mobile app Sar'Connect. Our mHealth app is an example in which digital health is a useful tool to reduce disparities in the optimal management for patients with sarcoma.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Supplementary materials.
[DOCX File , 776 KB - mhealth_v10i11e40718_app1.docx]

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Abbreviations

FSG: French Sarcoma Group
mHealth: mobile health
MRI: magnetic resonance imaging
MTB: multidisciplinary tumoral board
PRO: patient reported outcome
STS: soft tissue sarcoma
STT: soft tissue tumor

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Original Paper

Digital Coaching Using Smart Inhaler Technology to Improve Asthma Management in Patients With Asthma in Italy: Community-Based Study

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Abstract

Background: Reliance on short-acting β-2 agonists and nonadherence to maintenance medication are associated with poor clinical outcomes in asthma. Digital health solutions could support optimal medication use and therefore disease control in patients with asthma; however, their use in community settings has not been determined.

Objective: The primary objective of this study is to investigate community implementation of the Turbu+ program designed to support asthma self-management, including adherence to budesonide and formoterol (Symbicort) Turbuhaler, a combination inhaler for both maintenance therapy or maintenance and reliever therapy. The secondary objective is to provide health care professionals with insights into how patients were using their medication in real life.

Methods: Patients with physician-diagnosed asthma were prescribed budesonide and formoterol as maintenance therapy, at a dose of either 1 inhalation twice daily (1-BID) or 2 inhalations twice daily (2-BID), or as maintenance and reliever therapy (1-BID and reliever or 2-BID and reliever in a single inhaler), and they received training on Turbu+ in secondary care centers across Italy. An electronic device attached to the patients' inhaler for ≥90 days (data cutoff) securely uploaded medication use data to a smartphone app and provided reminders, visualized medication use, and motivational nudge messages. Average medication

adherence was defined as the proportion of daily maintenance inhalations taken as prescribed (number of recorded maintenance actuations per day or maintenance inhalations prescribed per day) averaged over the monitoring period. The proportion of adherent days was defined as the proportion of days when all prescribed maintenance inhalations were taken on a given day. The Wilcoxon test was used to compare the proportion of adherent days between patients in the maintenance regimen and patients in the maintenance and reliever regimen of a given dose.

Results: In 661 patients, the mean (SD) number of days monitored was 217.2 (SD 109.0) days. The average medication adherence (maintenance doses taken/doses prescribed) was 70.2% (108,040/153,820) overall and was similar across the groups (1-BID: 6332/9520, 66.5%; 1-BID and reliever: 43,578/61,360, 71.0%; 2-BID: 10,088/14,960, 67.4%; 2-BID and reliever: 48,042/67,980, 70.7%). The proportion of adherent days (prescribed maintenance doses/doses taken in a given day) was 56.6% (31,812/56,175) overall and was higher with maintenance and reliever therapy (1-BID and reliever vs 1-BID: 18,413/30,680, 60.0% vs 2510/4760, 52.7%; *P*<.001; 2-BID and reliever vs 2-BID: 8995/16,995, 52.9% vs 1894/3740, 50.6%; *P*=.02). Rates of discontinuation from the Turbu+ program were significantly lower with maintenance and reliever therapy compared with maintenance therapy alone (*P*=.01).

Conclusions: Overall, the high medication adherence observed during the study might be attributed to the electronic monitoring and feedback mechanism provided by the Turbu+ program.

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KEYWORDS

asthma control; asthma management; connected devices; digital health; eHealth; inhalers; maintenance and reliever therapy; mobile phone

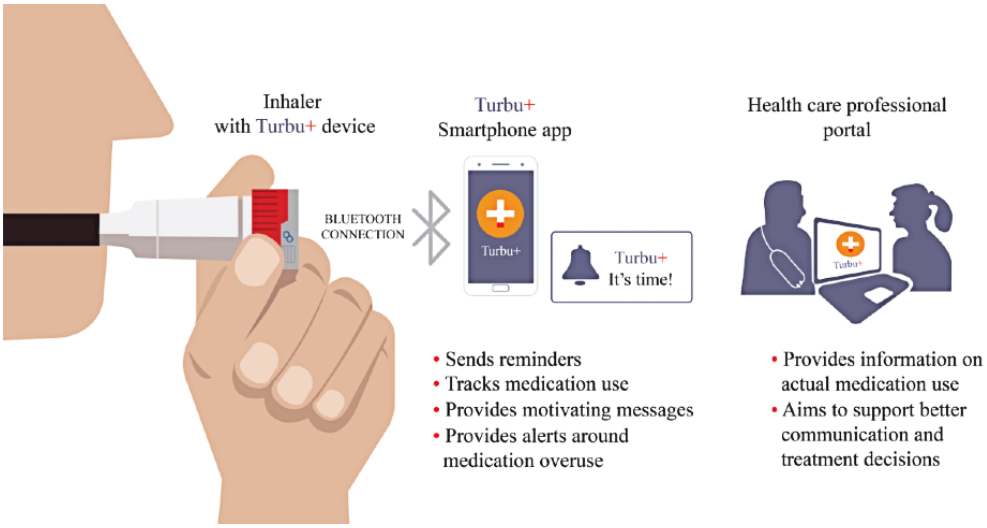
Introduction

Asthma control is suboptimal in approximately half of adult patients worldwide and is reflected by poorly controlled symptoms, impairment in daily activities, and increased use of health care resources [1-3]. Suboptimal asthma management can result from reliance on the use of short-acting β-2 agonists (SABAs) and poor adherence to prescribed medication, either intentionally (intelligent nonadherence) or unintentionally (erratic or unwitting nonadherence) [4-6]. Patients may also exhibit inconsistent patterns of adherence based on the presence or absence of symptoms (eg, underuse or total nonuse when asymptomatic) or on the types of medications prescribed (eg, overuse of SABA-reliever therapy and underuse of maintenance therapy) [5].

Overall, adherence to asthma medication is generally poor, with reported rates of nonadherence ranging from 30% to 70% [7], with adherence rates in community settings as low as 20%-30% [8-10]. Moreover, poor asthma control, including nonadherence to therapy, is associated with an increased risk of severe exacerbations, a reduction in health-related quality of life, and an increase in health care costs [2,11,12]. Consequently, there is a need for a more personalized and integrated approach to address this issue. Over the past decade, new technologies and innovations in digital health care have been introduced to support optimal medication use and disease management in patients with asthma. Notably, randomized controlled trials using these technologies have demonstrated the effectiveness of electronic medication use monitoring, including electronic reminders and feedback, in improving adherence and achieving asthma control [13-15]. However, the implementation of such technologies in community settings, where patients are not supported by the structure and commitment of a clinical trial, is yet to be determined.

One such innovative digital health technology is the Turbu+ program (Figure 1), which has been designed to improve adherence to prescribed therapy and increase asthma control, thereby supporting asthma management with budesonide and formoterol (Symbicort) Turbuhaler, a combination inhaler for both maintenance therapy or maintenance and reliever therapy (also known as maintenance and anti-inflammatory reliever therapy) in the community setting. The aim of the Turbu+ program is to assist patients in developing beneficial asthma self-management behaviors, either with their existing treatment or early in the use of a new treatment before less optimal patterns of inhaler use are established [16]. This can be achieved through digital coaching, with the provision of medication reminders [17,18], visualized medication use, and motivational messages [17] via Smartinhaler technology, which has been shown to improve adherence when compared with standard care as a part of asthma management [15]. Other research on attribute-framing effects reported more favorable responses to positive attribute frames than negative attribute frames, with positive frames evoking favorable associations in memory [19,20]. For example, results from a recent clustered, controlled pilot study of the Turbu+ program, which enrolled 80 patients in the Netherlands, reported that patients using Turbu+ were more likely to be adherent (4.5 times more likely to have a refill adherence of >80% prescribed; 95% CI 1.56-13.1) than those not using Turbu+. In patients with not well controlled asthma at baseline (Control of Allergic Rhinitis and Asthma Test scores <23 points), the odds of improvement after 6 months were 2.87 (95% CI 0.61-13.6) for the Turbu+ group compared with the control group [21]. In addition to supporting patients' asthma self-management, the Turbu+ program also provides health care professionals with objective information on when and how often patients use their medication, which reinforces mutual sharing of information and treatment decision making.

Figure 1. Digital technology used in the Turbu+ program (V2.1). Turbu+ device is manufactured by Adherium (NZ) Ltd.



Given the central role that treatment adherence plays in effective asthma control and the increasing importance of digital interventions in promoting engagement and self-management among users, we implemented the Turbu+ program in adult patients with asthma in Italy, where asthma is reported to affect approximately 2.5 million patients [22] and the rates of adherence to asthma therapy are low [23]. We hypothesized that the integration of asthma care into the everyday use of patients' own mobile phones would enhance engagement with self-management, thereby improving adherence and overall asthma control.

Methods

Study Design and Patient Population

This was a community-based study that used electronic monitoring (Turbu+ device) and feedback via the Turbu+ app. Patients with physician-diagnosed asthma who were prescribed or receiving treatment with budesonide and formoterol maintenance therapy at a dose of either 1 inhalation twice daily (1-BID) or 2 inhalations twice daily (2-BID) or budesonide and formoterol maintenance and reliever therapy (1-BID and reliever or 2-BID and reliever in a single inhaler, also referred to as Symbicort maintenance and anti-inflammatory reliever therapy) were enrolled in the Turbu+ program by pulmonologists and allergists in public and private secondary care centers across Italy. Practices were representative of Italy and distributed across the country. To minimize interference with usual care, there was no formal protocol for the Turbu+ program; therefore, each physician used a personalized approach. However, based on individual conversations between physicians and patients, patients were enrolled for a range of different reasons: (1) to monitor the effectiveness of the treatment; (2) to help transition patients, either gradually or immediately, from an inhaled corticosteroid (ICS) and long-acting β agonist (LABA) treatment and a SABA to budesonide and formoterol inhaler maintenance and reliever therapy; (3) to monitor the appropriate use of budesonide and formoterol as reliever therapy, instead of SABA, within the context of maintenance and reliever therapy; and (4) to improve asthma control by enabling physicians to use real-life Turbu+ data in their dialog with their patients. Physicians registered patients into the Turbu+ program, which triggered the generation of a link that was sent to the patients' email account. Patients could then download the app and log in.

In line with the noninterventional nature of this study design, minimal patient demographic information was collected (ie, age, sex, and treatment regimen). The data reported here are based on a statistical analysis of the aggregated and anonymized data captured by the Turbu+ program. The data underlying the findings described in this manuscript may be obtained in accordance with AstraZeneca's data sharing policy [24].

Inhaler Monitoring

Patients were provided with a Turbu+ device that could be attached to their Turbuhaler by their physicians. All patients received instructions on the Turbu+ program and the Turbu+ device. The device recorded the date and time of each inhalation and securely transferred use data to a companion smartphone app available to the patient and to a secure web-based portal accessible by the prescribing health care professional (Figure 1). Data management and storage were in line with General Data Protection Regulation (GDPR).

Inhaler Reminders, Visualized Medication Use, Motivational Messages, and Personalized Asthma Management Discussions

The smartphone app enabled patients to track their inhalations and provided reminders (both adjustable and customized for weekdays and weekends) and motivational nudge messages (VOICE messages) for missed inhalations and to encourage patients to adhere to their prescribed treatment (eg, "What, no symptoms? Use your inhaler to help stay that way," "Laugh louder, dance harder, run faster, help make asthma smaller," and "Your inhaler was developed with you in mind. Use it daily to help leave asthma symptoms behind."). The VOICE messages are short messages developed by Professor Rob Horne, University College London, by applying principles based on research into patient perceptions of treatment and drivers and barriers of treatment engagement [25]. In addition, the smartphone app provided tailored digital coaching that included updates on weekly medication use, alerts regarding treatment overuse, and changes to drug regimen or device utility messages

(eg, to turn Bluetooth on and the battery status of the Turbu+ device).

Changes in treatment regimens were uncommon and handled by the patients' physicians as per usual care. Only physicians were authorized to revise or update the treatment regimen in the smartphone app. However, the patients received a notification about the regimen change in the app. Data on the secure portal were available to physicians to support discussions on patterns of medication use between health care professionals and patients. Patients on multiple regimens or who changed treatment regimens during the study were excluded from the analysis.

Analysis Population and Adherence Calculations

Patients who had joined the Turbu+ program before November 11, 2018, and had been enrolled in the program for at least 90 days were included in the analysis. The analysis was restricted to a minimum of 90 days to provide a sufficient number of patients with an adequate follow-up period. Daily maintenance inhalations were 2 inhalations per day for the 1-BID and 1-BID and reliever regimens and 4 inhalations per day for the 2-BID and 2-BID and reliever regimens. For the purpose of analysis, the scheduled maintenance doses were calculated as the first 2 inhalations of budesonide and formoterol Turbuhaler taken (actuation recorded) each day (day was defined as the time from 12 AM to 11:59 PM) by patients prescribed 1-BID and reliever regimens and the first 4 inhalations of budesonide and formoterol Turbuhaler taken by those prescribed 2-BID and reliever regimens. As it was not possible to entirely distinguish between inhalations taken for maintenance and inhalations taken for reliever therapy, certain assumptions were made for the purpose of analysis. On the basis of the total number of inhalations per day, if the maintenance dose was exceeded, it was considered as a reliever dose. Average medication adherence, the proportion of adherent days, and full adherence and zero adherence days were all analyzed (definitions are provided in Table 1).

Adherence by morning or evening was not analyzed, but the average morning and evening medication use times were plotted. The day of the first inhalation was considered as day 1 for the analysis. Consequently, patients with a medication delay after commencement of use of the smartphone app (defined as the gap between the start of using the app and the start of the first medication) were not excluded from the analysis.

The number of high-use days (>12 inhalations per day) was analyzed. On the basis that adherence in the first few weeks of the Turbu+ program was expected to be higher compared with long-term use, adherence in the first 15 days (proportion of maintenance inhalations taken over this period) was used to categorize patients into low (0% to <70%), medium (70% to <90%), and high (≥90%) adherence groups. These cutoffs were chosen to obtain an approximately equal number of patients in each group (<70% was considered as low adherence). Kaplan-Meier curves were then computed starting from >15 days.

Kaplan-Meier curves were used to analyze discontinuation from the Turbu+ program over time, with discontinuation from the program defined as the last recorded treatment for a patient more than 30 days before the date of data cutoff; the discontinuation date was the date of the last dose. All other patients (ie, patients who continued to receive treatment during the last 30 days before data cutoff) were assumed to be continuing the treatment, and these patients were censored on the date of the last recorded dose intake. Discontinuation from the Turbu+ program merely meant that no data were received in the app, with patients potentially having the app closed; it did not automatically mean discontinuation of the medication inhaler.

Table 1. Adherence definitions used in the study.

Adherence	Definition
Average medication adherence	Proportion of daily maintenance inhalations taken as prescribed (number of recorded maintenance actuations per day/number of maintenance inhalations prescribed per day[a,b]) and averaged over the monitoring period
Fully adherent days	Proportion of days during which all prescribed maintenance inhalations were taken (ie, recorded as actuated) in a given day
Zero adherence day	No inhalations taken in a given day (ie, a zero-dose day)

[a]For the purpose of analysis, the scheduled maintenance inhalations were calculated as the first 2 inhalations of budesonide and formoterol Turbuhaler taken each day by patients prescribed 1 inhalation twice daily and a reliever and the first 4 inhalations taken by those prescribed 2 inhalations twice daily and a reliever.

[b]Day was defined as the time from midnight to 11:59 PM.

Statistical Analyses

Mean adherence was compared by using an analysis of variance model; adherence plots were based on moving averages, and the trend curves were smoothed using 3- or 5-day moving averages. The Wilcoxon test was used to compare the proportion of adherent days between patients in the maintenance regimen and patients in the maintenance and reliever regimen. A Cox model was designed to evaluate factors that most contributed to discontinuation of using the app. A *P* value of <.05, computed using the log-rank test, indicated that the differences among the Kaplan-Meier curves were statistically significant when compared using an analysis of variance model.

Results

Patient Demographics

Of the 1575 patients enrolled in the Turbu+ program, 661 patients who had been followed up in the program for ≥90 days (1-BID, n=56; 1-BID and reliever, n=361; 2-BID, n=44; and

2-BID and reliever, n=200) were included in the analysis (Table 2). Patients were aged between >18 years and <75 years, with the largest proportion of patients (165/661, 25.1%) aged between 46 years and 55 years. There was a similar proportion of female and male patients (female: 356/658, 54.1%; ranging from 45.5% to 64.3% across the 4 treatment groups).

Overall, the mean (SD) number of days monitored was 217.2 (SD 109.0) days: 1-BID: 235.7 (SD 126.0) days, 1-BID and reliever: 215.4 (SD 106.8) days, 2-BID: 181.9 (SD 104.4) days, and 2-BID and reliever: 223.0 (SD 107.8) days. The median (IQR) number of inhalations taken per day were as follows: 1-BID: 2 (IQR 1-2) inhalations, 1-BID and reliever: 2 (IQR 1-2) inhalations, 2-BID: 4 (IQR 2-4) inhalations, and 2-BID and reliever: 4 (IQR 2-4) inhalations.

Table 2. Demographic characteristics of patients who remained in the program for ≥90 days and who discontinued earlier. Patients with missing age or sex details were excluded.

Characteristic	<90 days[a]	≥90 days	*P* value[b]
Number of patients, n (%)	914 (58)	661 (42)	N/A[c]
Regimen, n (%)			<.001
1-BID[d]	137 (15)	56 (8.5)	
1-BID and reliever	491 (53.7)	361 (54.6)	
2-BID[e]	56 (6.1)	44 (6.7)	
2-BID and reliever	230 (25.2)	200 (30.3)	
Sex, n (%)			.66
Male	408 (44.6)	302[f] (45.9)	
Female	506 (55.4)	356[f] (53.9)	
Age (years), n (%)			<.001
<18	90 (9.9)	44 (6.7)	
18-25	186 (20.6)	91 (13.8)	
26-35	170 (18.8)	111 (16.9)	
36-45	151 (16.7)	117 (17.8)	
46-55	153 (16.9)	165 (25.1)	
56-65	96 (10.6)	86 (13.1)	
66-75	50 (5.5)	36 (5.5)	
>75	9 (1)	8 (1.2)	
Age group (years), n (%)			<.001
<36	446 (48.8)	246 (37.2)	
36-55	304 (33.3)	282 (42.7)	
>55	164 (17.9)	133 (20.1)	
Age group per sex (years), n (%)			<.001
Female			
<36	216 (23.6)	144[f] (21.9)	
36-55	188 (20.6)	149[f] (22.6)	
>55	102 (11.2)	63[f] (9.6)	
Male			
<36	230 (25.2)	102[f] (15.5)	
36-55	116 (12.7)	133[f] (20.2)	
>55	62 (6.8)	67[f] (10.2)	

[a]<90 days: patients who discontinued <90 days after the first dose.

[b]*P* values were based on analysis of variance tests for continuous variables and the chi-square test for categorical variables.

[c]N/A: not applicable.

[d]1-BID: 1 inhalation twice daily.

[e]2-BID: 2 inhalations twice daily.

[f]N=658.

Average Medication Adherence

Average medication adherence to maintenance treatment (maintenance doses taken/doses prescribed) showed similar trends across the 4 treatment groups over time (Figure 2; Multimedia Appendix 1). Overall, average medication adherence was 70.2% (108,040/153,820): 1-BID: 66.5% (6332/9520), 1-BID and reliever: 71.0% (43,578/61,360), 2-BID: 67.4%

(10,088/14,960), and 2-BID and reliever: 70.7% (48,042/67,980).

In exploratory analyses, the mean medication adherence was comparable for female and male patients (female, n=356, 70.8%; male, n=302, 69.9%; *P*=.65), with the lowest adherence observed in the youngest age group (Table 3). In addition, compared with other weekdays, adherence was lower on Fridays and weekends among all 4 treatment groups (Figure 3).

Figure 2. Average medication adherence by regimen and number of days in the program. Graphs are based on 5-day moving averages. Overall, the average medication adherence was 70.2% (1 inhalation twice daily [1-BID]: 66.5%, 1-BID and reliever: 71.0%, 2 inhalations twice daily [2-BID]: 67.4%, and 2-BID and reliever: 70.7%). 1-BID: 1 inhalation twice daily; 2-BID: 2 inhalations twice daily.

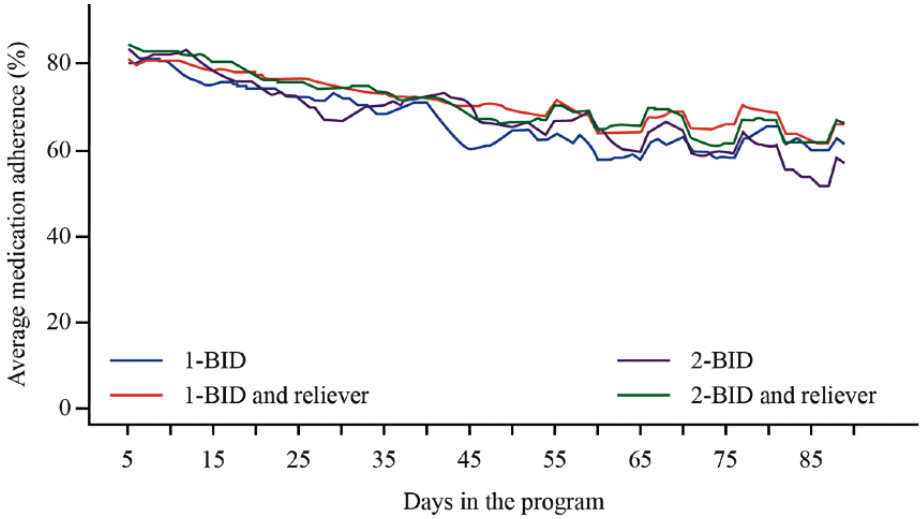


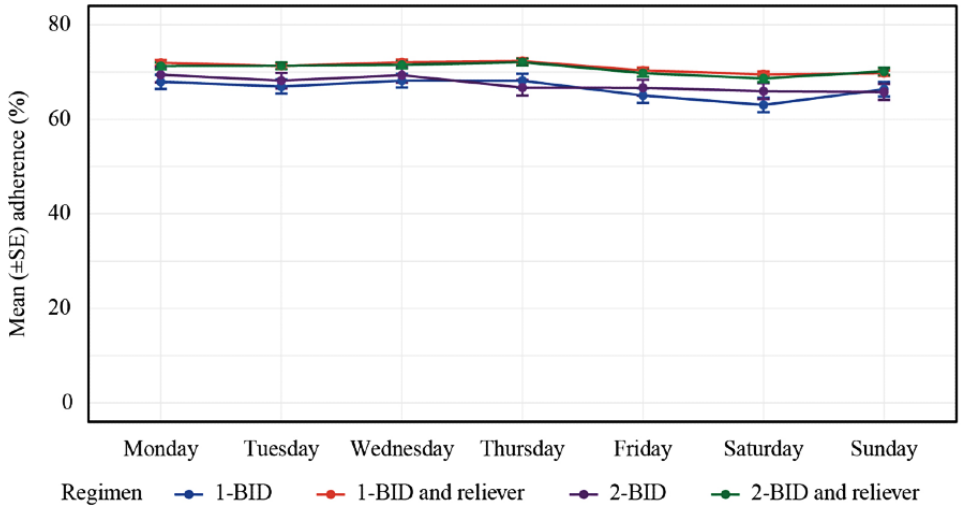
Table 3. Mean adherence by age and sex.

Characteristic	Patients, n	Percentage of adherence[a], mean (SD)	*P* value[b]
Sex			.65
Female	356	70.7 (23.1)	
Male	302	69.8 (25.7)	
Age (years)			.02
<18	44	60.3 (25.7)	
18-25	91	66.3 (24.3)	
26-35	111	69.7 (22.6)	
36-45	117	71.1 (24.5)	
46-55	165	73 (22.5)	
56-65	86	75.6 (25)	
66-75	36	67 (29.6)	
Age group (years)			.02
<36	246	66.8 (23.9)	
36-55	282	72.2 (23.3)	
>55	133	72.8 (26.4)	
Age group per sex (years)			.05
<36			
Female	144	66 (24.3)	
Male	102	67.8 (23.4)	
36-55			
Female	149	72.9 (21.8)	
Male	133	71.4 (25)	
>55			
Female	63	76 (21.7)	
Male	67	69.8 (30)	

[a]Adherence was restricted to patients with ≥90 days since the start of medication; data includes day 90.

[b]*P* values are based on analysis of variance tests for continuous variables and the chi-square test for categorical variables.

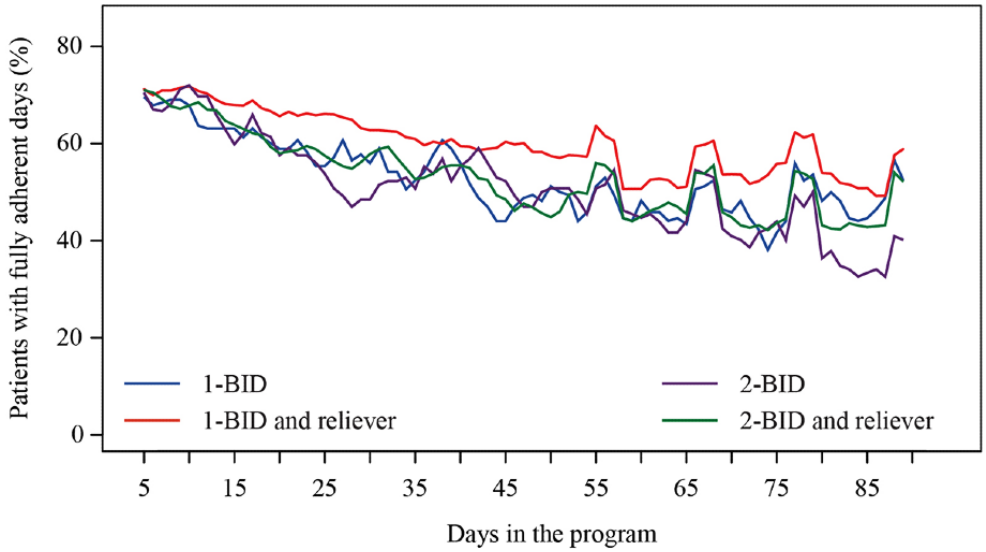
Figure 3. Adherence by weekday based on regimen. Data correspond to the mean per regimen and weekday during the first 90 days. 1-BID: 1 inhalation twice daily; 2-BID: 2 inhalations twice daily.



Proportion of Patients With Fully Adherent Days

The proportion of patients with fully adherent days (days during which all prescribed maintenance inhalations were taken) varied across the 4 treatment groups (Figure 4; Multimedia Appendix 2). The proportion of patients with fully adherent days was 56.6% (31,812/56,175) overall and was higher with maintenance and reliever therapy than with budesonide/formoterol maintenance therapy (1-BID and reliever vs 1-BID: 18,413/30,680, 60.0% vs 2510/4760, 52.7%, respectively; $P<.001$ and 2-BID and reliever vs 2-BID: 8995/16,995, 52.9% vs 1894/3740, 50.6%, respectively; $P=.02$).

Figure 4. Proportion of patients with fully adherent days, by regimen and number of days in the program. Graphs are based on 3-day moving averages. The mean number of fully adherent days were as follows: 1 inhalation twice daily (1-BID): 60.0%, 1-BID and reliever: 52.7%, 2 inhalations twice daily (2-BID): 52.9%, and 2-BID and reliever: 50.6%. 1-BID: 1 inhalation twice daily; 2-BID: 2 inhalations twice daily.



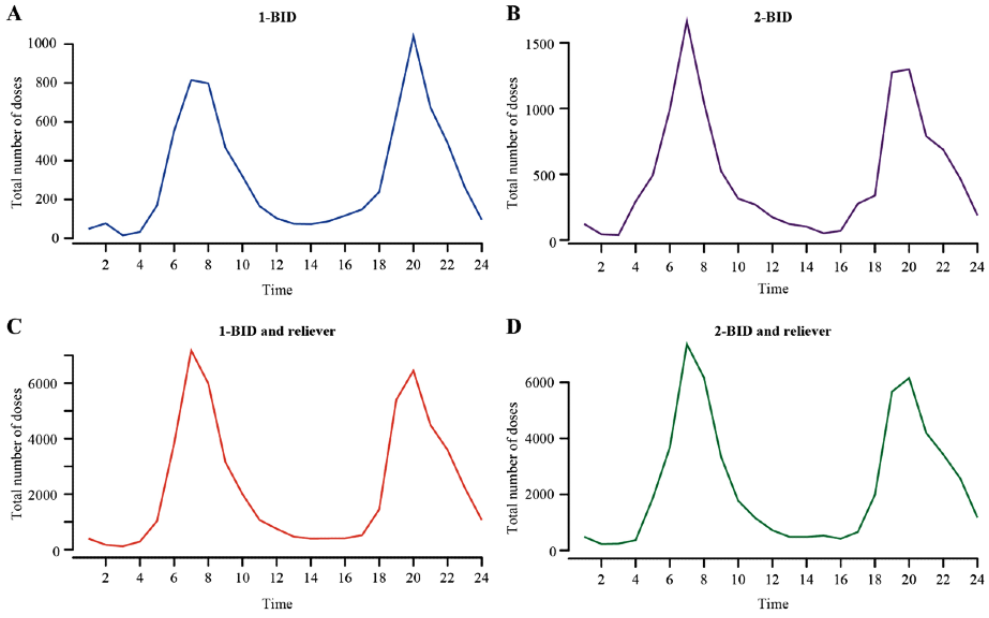
Proportion of Zero Adherence Days

Overall, the proportion of zero adherence days (no inhalations per day) was 17.0% (9534/56,175) and was similar between the treatment regimens: 1-BID and reliever versus 1-BID: 18.0% (5515/30,680) versus 19.7% (938/4760), respectively ($P=.07$); and 2-BID and reliever versus 2-BID: 14.5% (2462/16,996) versus 16.6% (619/3740), respectively ($P=.21$; Multimedia Appendix 3).

Inhalations Taken at Specific Times of the Day

For each regimen, the time of morning inhalation was generally between 6 AM and 10 AM and evening inhalation was between 6 PM and 10 PM (Figure 5).

Figure 5. Inhalations taken at specific time of the day (24-hour clock) during the first 90 days. The y-axis includes the total number of inhalations (ie, the sum of the number of maintenance and reliever inhalations taken) per given time point across all days in the 90-day period and across all patients. 1-BID: 1 inhalation twice daily; 2-BID: 2 inhalations twice daily.



High-Use Days

Of the 143,562 person-days in the program, the proportion of high-use days (>12 inhalations per day) was low (approximately 0.03/100 person-days). Overall, 24 patients recorded >12 inhalations per day on 42 days (mean 1.75 days; median 1 day, range 1-10 days; Multimedia Appendix 4; Table 4). Many high-use days occurred in the first week (17 of the 42 high-use days occurred between days 1 and 4).

Table 4. High-use days: >12 inhalations a day (any day).

Regimen	Patients (N=661)	Days	Person-days
	n (%)	n (%)	n
1-BID[a]	1 (0.15)	3 (0.02)	13,198
1-BID and reliever	10 (1.51)	12 (0.02)	77,764
2-BID[b]	3 (0.45)	3 (0.04)	8004
2-BID and reliever	10 (1.51)	24 (0.05)	44,596

[a]1-BID: 1 inhalation twice daily.

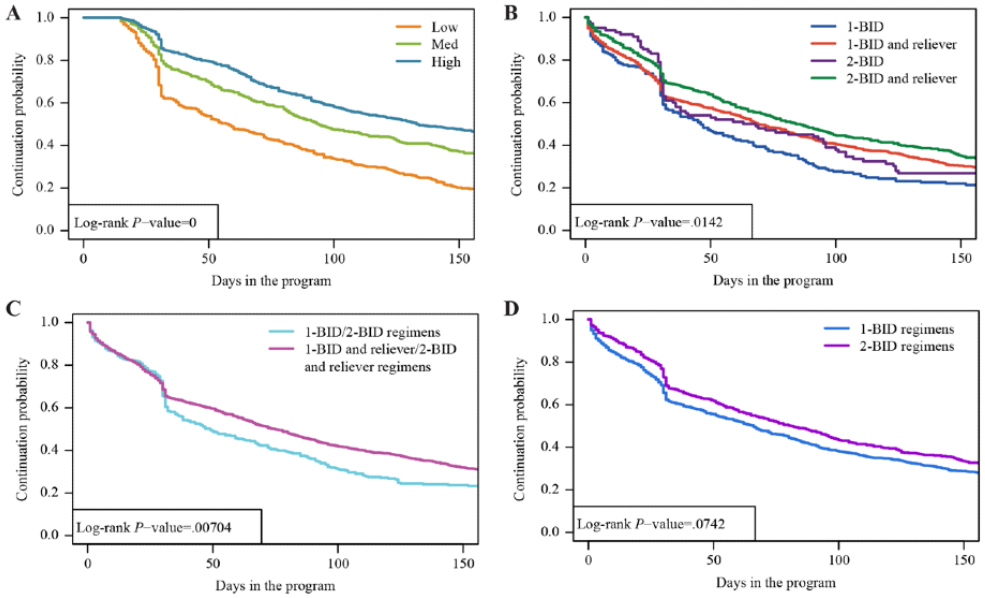
[b]2-BID: 2 inhalations twice daily.

Discontinuation From the Turbu+ Program

Of all the patients enrolled in the Turbu+ program, patients who were categorized in the low adherence group in the first 15 days of the program discontinued the Turbu+ program at much faster rates up to day 30 compared with patients categorized in the medium adherence and high adherence groups. A sharp increase in discontinuation from the Turbu+ program was observed between days 30 and 40. After day 30, the discontinuation rates were similar across the 3 adherence groups (Figure 6). Overall, the rates of discontinuation from the program were significantly higher with maintenance therapy alone than with maintenance and reliever therapy (Figure 6B and 6C). Discontinuation rates were similar in the 1-BID and 2-BID regimens (Figure 6D). For those patients receiving maintenance and reliever therapy, similar proportions within each treatment group continued in the program after 90 days compared with patients who discontinued earlier than 90 days (1-BID and reliever: 361/661, 54.6% vs 491/914, 53.7%; 2-BID and reliever: 200/661, 30.3% vs 230/914, 25.2%; Table 2).

Treatment regimen and sex did not affect the overall discontinuation from the Turbu+ program. However, patient age and adherence in the first 15 days had a significant effect. Patients in the <36 years age group were more likely to discontinue the program than those in the ≥36 years age group (36-55 years: hazard ratio [HR] 0.75; 95% CI 0.66-0.86; P<.001 and >55 years: HR 0.76; 95% CI 0.64-0.90; P=.001). Likewise, patients categorized in the low adherence group were more likely to discontinue the program than those categorized in the medium adherence (HR 0.63; 95% CI 0.54-0.73; P<.05) or high adherence (HR 0.50; 95% CI 0.43-0.58; P<.05) groups (Multimedia Appendices 5 and 6).

Figure 6. Time to discontinuation from the Turbu+ program, (A) by adherence group in the first 15 days (low, medium, or high) and (B, C, and D) by regimen. Low: n=385; medium: n=419; high: n=512 (patients with <15 days of follow-up were excluded from this analysis). 1-BID: 1 inhalation twice daily; 2-BID: 2 inhalations twice daily.



Discussion

Principal Findings

The Turbu+ program, designed to support asthma self-management and adherence to budesonide and formoterol Turbuhaler in a community setting, reported an average medication rate of 70%. This program conforms to the high-quality real-life respiratory research recommendations of the Respiratory Effectiveness Group [26]. There was no formal protocol for enrollment in the Turbu+ program; instead, physicians used a personalized approach to recruitment based on individual conversations between physicians and patients. Patients were enrolled for a multitude of reasons, taking patients' individual needs and preferences into consideration. This enabled patients to develop the knowledge and skills required to effectively manage and make informed decisions about their asthma. There is a wealth of evidence highlighting that a patient's ability to self-manage asthma improves clinical outcomes, patient satisfaction, and quality of life [27].

The implementation of the Turbu+ program in patients with asthma in Italy was continued for more than 90 days in over 600 patients across a wide range of age groups, suggesting that, for those who engaged in the program, it was well accepted and feasible for use by adolescents and young adults through to older adults. Moreover, to the best of our knowledge, this is the first study to provide detailed patterns of daily use of budesonide and formoterol maintenance therapy or budesonide and formoterol maintenance and reliever therapy in a real-life community setting.

The adherence rate observed in this study was considerably higher than that generally reported in Italy [22,23]. Results from the cross-sectional phase of the PRISMA (Prospective Study on Asthma Control) study, which investigated the level of asthma control in 2853 patients recruited from 56 respiratory clinics in Italy, indicated that although 64.4% of patients had controlled asthma, over one-third of patients were still uncontrolled or partly controlled. The main reason for poor asthma control, as indicated by the treating physicians, was low adherence to treatment in 43.3% of patients [23]. Similarly, the majority of 174 Italian allergists who completed a survey that was available on the website of Società Italiana di Allergologia, Asma Immunologia Clinica between April 2015 and October 2015 considered poor adherence to therapy to be an important cause of symptom worsening, with 37% believing that it was the prevalent cause [22]. The adherence rates observed in our study were generally higher than those reported in other studies, where low adherence rates to ICS and LABAs have generally been reported. Indeed, results from an observational study based on the Veneto region Drug Regulatory Agency database in Italy reported suboptimal adherence (defined as <80% prescriptions issued) in 57.6% of patients with asthma prescribed ICS and LABA in a 6-month period before the start of biologic treatment [28]. Using the same threshold of <80% prescriptions, 62.4% of patients prescribed combined ICS and LABA inhalers over the previous 12 months had suboptimal adherence in a retrospective observational study in the United Kingdom [29]. Results from a multinational, real-world observational study in Europe showed that only 34.4% of patients receiving ICS and LABA therapy reported high adherence (score=8) based on the Morisky Medication Adherence Scale questionnaire over a 3-month period [30]. However, results from another retrospective new-user active-comparator database study, using the IQVIA Medical Research Database in the United Kingdom, reported treatment persistence for ICS and LABA therapies ranging from 53% to 69% at 12 months, depending on the inhaler used [31]. Although direct comparisons of adherence rates with other studies could not be made because of variations in the measurement of adherence calculations, differences in study designs and duration, and the innovative community design of this study, our study results demonstrate that the use of the Turbu+ program, through the provision of reminders, visualized medication use, and motivational messages to patients as part of digital coaching, improves adherence (>70%) to inhaled medications. Because targeting adherence interventions to patients with the most to gain may improve asthma outcomes and optimize cost-effectiveness [32], further research is required to determine who will benefit most from the Turbu+ program. In addition, an evaluation of the cost-effectiveness of the Turbu+ program in the community setting may be required to ensure its widespread adoption. Recent work undertaken by the @IT-2020 project reported high rates of adherence using a blended care approach (face-to-face visits with internet-based support technologies) in patients from Italy with seasonal allergic rhinitis [33]. Incorporating such a blended approach with the Turbu+ program may further improve adherence.

Overall, a large proportion of patients (n=914) did not continue in the Turbu+ program for 90 days or more. The sharp increase in discontinuation from the Turbu+ program observed between days 30 and 40 was likely due to the fact that patients were transitioning to another inhaler, as most devices contain a month's supply of medication. However, it is important to note that anecdotal evidence indicated that some physicians used the Turbu+ program only for a limited period to assess clinical effectiveness and appropriate use of budesonide and formoterol maintenance and reliever therapy, and once reassured about the appropriateness of treatment, they agreed that patients could discontinue the Turbu+ program. The long-term Turbu+ program used in this analysis may not appeal to all patients or its design may not be engaging enough to encourage enduring use. Additional features, such as symptom tracking to encourage asthma self-management, may have resulted in greater engagement with the program. However, data generated from the patients who discontinued from the Turbu+ program provide valuable information for future research to understand what could be done to increase user engagement to improve patient retention in the program.

Indeed, the results demonstrated that lower levels of adherence in the first 2 weeks and younger age (<36 years) were predictors of patient discontinuation from the Turbu+ program. This reinforces the need for clinicians to spend more time with their patients during the early weeks, especially with the younger patient population, to assess medication use and establish the right patient behavior early on in a new treatment [16]. Moreover, the rapid identification of patients with poor adherence enables early interventions by clinicians that could

reduce the risks associated with long-term poor adherence, such as exacerbations and subsequent increased health care utilization [2,11,12], thereby improving asthma outcomes. The web-based portal provided physicians with objective, detailed, and valuable insights into their patients' medication use versus the prescribed regimen, thereby ensuring that subsequent conversations were based on their actual medication use. Although the frequency with which clinicians viewed the medication use data was not assessed in this study, the ability to access such information via the secure web-based portal would be advantageous in this regard.

Although female patients have a greater number of physician visits and, thus, a higher likelihood of having an asthma action plan than male patients [34], studies exploring the relationship between sex and adherence to asthma treatment have provided conflicting results [35,36]. Similarly, this study failed to find any significant difference between the sexes, with mean medication adherence rates similar between male and female patients enrolled in the Turbu+ program. However, as expected, a decrease in adherence was generally observed on weekends, thereby confirming previous reports that weekends and holidays disrupt medication routines [5,37].

Interestingly, the proportion of fully adherent days was higher and the rates of discontinuation from the Turbu+ program were lower with maintenance and reliever therapy than with maintenance therapy alone. This may demonstrate a preference for a patient-centric regimen that enables patients to engage with their treatment and condition. This is in line with the findings of the findings of the PRACTICAL (PeRsonalised Asthma Combination Therapy: with Inhaled Corticosteroid And fast-onset Long-acting beta agonist) study, a randomized controlled trial that assessed patients' preferences for symptom-driven maintenance plus reliever treatment or regular maintenance treatment in patients with mild to moderate asthma [38]. Overall, a significantly higher proportion of patients randomized to maintenance and reliever therapy preferred their therapy than those randomized to maintenance therapy alone. This finding further demonstrates patients' preference for rapid symptom relief and flexible regimens over which they are in control, highlighting the importance of symptom-driven medication use in addition to medication adherence [38]. In this study, however, it was not possible to entirely distinguish between inhalations taken for maintenance and reliever therapy, as this information was not recorded by the patients.

The Turbu+ program helped patients follow a regular schedule of medication, as evidenced by the majority of fixed inhalations being taken between 6 AM and 10 AM and between 6 PM and 10 PM. Reassuringly, the Turbu+ program can provide information on the potential overuse of medication. Furthermore, only 24 patients recorded >12 inhalations per day with a mean of 1.75 day, indicating that the risk of overuse was minimal. High-use days were more common during the first week of use, possibly due to higher patient engagement on account of the novelty factor or potentially due to patient experimentation with the device to enhance understanding, which may have resulted in a higher number of actuations being registered in the app (it cannot be definitively concluded that patients actually took the medication). However, the number of high-use days gradually decreased and stabilized after the first 2 weeks.

Limitations

The uniqueness of the design of this community-based Turbu+ program may have led to some of its limitations. Patients enrolled in the Turbu+ program for less than 90 days were excluded from the analysis to enable an examination of changes in patient behavior and its effect on adherence and asthma control after 90 days in the program. Reasons for discontinuation were not collected from those who discontinued from the Turbu+ program before 90 days; therefore, data for those patients who may have continued with their medication but discontinued from the Turbu+ program were also not captured. Data from the first 15 days in the program were excluded from the analysis to account for learning the program and technology. Limited baseline data were available on patient demographic and clinical characteristics because it was not part of the design of this physician-led program conducted in community-based clinical settings. Given that misdiagnosis of asthma is commonly reported, in part due to underuse of spirometry, it may have been beneficial to evaluate patients to accurately define their disease and to identify any symptoms caused by other factors before enrollment in the Turbu+ program [39-42]. Although the study population is suggestive of patients with moderate-to-severe asthma (Global Initiative for Asthma steps 3-5), formal asthma severity was not captured in the database. As a result of the study design, sizes of the treatment groups were not homogeneous; there were fewer patients receiving maintenance therapy alone compared with those receiving maintenance and reliever therapy. In addition, the strength of the doses was not captured. There was also a lack of randomization and the absence of a control or comparator group. Baseline adherence data at the start of using the Turbu+ program and reasons for adherence or nonadherence were not collected. Consequently, it is not known whether patient adherence was modified following enrollment in the Turbu+ program. However, these limitations are not unexpected, given the numerous challenges that have been previously observed in recruitment for studies using mobile phone technology, highlighting the need to pilot the recruitment process and design such trials accordingly [43]. However, with recent advances and the adoption of digital health technology during the COVID-19 pandemic, recruitment challenges in future studies may not be an issue.

Conclusions

To the best of our knowledge, this is the first study to investigate the community implementation of the Turbu+ program and provide real-life information on the use of budesonide and formoterol Turbuhaler in over 600 patients who had been enrolled in the program for at least 90 days. The Turbu+ program provided patients with an effective tool to improve self-management of their asthma by tracking medication use and providing them with reminders and motivational messages. It provided health care professionals insights into their patients' medication use, which supported treatment optimization and facilitated conversation between the health care professional and the patient. Additional prospective research on the Turbu+

program is required to understand who would benefit the most from this type of community-based adherence support and how to enhance user engagement. A longer follow-up period and an evaluation of asthma-related outcomes will further determine the contribution of the Turbu+ program in optimizing asthma outcomes.

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Authors' Contributions

JWHK contributed to the study design, interpretation of results, and review of the manuscript. All authors contributed to the acquisition and interpretation of the data, provided critical review of the important intellectual content of the manuscript, and approved the final version of the manuscript.

Conflicts of Interest

GR, CC, GV, and RC have no conflicts of interest to disclose. GWC reports having received research grants as well as being a lecturer or having received advisory board fees from A. Menarini, ALK-Abelló, Allergy Therapeutics, AstraZeneca, Boehringer Ingelheim, Chiesi Farmaceutici, Genentech, Guidotti-Malesci, GlaxoSmithKline, Hal Allergy, Mylan, Merck, Merck Sharp & Dohme, Mundipharma, Novartis, Regeneron, Roche, Sanofi-Aventis, Sanofi-Genzyme, Stallergenes-Greer, UCB Pharma, Uriach Pharma, Valeas, and Vibor-Pharma. JMF has received fees from AstraZeneca for participation in a steering committee meeting and from AstraZeneca; Boehringer Ingelheim; and the National Prescribing Service Ltd, Australia, for providing independent educational presentations in the last 12 months. NHC's department has received grants from Novartis, Boehringer Ingelheim, and AstraZeneca. ER is an employee of AstraZeneca. JWHK reports grants, personal fees, and nonfinancial support from AstraZeneca and Boehringer Ingelheim; grants and personal fees from Chiesi Farmaceutici and Novartis; grants, personal fees, and nonfinancial support from GlaxoSmithKline; and grants from Mundipharma and TEVA outside the submitted work. JWHK also holds 72.5% of shares in the General Practitioners Research Institute. FB reports having received grants for lectures or advisory boards from A. Menarini, AstraZeneca, Boehringer Ingelheim, Chiesi Farmaceutici, Guidotti-Malesci, GlaxoSmithKline, Merck Sharp & Dohme, Mundipharma, Novartis, Sanofi-Genzyme, Valeas, and Dompè.

Multimedia Appendix 1
Average medication adherence, by regimen and time. Graphs are based on 5-day moving averages. The dotted lines show the spread of data (±SE). 1-BID: 1 inhalation twice daily; 2-BID: 2 inhalations twice daily.
[PNG File , 179 KB - mhealth_v10i11e25879_app1.png]

Multimedia Appendix 2
Proportion of patients with fully adherent days, by regimen and days in the program. Graphs are based on 3-day moving averages. The dotted lines show the spread of data (±SE). 1-BID: 1 inhalation twice daily; 2-BID: 2 inhalations twice daily.
[PNG File , 255 KB - mhealth_v10i11e25879_app2.png]

Multimedia Appendix 3
Proportion of patients with zero adherence days, by regimen and days in the program. Graphs are based on 5-day moving averages. The dotted lines show the spread of data (±SE). 1-BID: 1 inhalation twice daily; 2-BID: 2 inhalations twice daily.
[PNG File , 198 KB - mhealth_v10i11e25879_app3.png]

Multimedia Appendix 4
High-use days: a histogram of >12 inhalations a day (any day). This includes all patients, and one patient may be considered multiple times if he/she exceeded >12 inhalations for >1 day.
[PNG File , 45 KB - mhealth_v10i11e25879_app4.png]

Multimedia Appendix 5
Cox model evaluating factors that contributed the most to discontinuation from the Turbu+ program. *P<.01; **P<.001; 1-BID: 1 inhalation twice daily; 2-BID: 2 inhalations twice daily; High=High adherence (≥90%) at day 1 to day 15 in the program; Medium=medium adherence (70%-<90%) at day 1 to day 15 in the program.

[PNG File , 150 KB - mhealth_v10i11e25879_app5.png]

Multimedia Appendix 6
Cox model evaluating factors that contributed the most to discontinuation from the Turbu+ program.
[DOCX File , 15 KB - mhealth_v10i11e25879_app6.docx]

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Abbreviations

1-BID: 1 inhalation twice daily
2-BID: 2 inhalations twice daily
GDPR: General Data Protection Regulation
HR: hazard ratio
ICS: inhaled corticosteroid
LABA: long-acting β agonist
PRACTICAL: PeRsonalised Asthma Combination Therapy: with Inhaled Corticosteroid And fast-onset Long-acting beta agonist
PRISMA: Prospective Study on Asthma Control
SABA: short-acting β-2 agonist

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Original Paper

The Effects of an Exposure-Based Mobile App on Symptoms of Posttraumatic Stress Disorder in Veterans: Pilot Randomized Controlled Trial

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Abstract

Background: Barriers to accessing in-person care can prevent veterans with posttraumatic stress disorder (PTSD) from receiving trauma-focused treatments such as exposure therapy. Mobile apps may help to address unmet need for services by offering tools for users to self-manage PTSD symptoms. Renew is a mobile mental health app that focuses on exposure therapy and incorporates a social support function designed to promote user engagement.

Objective: We examined the preliminary efficacy of Renew with and without support from a research staff member compared with waitlist among 93 veterans with clinically significant PTSD symptoms. We also examined the impact of study staff support on participant engagement with the app.

Methods: In a pilot randomized controlled trial, we compared Renew with and without support from a research staff member (active use condition) with waitlist (delayed use condition) over 6 weeks. Participants were recruited through online advertisements. The Posttraumatic Stress Disorder Checklist for Diagnostic and Statistical Manual of Mental Disorders, fifth edition (DSM-5) was used to measure PTSD symptoms at pre, post, and 6-week follow-up. Usage data were collected to assess engagement with Renew.

Results: Results indicated a small effect size (d=–0.39) favoring those in the active use conditions relative to the delayed use condition, but the between-group difference was not significant (*P*=.29). There were no differences on indices of app engagement between the 2 active use conditions. Exploratory analyses found that the number of support persons users added to the app, but not the number of support messages received, was positively correlated with app engagement.

Conclusions: Findings suggest Renew may hold promise as a self-management tool to reduce PTSD symptoms in veterans. Involving friends and family in mobile mental health apps may help bolster engagement with no additional cost to public health systems.

Trial Registration: ClinicalTrials.gov NCT04155736; https://clinicaltrials.gov/ct2/show/NCT04155736

(JMIR Mhealth Uhealth 2022;10(11):e38951) doi:10.2196/38951

KEYWORDS

posttraumatic stress disorder; veteran's health; exposure therapy; cognitive behavioral therapy; mHealth; mobile apps; self-management

Introduction

Posttraumatic stress disorder (PTSD) is an often chronic and debilitating condition associated with psychiatric and physical comorbidities, functional impairments [1], and elevated health care utilization [2]. PTSD affects a significant minority (8%) of the general US population. An estimated 14% of veterans returning from Iraq and Afghanistan meet the diagnostic criteria for PTSD [3] and an additional 7.6% experience clinically significant symptoms that warrant intervention but do not meet diagnostic criteria [4].

Trauma-focused psychotherapy (ie, therapy that addresses traumatic memories and trauma-related appraisals and includes exposure or cognitive restructuring as a primary therapeutic component) is recommended as the first-line treatment for veterans with PTSD [5]. However, not all veterans with clinically significant symptoms of PTSD are willing or able to access this kind of care. A lack of trained providers, logistical barriers (eg, travel for in-person care), and concerns about stigmatization may prevent veterans from receiving these gold-standard interventions [6]. Mobile mental health apps that include trauma-focused techniques may be able to overcome these barriers and increase the reach of such effective intervention approaches.

Mobile mental health apps have proliferated in recent years and are accessible to the 97% of US adults who now own smartphones [7]. They can provide anonymous, on-demand intervention 24/7 at very low cost. However, despite the growing number of mobile mental health apps, apps targeting PTSD are less common, and more evidence testing the efficacy of apps addressing PTSD symptoms is needed [8,9].

The most well-supported app for PTSD is PTSD Coach, a self-management tool designed to help users cope with symptoms of PTSD. PTSD Coach has been evaluated in 3 randomized controlled trials (RCTs) to date. A small initial pilot compared 8 weeks of PTSD Coach use with and without clinician coaching in a small sample of veterans and found that both groups experienced reductions in PTSD symptoms, with a medium effect size (d=0.54) favoring coaching but no statistically significant group differences (P=.02; N=20; [10]). The next pilot trial compared 1 month of app use with waitlist among community members with elevated PTSD symptoms (N=49) and found a small effect favoring PTSD Coach (d=0.25) that did not reach statistical significance (P≥.05) [11]. The third trial examined 12 weeks of app use among community members with elevated PTSD symptoms (N=120) and found that participants who received PTSD Coach showed significantly greater reductions in symptoms compared with waitlist, (P=.035) with improvements maintained at the 3-month follow-up (P=.113) [12]. However, differences between the PTSD Coach group and waitlist were not significant (P≥.05) at the postintervention period.

Aside from studies of PTSD Coach, another RCT provided service members with moderate PTSD symptoms (N=144) access to several mobile apps that included psychoeducation, social engagement, and relaxation exercises. Participants then received either a 6-week cognitive behavioral program designed to promote app use or 6 weeks of daily inspirational SMS text messages [13]. There were no differences between groups; both groups showed reductions in PTSD that were maintained at 3-month follow up, but deteriorated slightly 6-12 months later.

In summary, mobile apps may be useful for individuals with PTSD symptoms, whether used alone or with coaching, but current evidence is relatively weak and limited to only a few RCTs. Currently, PTSD Coach is the only app for PTSD with evidence to support its use as a stand-alone self-management tool. However, because PTSD Coach does not directly address thoughts, feelings, or memories of the traumatic event(s) through exposure or cognitive restructuring, it is not a trauma-focused intervention.

The most studied trauma-focused treatment for PTSD is exposure therapy. Exposure therapy involves approaching the traumatic memory (imaginal exposure) or trauma-related situations and stimuli in real life (in vivo exposure). Extensive evidence supports exposure therapy's efficacy for treating PTSD in a range of trauma survivors [14]. It is also underutilized by mental health providers because many providers believe exposure therapy is more difficult for patients to tolerate than other evidence-based treatments [15,16], although this perception is not supported by empirical evidence [17,18]. Exposure has been implemented successfully in web-based interventions, including cognitive behavioral programs with written imaginal exposure [19-22], in vivo exposure [23], and both [24]. However, despite promising findings from web-based interventions, a recent review found that fewer than 10% of all mobile apps targeting PTSD include any exposure component [8], and to our knowledge, no studies have examined the efficacy of PTSD self-management apps that use exposure techniques. An important question, then, is whether apps that include exposure therapy exercises can reduce PTSD symptoms.

Sustained user engagement is a key challenge with all mobile mental health apps [25]. Most apps show a steep reduction in usage after download, with only 1%-5% of users continuing to use the app after 30 days [26]. Human feedback can provide guidance, emotional support, and encouragement to increase accountability and engagement with app-based interventions [27-29]. Studies suggest that telephone support from trained peer coaches [30] or clinicians [31] may improve engagement with PTSD Coach. However, use of trained support personnel limits scalability of such interventions due to challenges associated with training, supervising, and monitoring coaches. Thus, another unanswered question is whether support from a friend or a family member can provide the same benefit.

To address these research gaps, we developed Renew, an exposure-based self-management mobile app for PTSD that includes a peer support component. We recently demonstrated the feasibility and acceptability of Renew in a small study of 18 adults who had experienced a traumatic event [32]. Qualitative data from this study suggested that users who were motivated to work independently to manage their PTSD felt the app would be helpful in reducing symptoms. Building on this initial study, this RCT aimed to assess the preliminary efficacy of Renew in reducing PTSD symptoms for veterans with PTSD, as well as examine the impact of the support component on app

engagement. We hypothesized that veterans who used Renew for 6 weeks (*active use condition*) would show greater reductions in PTSD symptoms relative to the *delayed use condition*, and that those who were assigned to receive support from project staff (*support condition*) would show greater app engagement than those who were not provided with a support person (*no support condition*). We also explored relationships between indices of support (number of peer support persons added to the app and number of support messages received from peer supporters) and indices of app engagement (time spent using the app, time spent using exposure components of the app, and number of points gained in the app, as a proxy for activity completion).

Methods

Description of the Renew App

Renew is a self-management app for symptoms of PTSD. Renew is unique from PTSD Coach in that it was designed to treat PTSD symptoms, whereas PTSD Coach was designed to help people manage and reduce acute experiences of distress. Renew was developed by Vertical Inc. and is owned by the Department of Veterans Affairs. An initial build of the app was revised using feedback from volunteers who had experienced a traumatic event during a small feasibility and usability study of Renew [32].

The app includes 2 primary exposure components, namely, *process* and *approach*. Both include a rationale, detailed instructions, and examples, with prompts for users to provide a 0-100 subjective unit of distress (using the Subjective Units of Distress Scale [SUDS]) rating before and after each activity. *Process* guides users through imaginal exposure (ie, approaching trauma memories through imagination) using a series of writing prompts. In this activity, users describe their worst traumatic event for at least 20 minutes, using either their phone keyboard or the talk-to-text function. *Approach* guides users through in vivo exposure by identifying real-life situations they have been avoiding due to their trauma and building a hierarchy of situations for them to approach.

A *learn* section includes psychoeducation about common reactions to trauma, the development of PTSD symptoms, the role of avoidance in maintaining symptoms, and the science behind exposure therapy techniques. The *self-care* section allows users to identify and schedule self-care activities that promote relaxation, physical activity, and social engagement. *Support* allows users to invite trusted friends or family members to be part of their support team in Renew. Support persons are invited to download “Renew Support” (available on Apple and Android smartphones), which provides psychoeducation about PTSD symptoms and information on how to support someone who is working on managing PTSD symptoms. Support team members receive notifications when the primary user earns points or achieves a new level and are instructed to send an encouraging message through the app’s 1-way message system. *Motivate* allows users to personalize the app by selecting quotes, videos, and images that motivate them to work on managing their PTSD symptoms. Users may add their own or select from Renew’s built-in options. In *progress*, users can complete a 5-item “symptom tracker” assessing coping self-efficacy, depression, and PTSD symptoms. Users can view the results of these assessments, as well as the SUDS data from *process* and *approach*, over time in a graph view (Figures 1-6). Renew prompts users to complete assessments every 2 weeks.

In addition to the main sections, Renew includes elements of gamification: users earn points for completing activities in the app and can level up to unlock new features and activities. Crisis resources are also listed in the app. Users can turn on daily notifications and receive reminders to use Renew.

Figure 1. Sample screenshot of the Renew app home screen. The home screen displays the 6 primary components of the app. During onboarding, the "Begin" button takes users to a short, animated video that outlines the features of Renew and the rationale behind exposure as an approach to managing posttraumatic stress.

Figure 2. Sample screenshots of the Renew app—*support*. The image on the left displays some of the explanation of the *support* feature in Renew. The image on the right displays an example of the messages a user might see from one of their *support* team members in response to usage notifications.

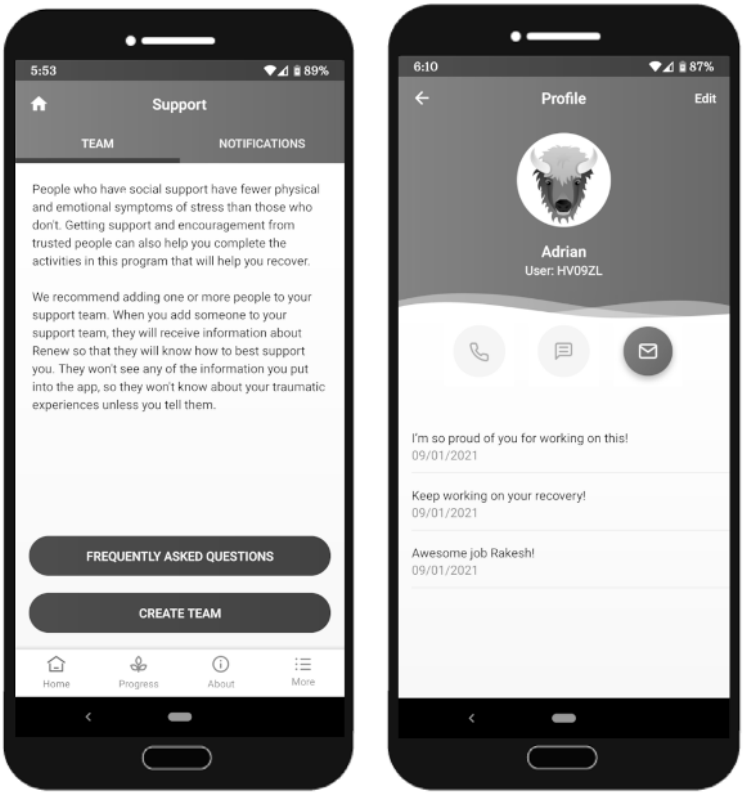


Figure 3. Sample screenshot of the Renew app—*process*. This image shows the writing prompts available to users. Prompts are unlocked as the user progresses in the program.

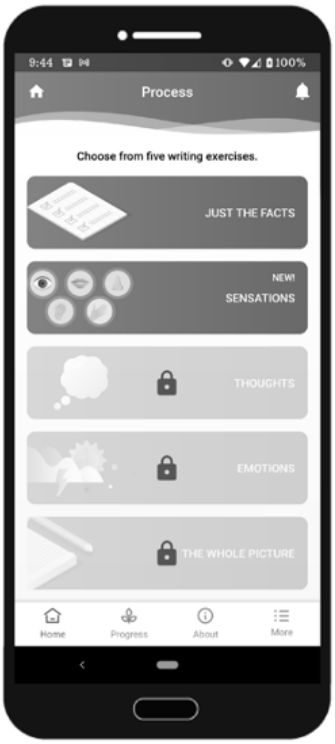


Figure 4. Sample screenshot of the Renew app—*process*. This image shows a portion of the instructions shown to users after clicking on the writing prompt sections.

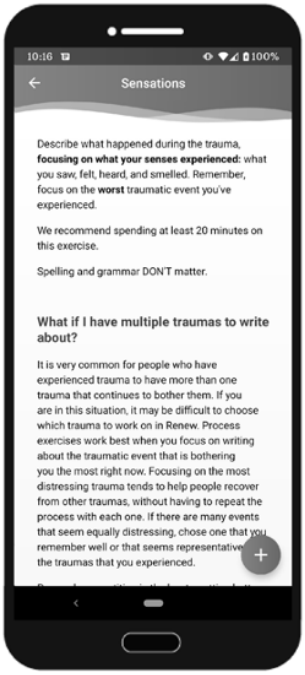


Figure 5. Sample screenshot of the Renew app—*approach*. This image shows some of the instructions shown to users in the *approach* section of the app.

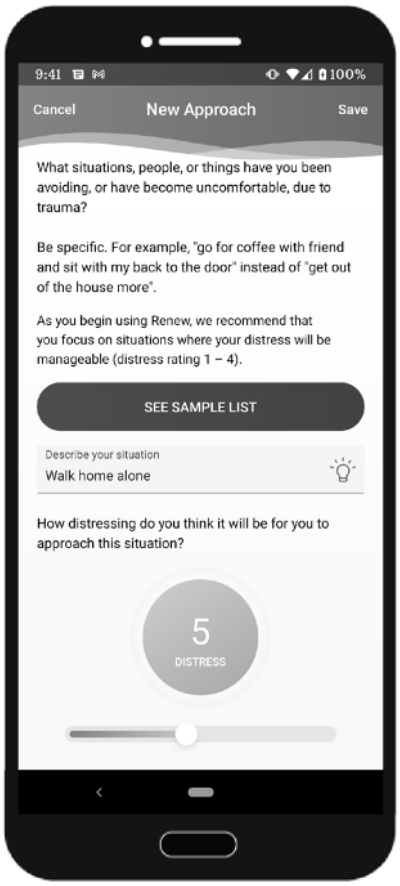
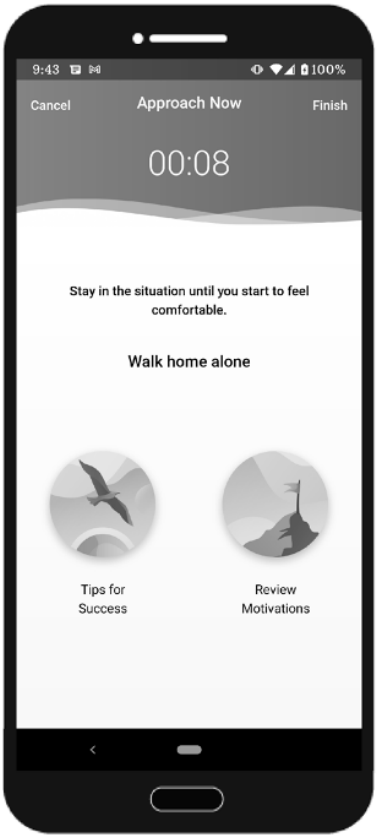


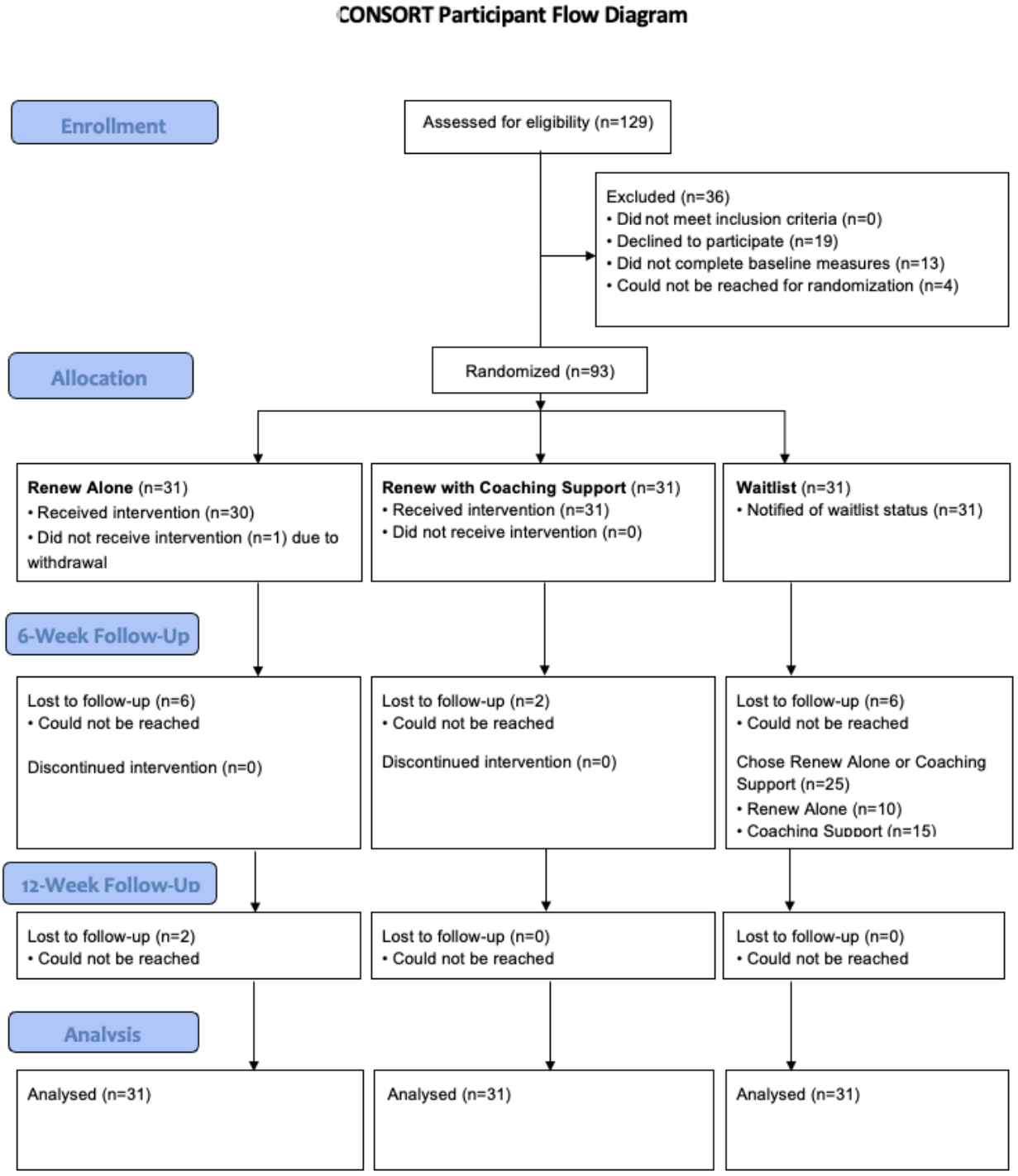
Figure 6. Sample screenshot of the Renew app—*approach*. This image displays the screen shown to users who have initiated an *approach* activity. The activity is timed, and they have access to a list of tips as well as the content in the motivation section.



Participants

Participants were recruited via online advertisements from across the United States (Figure 7 and Multimedia Appendix 1). Inclusion criteria were age 18 years or older, veteran status, exposure to a criterion A trauma, a PTSD symptom severity score of 31 or greater [33] on the PTSD Checklist for the Diagnostic and Statistical Manual of Mental Disorders, fifth edition (DSM-5) [34], and access to an Android smartphone.

Figure 7. CONSORT (Consolidated Standards of Reporting Trials) participant flow diagram.



Measures

Demographics

This is a 14-item baseline measure of demographic information, including race, ethnicity, age, gender, and military service.

Posttraumatic Stress Disorder Checklist for DSM-5

The Posttraumatic Stress Disorder Checklist for DSM-5 (PCL-5) [34] is a 20-item self-report measure of PTSD symptoms as defined by the Diagnostic and Statistical Manual of Mental Disorders [35]. The PCL-5 has high internal consistency (Cronbach α=.91–.95 [36]) and strong test-retest reliability [37,38]. The PCL-5 was delivered as an online survey. The psychometric properties of the PCL-5 have been previously tested when used in an online format [38].

Renew Usage Data

A research dashboard collected information on app usage, including button presses, activities completed, length of time users engaged with each app section, and number of characters entered into free text fields of the app. No identifying information was collected.

To measure user engagement with the Renew app, the following variables were included in our analyses: time spent using the app, time spent completing exposure activities, and the number of points a user gained for completing activities in the app. All time variables were measured in seconds, but are presented in minutes in this paper for ease of interpretation. "Exposure activities" included both in vivo and written exposure tasks (activities in the approach and process sections of the Renew app). Users gained points for completing activities in the app, with users gaining more points for completing exposure activities than for nonexposure activities. The number of points a user gained over the 6-week period serves as a nontemporal metric of engagement and a proxy for the number and type of activities users completed over the app-use period. All usage variables reported in this paper describe app usage during the 6-week active use period for all participants, regardless of study condition.

Study Conditions

Renew Alone

Participants received a 30-minute orientation to Renew and were invited to use the app as much as they wanted for 6 weeks. Participants were allowed, but not instructed, to invite peer support persons who could send 1-way messages of encouragement through the Renew app.

Renew With Study Staff Support

Participants received a 30-minute orientation to Renew and were instructed to add a study research assistant (RA) to their support team. Participants were allowed to invite additional peer support persons as they wished. Support team members are notified when the participant levels up or earns points. The assigned study RA responded to all notifications with reinforcing messages (ie, "Great job staying focused on recovery!") or when the participant had not earned points or gained a level in 7 or more days (ie, "Hey, it's been a while since you've used Renew. Do you have time to focus on recovery today?"). Participants were instructed to use the app as much as much as they wanted for 6 weeks.

Delayed Use

Participants were informed that an RA would reach out to them in 6 weeks to schedule the app orientation session with them and that they could elect to receive study staff support or not.

Procedures

Potential participants completed an online screening assessing study enrollment criteria. Eligible participants were then emailed the informed consent information sheet and met with a study RA by phone to complete the informed consent process (see Multimedia Appendix 2). After completing a baseline assessment, consented participants were randomized by the study RA and informed of their condition assignment over the phone, at which point participants and researchers were unblinded to study condition. Randomization was done by a study RA using an online random block generator allocating participants to the 3 groups using a 1:1:1 ratio. Participants assigned to either of the 2 active treatment conditions were guided through downloading Renew and given a special code to allow them access to Renew's content during a 30-minute in-depth orientation to the app delivered by a study RA.

After the 6-week app-use phase, participants completed a postuse online survey and a brief telephone interview. All surveys were sent to the participants' emails via REDCap, a secure online data collection tool that enables users to design and administer questionnaires. Interviews were audio-recorded and transcribed by study RAs. Participants in the active use conditions completed a follow-up assessment online 6 weeks after the postuse assessment (ie, week 12). Participants in the delayed use condition only completed pre- and postuse surveys. Participants were compensated with an online gift card in the amount of US $100 after study completion. Study data were collected from July 18, 2020, to February 3, 2021.

Statistical Analysis

Our first hypothesis was that veterans in either treatment condition would show greater reductions in PTSD symptoms relative to delayed use. We also hypothesized that veterans who were assigned a support team member would engage with Renew more and show greater reductions in PTSD symptoms than those who were not assigned a support team member. In addition, we explored the relationship between indices of support and indices of app engagement.

The primary hypothesis was tested using the MIXED procedure [39] in SAS 9.4 (SAS Institute) [40] to fit a mixed analysis of variance (ANOVA) model. Restricted maximum likelihood estimation was used to conduct the analysis following the intention-to-treat principle and allow for missing data. For the equally spaced time points, which included the 6 weeks from baseline to posttreatment and the 6 weeks from posttreatment to follow-up, the model assumed an autoregressive error covariance structure. The model included time and treatment group as factors with the interaction term testing group differences in PCL-5 change or slope, which was the primary outcome of interest.

For analyses of indices of support, the variables of interest were characterized by skew distributions where nonparametric tests are more appropriate: for the secondary hypothesis comparing indices of support between the 2 active use conditions, we used the Mann-Whitney-Wilcoxon test and area under the receiver operating characteristic curve effect size [41]. For the exploratory analysis of associations with indices of support, we used the Spearman's rank correlation coefficient.

Ethics Approval

This study was approved by the Stanford Institutional Review Board (IRB-52829).

Results

After trial commencement, participants detected a bug that caused the app to crash when the *approach* feature was opened. This was reported by 11 participants before it was corrected halfway through the study period.

Participant demographics are reported in Table 1. Participants were predominately women (64/93, 69%) and reported a mean age of 49 (SD 9.3) years.

The mixed model ANOVA estimates showed a larger PCL-5 decrease during the 6-week period for the active use group compared with the delayed use group (–6.14 vs –1.84; Figure 8). This difference was not significant (P=.29), with a small effect size (d=–0.39) [42]. Using the model estimates, the within-group PCL-5 change from baseline to posttreatment was significant for the combined active use participants (–6.14, 95% CI –10.66 to –1.62; P=.008), but not for the delayed use group. During the usage period from 6 to 12 weeks for the delayed use group, the within-group PCL-5 change was also significant (–10.1, 95% CI –15.7 to –4.44; P<.001).

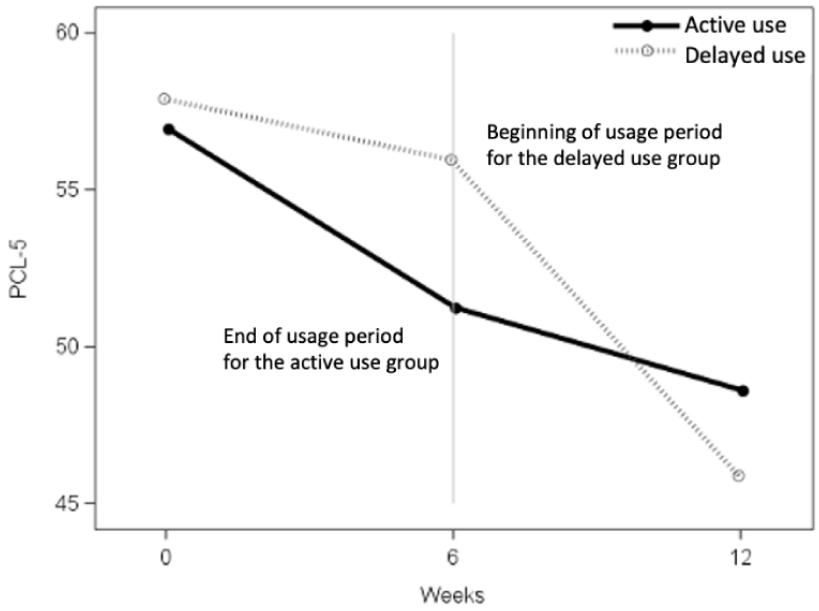
Table 1. Participant demographics (N=93).

Demographics	Values, n (%)
Gender[a]	
Men	29 (31)
Women	64 (69)
Race[b]	
White or European American	59 (63)
Black or African American	22 (24)
Another racial identity	11 (12)
American Indian or Alaska Native	5 (5)
Asian or Asian American	3 (3)
Middle Eastern/North African	1 (1)
Ethnicity	
Not Hispanic or Latinx	83 (89)
Hispanic or Latinx	10 (11)
Relationship status	
Married/partnered	33 (35)
Single, not in a relationship	23 (25)
Separated/divorced	20 (22)
Single, in a relationship	15 (16)
Widowed	2 (2)
Education	
Some high school	1 (1)
Some college or a 2-year degree	47 (51)
Earned a 4-year degree	21 (23)
Postgraduate	19 (20)
High school or General Educational Development	5 (5)
Employment	
Not currently working for pay	35 (38)
Full-time work	29 (31)
Retired	20 (22)
Part-time work	9 (10)
Military status	
Veteran	81 (87)
Retired	11 (12)
National Guard	1 (1)

[a]No participants identified as transgender, nonbinary, or another gender identity.

[b]Participants were allowed to select more than 1 race.

Figure 8. PCL-5 score comparison—active use versus delayed use. PCL-5: Posttraumatic Stress Disorder Checklist for DSM-5.



During the 6-week active use period, the median number of minutes spent using Renew was 104.75 (IQR 42.32-218.42). There were no differences between the support and no support groups on engagement indices (Table 2). Comparing the PCL-5 changes between the 2 active use conditions, the 0- to 6-week change in PCL-5 estimated by the mixed ANOVA model was –8.54 (95% CI –15.2 to –1.93) for the no support condition compared with –4.02 (95% CI –10.3 to 2.24) for the support condition, resulting in a small effect size difference of –0.40. This difference was not significant (*P*=.28).

Table 2. IQR, *P* values, and AUC[a] for usage variables.

Variables	No support (n=30), median (IQR)	Support (n=31), median (IQR)	Mann-Whitney-Wilcoxon test, *P* value	Effect size AUC (rating)
Time[b] in app (minutes)	102 (67-267)	122 (57-231)	.72	0.53 (null)
Time[b] in exposure (minutes)	41 (3-113)	27 (6-106)	.91	0.49 (null)
Number of points	155 (50-410)	185 (60-510)	.52	0.55 (null)

[a]AUC: area under the receiver operating characteristic curve.

[b]All time variables were measured in seconds but are presented here in minutes for ease of interpretation.

Because participants in both the support and no support conditions were able to add their own support team members (eg, family or friends), we explored the impact of the support feature in 2 additional ways: the number of total support messages received (including study staff and peer messages; these could not be disaggregated) and the number of support team members added (excluding the study staff member). Participants in the support condition received a median of 19 messages (IQR 18-21) and participants in the no support condition received a median of 0 messages (IQR 0-0). As shown in Table 3, none of the associations were significant or met the criterion for moderate effect size rating (Spearman ρ≥0.3; *P*≥.05). However, when support is operationalized as the number of support persons added (excluding the staff person among those in the support condition), there are significant associations (*P*=.004 for time in app, *P*=.02 for time in exposure, and *P*=.005 for number of points; Table 3). with engagement variables. More support persons added was associated with greater time in app, more time in exposure, and a greater number of points.

Table 3. Correlation (Spearman ρ) between number of support messages/support persons and app engagement (all groups combined).

Variable	Number of messages, ρ (95% CI)	*P* value	Number of people, ρ (95% CI)	*P* value
Time in app (seconds)[a]	0.17 (–0.05 to 0.37)	.13	0.31 (0.10 to 0.49)	.004
Time in exposure (seconds)	0.08 (–0.13 to 0.29)	.45	0.26 (0.05 to 0.44)	.02
Number of points	0.21 (–0.00 to 0.40)	.05	0.30 (0.09 to 0.48)	.005

[a]Although time variables are presented elsewhere in the paper in terms of minutes for ease of interpretation, our analyses were conducted in terms of seconds, so that is how our data are presented in this table.

Discussion

Principal Findings

Our results provide support for the preliminary efficacy of Renew, with a small effect favoring app use compared with delayed use. The between-group difference was not significant, although veterans who used Renew reported reductions in PTSD symptoms, whereas veterans in the delayed use condition did not, until they began using Renew. PTSD symptom reduction during the active use phase was approximately 6 points on the PCL-5 for those in the active use condition and 10 points for those in the delayed use condition, which is comparable to findings from a study of PTSD Coach in a community sample of trauma survivors over a 1-month period (7 points) [11]. These findings suggest that Renew may represent another effective self-management tool to reduce PTSD symptoms.

The 6-week use period was short relative to other studies and may have underestimated the effect of Renew. The pattern of PTSD symptom change indicates some continued improvement during the follow-up period, which is consistent with research on PTSD Coach showing that symptoms declined over a 3-month use period and, to a lesser degree, a subsequent 3-month follow-up [12]. Thus, it seems warranted to examine the impact of Renew over a longer use period in future studies.

Contrary to hypothesis, we did not see greater app engagement or PTSD reduction among those in the support condition, who were assigned a study staff person as one of their support team members relative to those in the no support condition. The support condition may not have been impactful because the study staff person is not someone the veteran knows personally.

Consistent with this interpretation, the results of the exploratory analyses suggested that adding friends or family as support team members did promote engagement with Renew. The number of support persons added (ie, beyond the study staff person as required by study condition) was associated with greater overall time spent in Renew, greater time spent in exposure, and achieving a greater number of points. Potential reasons for this association could be that adding a support team member, which informs that person that the user is working to manage symptoms of posttraumatic stress, could promote self-accountability or could open the door to more direct forms of social support (eg, supportive conversations between the participants and their support person). The effect could also be related to receiving encouraging messages from the peer support person(s) through Renew. This finding has important public health implications because it suggests that incorporating peers may represent an effective approach to improve app engagement at no cost. However, it is important to keep in mind that we do not know the direction of this relationship. Participants who engaged more with Renew could have been more inclined to add support persons, or those who added more support persons could have felt more encouraged to use Renew. We did not find that the number of support messages received was related to app use, but we were not able to isolate messages from peer support team members from study staff members.

Veterans in this study were instructed to use the app as much as they wanted for 6 weeks and were oriented to and encouraged to try all components of Renew. Although those in the support condition received messages in response to their use of Renew, there was no synchronous coaching provided (eg, coaching phone calls). This allowed us to approximate what the effect of Renew may be in routine use, with no additional resources provided. However, it is possible that scaffolding to support app engagement would have resulted in greater clinical benefit. Future studies could explore the impact of Renew with coaching or as an adjunct to more traditional care (eg, including a therapist as a support team member). The Efficiency Model of Support [43] could be a relevant protocol to use in future studies of Renew to further evaluate the effectiveness of the support function.

Limitations

Several study limitations should be considered. First, participants were veterans and therefore the findings may not generalize to other populations, including civilians. Second, most of the data collection occurred during the first wave of the COVID-19 pandemic in the United States, when movement restrictions were high and vaccines were unavailable. It is unclear how much COVID-19–related stress impacted PTSD symptoms, app engagement, or outcomes in our study sample. Other research with veterans enrolled in PTSD psychotherapy suggests that the COVID-19 pandemic worsened PTSD symptoms [44] and negatively impacted engagement with treatment [45]. It may be that COVID-19–related stressors had a similarly negative impact on PTSD symptoms and engagement with Renew. We are currently examining data on COVID-19 stressors in this sample in an effort to better understand the impact of the pandemic on the veteran's experience using Renew. Finally, we were not able to disaggregate the number of support message from study staff and peers, limiting our ability to understand how this feature was related to engagement.

Future Directions

Given the preliminary efficacy of Renew, future research evaluating the app is warranted and several possible directions can be considered. First, based on the pattern of change during the follow-up period and findings from PTSD Coach [11], we recommend that Renew be tested in a longer use period than 6 weeks. This would allow researchers to explore an optimal "dosage" of Renew. Second, in light of the exploratory findings on the support feature, future work may also examine ways to encourage users to develop a personal support team. Third, research examining engagement with different components of Renew may be useful to determine whether the use of particular features (eg, exposure components) is most closely associated with symptom reduction. Finally, future work may consider testing Renew as a supplement to psychotherapy or as part of a stepped care model. For example, Renew may be useful for individuals waiting to initiate psychotherapy or who have completed psychotherapy and might benefit from Renew as a tool to help them maintain their therapy gains.

Conclusions

Study limitations notwithstanding, our findings indicate that Renew holds promise as a self-management tool for PTSD symptoms. The effect of Renew relative to the delayed use condition was small over 6 weeks of use. However, given the scalability and cost-effectiveness of mobile mental health apps, even tools with a small effect have potential to help address the unmet need for mental health care among individuals struggling with PTSD symptoms. While not a replacement for traditional treatment, self-management tools such as Renew may represent a sufficient level of care for a proportion of veterans struggling with PTSD symptoms and may also help veterans seek a higher level of care as needed.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
CONSORT (Consolidated Standards of Reporting Trials)-EHEALTH checklist.
[PDF File (Adobe PDF File), 1387 KB - mhealth_v10i11e38951_app1.pdf]

Multimedia Appendix 2
Renew verbal consent script.
[DOCX File , 17 KB - mhealth_v10i11e38951_app2.docx]

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Abbreviations

ANOVA: analysis of variance
CONSORT: Consolidated Standards of Reporting Trials
DSM-5: Diagnostic and Statistical Manual of Mental Disorders, fifth edition
PCL-5: Posttraumatic Stress Disorder Checklist for DSM-5
PTSD: posttraumatic stress disorder
RA: research assistant
RCT: randomized controlled trial
SUDS: Subjective Units of Distress Scale

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Original Paper

Effectiveness of Mental Health Apps for Distress During COVID-19 in US Unemployed and Essential Workers: Remote Pragmatic Randomized Clinical Trial

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Abstract

Background: During the COVID-19 pandemic, the general public was concerned about the mental health impacts of unemployment due to COVID-19 and the stress essential workers experienced during this time. Several reports indicated that people in distress were turning to digital technology, but there was little evidence about the impact of these tools on mitigating distress.

Objective: This study seeks to determine the acceptability, feasibility, usability, and effectiveness of mobile mental health apps for decreasing mental health symptoms in essential workers and unemployed individuals with suicide risk.

Methods: We recruited participants who indicated that they were unemployed because of COVID-19 or were COVID-19–designated essential workers. Participants were randomized to 1 of 4 free commercial mobile apps for managing distress that were (1) highly rated by PsyberGuide and (2) met the criteria for intervention features these participants indicated were desirable in a previous survey. Participants used the apps for 4 weeks and completed baseline and 4-week self-assessments of depression, anxiety emotional regulation, and suicide risk.

Results: We found no differences between the apps in any outcome but did find significant changes in depression and anxiety over time (Patient Health Questionnaire [PHQ]-9: estimate=–1.5, SE 0.2, 95% CI –1.1 to –1.8, P<.001; Generalized Anxiety Disorder Scale [GAD]-7: estimate=–1.3, SE 0.2, 95% CI –1.0 to –1.6, P<.001). We found no significant changes in suicidal behavior (Suicide Behaviors Questionnaire-Revised [SBQ-R]) or emotional regulation (Difficulties in Emotion Regulation Scale – Short Form [DERS-SF]) for the 4 weeks. We did find a significant dose-response pattern for changes in depression and anxiety. Using the app at least once a week resulted in greater improvements in treatment conditions over time on depression (estimate=–0.6, SE 0.2, 95% CI 1.0-0.2, P=.003) and anxiety (estimate=0.1, SE 0.2, 95% CI 0.4-0.6, P=.78). There was no association between app frequency and changes in suicidal behavior (SBQ-R) or emotional regulation (DERS-SF). We further found a significant difference between the conditions with regard to app usability, with the control app being the most usable ($mean_{Beautiful\ Mood}$ 72.9, SD 16.7; $mean_{COVID\ Coach}$ 71.2, SD 15.4; $mean_{Calm}$ 66.8, SD 17.3; $mean_{7\ Cups}$ 65.2, SD 17.7). We found no significant differences for app acceptability or appropriateness.

Conclusions: Few studies have evaluated prospectively the utility and usability of commercial apps for mood. This study found that free, self-guided commercial mobile mental health apps are seen as usable, but no one app is superior to the other. Although we found that regular use is indicated for effects on depression and anxiety to occur in those who are more symptomatic, regression to the mean cannot be ruled out.

Trial Registration: ClinicalTrials.gov NCT04536935; https://tinyurl.com/mr36zx3s

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KEYWORDS

COVID-19; COVID; coronavirus; pandemic; SARS-CoV-2; essential worker; suicide; suicidal; commercial app; mental health apps; health app; mental health; mHealth; mobile health; occupational health; employee; employment; unemployed; worker; job; depression; anxiety; stress; distress; mobile app; RCT; pragmatic trial; randomized; health care worker; health care provider; frontline staff

Introduction

Background

Access to mental health care by essential workers and the people unemployed due to COVID-19–related business closures and social distancing policies has been challenging [1-3]. To address this problem, health care organizations have created free mobile apps for stress related to COVID-19. Although overall app use during COVID-19 has been low (16%) [4,5], technology companies report substantial increases in the use of their tools.

There is limited information about the effectiveness of mental health apps, particularly free, self-guided commercial apps. Research on self-guided apps is mixed, with some studies finding them to be minimally effective [6-8] and others reporting beneficial effects; we note here that most evidence points to the superiority of coach-based apps for depression and anxiety outcomes, but effect sizes for self-guided apps are still notable [9] and offer an opportunity for stress management in populations that do not have the financial or time resources to avail themselves of coaching services [10]. It is important to also note here that most studies that find positive effects use research grade tools with a paid participant pool and are typically not available to the public. Many commercial apps do include principals and features that are similar to research grade tools; however, there remains skepticism about the effectiveness of these derivations [11]. This has led to the need to create app review resources, such as One Mind PsyberGuide [12] and the American Psychiatry Association's App Advisor [13], which provide ratings of app effectiveness, transparency, and usability. Still, evidence for free commercial apps is limited, and calls for additional research [14,15], particularly in the context of COVID-19 [16], have been made.

Objective

We previously reported on a large-scale survey of essential workers and people unemployed due to COVID-19 for their preferences for mobile apps for mood management [4]. In this study, we found that participants had strong preferences for apps that focus on mindfulness approaches, information about coping with COVID-19, symptom tracking, and connection with others. In this pragmatic clinical trial, we randomized 838 of these participants who indicated they were depressed or anxious or had suicidal thoughts in order to use 1 of 4 commercial apps for 4 weeks. We selected the 4-week time frame because in our past research, we found that this is an optimal dose of digital mental health in a distressed sample [17] and other research has found that this is the length of time participants tend to engage with these tools [18,19]. Thus, we are interested in addressing the issues of app use and outcomes pragmatically, as it would occur in actual practice. The main objectives of this study were:

- Determine whether users of these apps show significant improvement in anxiety, depression, emotion regulation, and suicide risk.
- Identify differences between the apps in use, usability, and acceptability.
- Determine whether there is a dose-response relationship such that the frequency of app use is positively associated with improvement in depression, anxiety, emotional regulation, and suicide risk.
- Identify outcome differences between apps in this dose-response relationship.

Methods

Recruitment and Safeguards Against Bad Actors

Participants were recruited nationally via Prolific, an online research platform that includes several safeguards to preserve data quality [20-22] and minimize bad actors and has been shown to be reliable, efficient, and affordable for remote data collection for behavioral research [23]. Participants provided electronic informed consent prior to study completion. Additional survey safeguards were an attention check [24] and a review of open-ended items to screen out autofilled and nonsensical responses.

Ethical Approval

The study received ethical approval from the University of Washington Institutional Review Board (STUDY00010842). In the consent, participants were explained the purpose of the study, that it would be randomized to 1 of 4 mobile apps, and that they would be asked to complete surveys before treatment began and 4 weeks later. Participants were also told how data were stored and managed and approximately how long each survey would take.

Participants

Participants for this study were recruited from a larger study [4], which included a convenience sample of approximately 2000 participants that self-identified as COVID-19–designated essential workers or unemployed due to COVID-19 social distancing policies or COVID-19–related business closures. To identify as 1 of these 2 groups, participants responded to the following 2 questions: (1) Are you considered an essential worker during the COVID-19 pandemic? (2) Have you become unemployed as a result of the COVID-19 pandemic?

To be eligible for this study, inclusion criteria included (1) previously granting permission to be recontacted for future research; (2) age≥19 years, living in the United States, and English speaking; (3) access to a mobile device; and (4) report of depression (Patient Health Questionnaire [PHQ]-2 score≥3) [25], anxiety (Generalized Anxiety Disorder Scale [GAD]-2 score≥3) [26], risk for suicidal behaviors (Suicide Behaviors Questionnaire-Revised [SBQ-R] score≥7) [27], or a history of past suicide attempt [28]. Participants were offered crisis management resources when they endorsed the ninth item of the PHQ-9 or were over the cut-off for the SBQ-R.

Study Timeline

Participants were recruited from October through December 2020, during the middle of the initial COVID-19 variant, and shortly after vaccines were available to the public. Additionally, most states (with few exceptions) were continuing to institute public closures of restaurants, gyms, and other enclosed public places, meaning the unemployment rate due to COVID-19 was still quite high. Hospital censuses were at historically high rates, and essential workers were still mandated to wear protective gear. Thus, the sample is representative of people living under peak pandemic conditions. Participants were randomized after completing a web-based baseline assessment of mood and paid US $1 (see the Measures section). Participants were randomized to 1 of 4 apps and asked to use their assigned app as instructed by the developers. Participants completed a web-based posttreatment survey at 4 weeks postrandomization and app assignment. After completing follow-up, participants were compensated US $4.

Mobile Interventions and Attention Control

This remote pragmatic clinical trial used simple randomization with parallel assignment comparing 3 active apps to an attention control app. This study meets the definition of a pragmatic trial in that the study was designed to test the effects of mobile apps for depression, anxiety, emotion regulation, and suicide as they are typically used by the general public [29]. In pragmatic trials, the intent is to determine the effect of existing treatments in the context of real-world use compared to existing treatment options. In such trials, the control condition is not a placebo, which is not usually part of standard care [30]. Although a waitlist may be appropriate for a pragmatic trial, waitlist controls are appropriate only when this is part of usual practice and if they are ethically sound; however, previous research has found internal validity issues with waitlist controls, and in the context of self-guided commercial digital mental health, there is no waitlist control [31]. In our sample, which consisted of participants at risk for suicide, neither a placebo nor waitlist controls were ethical choices [32]. Thus, our decision to use an attention control app was based on what is considered appropriate for pragmatic trials of this nature in potentially high-risk populations [33,34].

We selected apps based on the following criteria: (1) they were free; (2) reflected desired app features during COVID-19, as identified in the survey study [4]; and (3) had good ratings on PsyberGuide [4]. The 3 active app interventions included (1) meditation (Calm), (2) COVID-19 coping (COVID Coach), and (3) chat and positive psychology (7 Cups of Tea). The attention control app used only mood tracking (Beautiful Mood) and did not include any intervention elements the other apps possessed (mindfulness meditation, emotional coping skills, social connection, or positive psychology approaches). Participants were randomized by study staff using random allocation functions in Microsoft Excel and received their app assignment through a URL to Google Play Store or Apple App Store. Participants confirmed app download prior to receiving compensation. Participants were blinded to the study hypotheses but not condition.

Rationale for the 4-Week Intervention Timeline

We feel it is important to note that although mental health apps are based on evidence-based treatment approaches, people use apps differently than the way they use traditional mental health services [35]. The optimal dose of mobile mental health apps is measured in the frequency of use rather than the number of weeks of use, and research shows that considerable improvement in mood and function can occur rapidly with digital mental health tools and as early as after 2 weeks of use [17,36,37]. We acknowledge that although other randomized clinical studies do show the greatest impact at 8 weeks [38], the general population tends to initially engage with digital mental health apps frequently over the course of 2 weeks, with notable disengagement by 4 weeks [11,18,19]. Based on the literature from the informatics field on typical engagement patterns with digital health tools in general, this is a common pattern of engagement and may mean the user has met their goal [18].

Measures

All data collected for this study are considered sensitive. We did not collect or store names, addresses, locations, IP addresses, or other digital identifiers. All survey data, including demographics, were immediately stored behind secure firewalls on servers at the University of Washington School of Medicine. The survey was developed by the study's lead investigators (authors PAA and KAM), measures were selected for their validity and reliability, and we selected those measures that had been validated for online use. The survey was programmed into REDCap, a web-based survey program developed by Vanderbilt University [39]. It has been used extensively for clinical research and is Health Insurance Portability and Accountability Act (HIPAA) compliant, highly secure, and intuitive to use. After the survey was built, we tested it with research group members naive to the study for readability, programming bugs, and time to completion.

Demographics

Participants provided information about age, race and ethnicity, gender identity, sexual orientation, education, income, and living situation. We used similar questions to those in the US Census categories [40]. This survey has been used successfully in other online studies [4,41]. See Multimedia Appendix 1. Race, ethnicity, and gender were assessed because mental health disparities were present in these groups [42,43].

Primary Clinical Outcomes

Participants completed measures of depression (PHQ-9) [25,44,45], anxiety (GAD-7) [26,46,47], emotion dysregulation (Difficulties in Emotion Regulation – Short Form [DERS-SF])

[48], and suicidal behaviors (SBQ-R) [27] at baseline and follow-up. The PHQ-9 score ranges from 0 to 27, with 0-4 indicating no depression, 5-9 indicating mild depression, 10-20 indicating moderate depression, and a score>20 indicating severe depression. The GAD-7 is scored from 0 to 21, with 0-4 indicating no anxiety, 5-9 indicating mild anxiety, 10-14 indicating moderate anxiety, and 15-21 indicating severe anxiety. The DER-SF is scored from 1 to 180 and, while showing strong psychometric properties in clinical populations, does not have a clinical cut-off. The SBQ-R is scored from 3 to 18 and has a nonclinical cut-off of 7 and a clinical cut-off of 8 for elevated suicide risk [49].

The PHQ-9 and GAD-7 have been used successfully as online survey instruments and have been validated as online instruments [50,51]. Although the DERS and SBQ-R have been used in online survey research [52,53], to the best of our knowledge, no formal tests of validity have been conducted. We still elected to use these scales as there is no existing validated instrument for emotion regulation and suicide behaviors and because, of the existing scales, these have the best psychometric properties, are valid and reliable across demographic groups, and are least burdensome to administer owing to a shorter length and ease of understanding [27,54-66].

App Use

As we were not able to collect in-app use data, participants were asked how often they used the app that they were assigned to over the past 4 weeks on a scale of 1 (*never downloaded the app*) to 8 (*multiple times per day*). To ease interpretation, results presented here are for response options collapsed into 4 categories, with findings highly similar in both categorization schemes. Categories included 1 (*never downloaded the app* and *downloaded but did not use the app*), 2 (*rarely* [*1-3 times in the past month*] and *infrequently* [*less than weekly*]), 3 (*weekly* and *more than weekly but less than daily*), and 4 (*daily* and *multiple times per day*).

Fidelity

A dichotomized fidelity measure was created in accordance with each app's recommended use found on its website. Daily use was recommended for the apps Beautiful Mood [67], COVID Coach [68], and Calm [69], while weekly use was recommended for 7 Cups of Tea [70].

Usability

App usability was assessed with the Intervention Usability Scale (IUS) [71], a 10-item measure that assesses psychosocial intervention usability through its likeability, learnability, difficulty, need for support, system integration, and efficiency. This measure is based on the System Usability Scale [72], a standardized, normed measure in industry for digital tools, and has been validated for online research [73,74]. The IUS is scored from 0 to 100, and a score of 85 or more is considered to be excellent usability [75].

Acceptability and Appropriateness

The degree to which the app was satisfactory and appropriate (ie, the fit and relevance of the intervention) was measured with the Acceptability Intervention Measure (AIM) and the Intervention Appropriateness Measure (IAM) [76]. These scales' scores range from 0 to 20, with higher scores indicating great acceptability (AIM) and appropriateness (IAM). Both measures contain 4 items that exhibit good psychometric properties, and the items have been validated by implementation scientists and mental health professionals. Although these measures have not been validated for online use, they are the only validated instruments for intervention acceptability and appropriateness, are brief, and face-valid [76].

Survey Administration

The survey was completed by volunteers identified through our initial sample [4]. Participation in the study, including survey completion, was voluntary. After volunteering on Prolific and providing consent, participants completed all measures in a web-based REDCap interface. The survey included 14 measures, each on a separate page, with 4-18 questions per measure. Participants were able to review and change their responses on each measure before proceeding to the next measure. The survey items were not randomized, as each scale used must be delivered in the order it was validated. We did not use skip patterns or other survey logic; participants were asked to complete all survey questions and had the option to not answer certain questions.

Statistical Methods

Prior to analyses, we examined the data and eliminated participants for not meeting inclusion or good-actor criteria. Good-actor criteria required participants to correctly answer an attention check item, answer at least 50% of the items on the survey, complete the survey faster than 33% of the median length of time, and not have any problems with the Prolific ID (not being an approved ID, being a duplicate ID, or having a missing ID). We performed *t* tests and cross-tabulations with chi-square tests to compare demographic and baseline clinical outcomes by missing data status at the follow-up time point. Chi-square tests examined the association between condition assignment and compliance (whether a participant used the app they were assigned or used an alternative app). All analyses were of the intention-to-treat (ITT) type. Analyses of variance were used to compare conditions on AIM, IAM, and IUS scores at follow-up, with Tukey honestly significant difference (HSD) tests making pairwise post hoc comparisons among all apps. Mixed effects models using restricted maximum likelihood estimation were built to test the linear time change on the PHQ-9, GAD-7, SBQ-R, and DERS-SF and to test for condition differences at follow-up and change slope. We applied mixed effects models with 2 time points with within-person nesting. We used this rather than alternatives, such as a simple regression, because mixed effects models efficiently (1) simplified simultaneous testing of within-person changes via testing slope coefficients and between-condition differences via testing condition coefficients; (2) facilitated testing as we built models progressively adding time trends, condition effects, and dosage effects; and (3) permitted the inclusion of random intercepts to account for variance at baseline, which was particularly important for testing models of dosage. Models were built and tested in an outwardly nested fashion, such that an initial null model was computed, followed by models that

added a random intercept, random time component, condition assignment with Beautiful Mood as the reference variable (the attention control condition), and condition × time interaction effects. To test whether there was a dose-response relationship such that the app use frequency was associated with the rate of change on the PHQ-9, GAD-7, SBQ-R, and DERS-SF scores, we computed another series of mixed effects models for each outcome. An initial model included variables for time and frequency of use, a second model added condition terms for each app using Beautiful Mood as the reference, a third model added condition × frequency interaction terms for each app, and a fourth model included time, frequency, and a time × frequency interaction term. Model comparisons applied –2 log likelihood (–2LL), the Akaike information criterion (AIC), and Bayesian information criterion (BIC) deviance statistics. To test the impact of app use frequency on change over time, similar nested model testing was applied using an initial null model, followed by models that added dosage, dosage × time interaction, and condition assignment.

Sample Size and Power

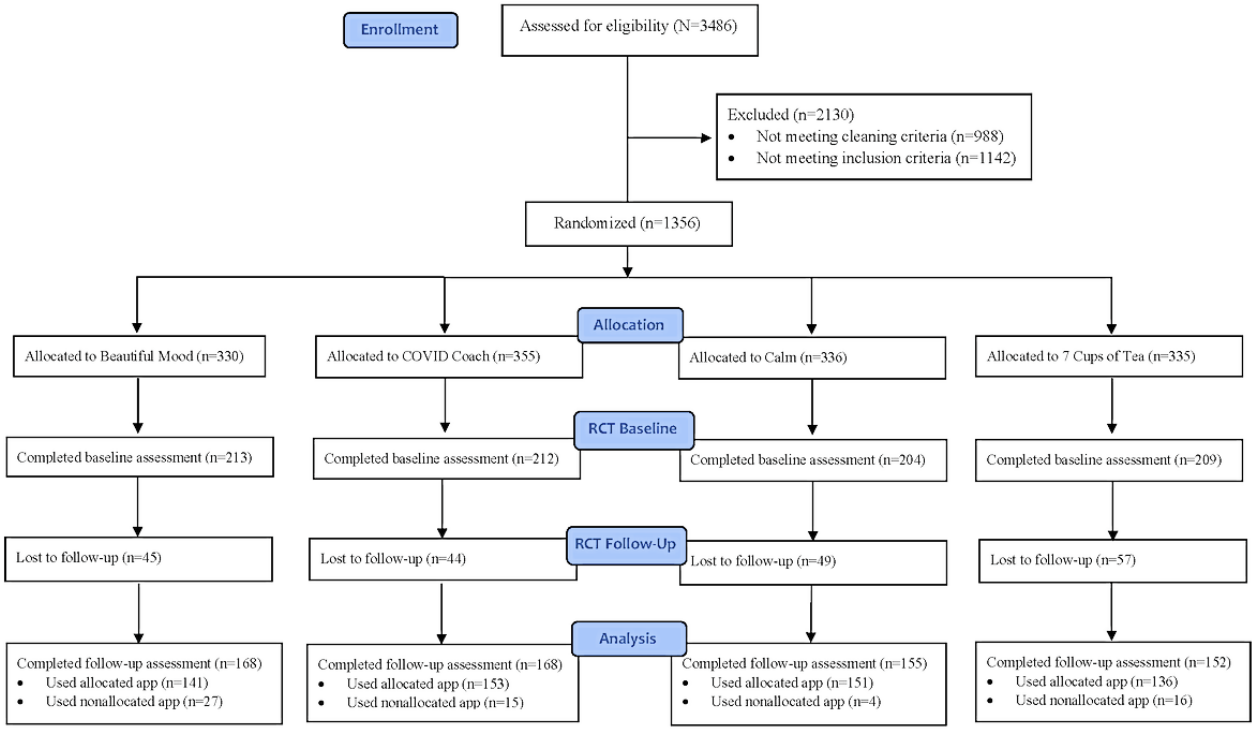
A priori power analysis for an ANOVA *F* test indicated that a sample size of 800 (n=200 participants in each of the active and control app conditions) would be sufficient with power=0.80 and α=.05 for a minimum detectable effect size (MDES) of Cohen d=0.24 for main effect comparisons between any 2 conditions. The post hoc power analysis for 643 participants with complete data found an MDES of Cohen d=0.29 for main effect comparisons between any 2 conditions. Previous research has found an average Hedges g effect size (a comparable effect size to Cohen d but corrected for small samples) on self-guided mental health apps to be 0.50 and for self-guided tools to be 0.24 [77].

Results

Recruitment

Figure 1 presents the Consolidated Standards of Reporting Trails (CONSORT) diagram. There were 3486 individuals assessed for eligibility, 2130 (61.1%) were excluded for not meeting good-actor criteria (n=988, 46.4%) or not meeting randomized clinical trial (RCT) inclusion criteria (n=1142, 53.6%). A total of 1356 (38.9%) individuals were randomized to Beautiful Mood (n=330, 24.3%), COVID Coach (n=355, 26.2%), Calm (n=336, 24.8%), or 7 Cups of Tea (n=335, 24.7%). Among those allocated to a condition, 838 (61.8%) participants completed the RCT baseline assessment, while 643 (47.4%) participants completed the follow-up assessment. In addition, 581 (90.4%) participants reported using the assigned app and 62 (9.6%) reported using a nonassigned app. For this ITT trial, all randomized participants were included in the primary analysis.

Figure 1. Consolidated Standards of Reporting Trails (CONSORT) table.



Sample Description

Table 1 presents individual-level demographic data. The analytic sample consisted of 838 adults, with a mean age of 31.1 (SD 9.5) years. Most patients identified as women (467/833, 56.1%) and White (616/838, 73.5%). Participants self-identified as unemployed due to COVID-19 (428/838, 51.1%) or COVID-19–designated essential workers (410/838, 48.9%). There were no significant differences in demographics by condition.

Table 1. Sample descriptive statistics for 4 conditions using different self-guided mobile apps.

Demographics	Beautiful Mood (n=213)	COVID Coach (n=212)	Calm (n=204)	7 Cups of Tea (n=209)	Total (N=838)
Race, n (%), *P*=.28[a]					
African American/Black	15 (7.0)	20 (9.4)	11 (5.4)	12 (5.7)	58 (6.9)
American Indian/Alaska Native	3 (1.4)	2 (0.9)	3 (1.5)	0	8 (1.0)
Asian	22 (10.3)	23 (10.8)	26 (12.7)	13 (6.2)	84 (10.0)
Multiracial	13 (6.1)	18 (8.5)	10 (4.9)	12 (5.7)	53 (6.3)
Other race[b]	4 (1.9)	7 (3.3)	5 (2.5)	3 (1.4)	19 (2.3)
White	156 (73.2)	142 (67.0)	149 (73.0)	169 (80.9)	616 (73.5)
Ethnicity, n (%), *P*=.79[a]					
Hispanic/Latinx	23 (10.9)	17 (8.2)	21 (10.3)	19 (9.1)	80 (9.6)
Not Hispanic/Latinx	188 (89.1)	190 (91.8)	183 (89.7)	189 (90.9)	750 (90.4)
Missing	2 (0.9)	5 (2.4)	0	1 (0.5)	8 (1.0)
Age (years), *P*=.16[c]					
Mean (SD)	31.8 (10.1)	29.9 (8.2)	31.4 (10.0)	31.4 (9.4)[d]	31.1 (9.5)[e]
Gender, n (%), *P*=.86[a]					
Women	116 (54.7)	118 (56.5)	118 (57.8)	115 (55.3)	467 (56.1)
Gender diverse	0	1 (0.5)	1 (0.5)	2 (1.0)	4 (0.5)
Men	85 (40.1)	80 (38.3)	78 (38.2)	83 (39.9)	326 (39.1)
Nonbinary	10 (4.7)	7 (3.3)	7 (3.4)	7 (3.4)	31 (3.7)
Transgender	1 (0.5)	3 (1.4)	0	1 (0.5)	5 (0.6)
Missing	1 (0.5)	3 (1.4)	0	1 (0.5)	5 (0.6)
Marital status, n (%), *P*=.41[a]					
Divorced	14 (6.7)	11 (5.3)	10 (4.9)	17 (8.2)	52 (6.3)
Married (including same-sex partnership)	61 (29.0)	56 (26.8)	56 (27.6)	61 (29.5)	234 (28.2)
Never married	134 (63.8)	136 (65.1)	131 (64.5)	123 (59.4)	524 (63.2)
Separated	1 (0.5)	6 (2.9)	4 (2.0)	3 (1.4)	14 (1.7)
Widowed	0	0	2 (1.0)	3 (1.4)	5 (0.6)
Missing	3 (1.4)	3 (1.4)	1 (0.5)	2 (1.0)	9 (1.1)
Education, n (%), *P*=.47[a]					
High school, General Educational Development (GED), or less	22 (10.3)	28 (13.3)	27 (13.2)	23 (11.0)	100 (11.9)
Some college	74 (34.7)	50 (23.7)	54 (26.5)	51 (24.4)	229 (27.4)
Trade/technical/vocational	19 (8.9)	27 (12.8)	25 (12.3)	32 (15.3)	103 (12.3)
Bachelor's degree	64 (30.0)	73 (34.6)	65 (31.9)	67 (32.1)	269 (32.1)
Higher education	34 (16.0)	33 (15.6)	33 (16.2)	36 (17.2)	136 (16.2)
Missing	0	1 (0.5)	0	0	1 (0.1)
Income (US $), n (%), *P*=.28[a]					
<10,000	30 (14.2)	37 (18.0)	31 (15.3)	30 (14.5)	128 (15.5)
10,000-31,199	60 (28.3)	56 (27.2)	58 (28.6)	53 (25.6)	227 (27.4)
31,200-33,280	17 (8.0)	17 (8.3)	5 (2.5)	8 (3.9)	47 (5.7)
33,281-49,999	29 (13.7)	31 (15.0)	31 (15.3)	31 (15.0)	122 (14.7)
50,000-59,999	11 (5.2)	16 (7.8)	23 (11.3)	17 (8.2)	67 (8.1)

Demographics	Beautiful Mood (n=213)	COVID Coach (n=212)	Calm (n=204)	7 Cups of Tea (n=209)	Total (N=838)
60,000-69,999	10 (4.7)	10 (4.9)	14 (6.9)	14 (6.8)	48 (5.8)
70,000-99,999	34 (16.0)	19 (9.2)	20 (9.9)	27 (13.0)	100 (12.1)
100,000-149,999	14 (6.6)	15 (7.3)	11 (5.4)	14 (6.8)	54 (6.5)
≥150,000	7 (3.3)	5 (2.4)	10 (4.9)	13 (6.3)	35 (4.2)
Missing	1 (0.5)	6 (2.8)	1 (0.5)	2 (1.0)	10 (1.2)
Employment, n (%), *P*=.47[a]					
Essential worker	112 (52.6)	107 (50.5)	95 (46.6)	96 (45.9)	410 (48.9)
Unemployed	101 (47.4)	105 (49.5)	109 (53.4)	113 (54.1)	428 (51.1)

[a]Chi-square *P* value.

[b]Other race: most common responses for race were Hispanic, Mexican, and mixed.

[c]ANOVA *F* test *P* value.

[d]N=208.

[e]N=837.

Missing Data

A total of 643/838 (76.7%) participants completed the follow-up assessment. There were no significant differences between those missing or not missing the follow-up assessment in the demographic data in Table 1 or clinical measures at baseline.

Randomization Adherence and Compliance

At follow-up, 62/643 (9.6%) participants reported being nonadherent to condition assignment and reported that they use a different app than the one they were randomly assigned to use. Participants who were randomized to Beautiful Mood were less likely to use their assigned app, while individuals randomized to Calm were more likely to use their assigned app (*P*<.001).

App Use

A cross-tabulation with the chi-square test found significant differences between the apps in the amount of use the participants reported; participants used Beautiful Mood more frequently and COVID Coach and 7 Cups of Tea less frequently (see Table 2).

Table 2. App compliance and use frequency[a] by condition (*P*<.001[b]).

App use and compliance	Beautiful Mood (n=168), n (%)	COVID Coach (n=168), n (%)	Calm (n=155), n (%)	7 Cups of Tea (n=152), n (%)	Total (N=643), n (%)
Adherent to app assignment	141(83.9)	153 (91.1)	151 (97.4)	136 (89.5)	581 (90.4)
App use					
Never downloaded/no use	18 (10.7)	14 (8.3)	15 (9.7)	21 (13.8)	68 (10.5)
Rarely/infrequently	*45 (26.8)* [c]	*80 (47.6)* [c]	62 (40.0)	*72 (47.4)* [c]	259 (40.3)
Weekly or more	56 (33.3)	55 (32.7)	55 (35.5)	52 (34.2)	218 (33.9)
Daily/multiple times per day	*49 (29.2)* [c]	19 (11.3)	23 (14.8)	*7 (4.6)* [c]	98 (15.2)

[a]According to their websites, Beautiful Mood, COVID Coach, and Calm apps recommend daily use, while 7 Cups of Tea recommends weekly use.

[b]Chi-square *P* value.

[c]Italicized values indicate a significant difference indicated by standardized residuals.

Usability, Acceptability, and Appropriateness

ANOVA found a significant difference on the IUS between the conditions ($mean_{Beautiful\ Mood}$ 72.9, SD 16.7; $mean_{COVID\ Coach}$ 71.2, SD 15.4; $mean_{Calm}$ 66.8, SD 17.3; $mean_{7\ Cups}$ 65.2, SD 17.7). Tukey HSD post hoc tests indicated Beautiful Mood is significantly more usable than Calm (mean difference 6.0, 95% CI 1.2-10.8, *P*=.01) and 7 Cups of Tea (mean difference 7.7, 95% CI 2.9-2.5, *P*<.001). COVID Coach was significantly more usable than 7 Cups of Tea (mean difference 6.1, 95% CI 1.2-10.9, *P*=.01). We found no significant differences in app acceptability (overall AIM mean 3.5, SD 1.0, 95% CI 3.4-3.6, *P*=.22) or appropriateness (overall IAM mean 3.6, SD 0.9, 95% CI 3.6-3.7, *P*=.48).

Clinical Outcomes

Table 3 displays the reporting sample size, mean scores, and SDs at each time point for the PHQ-9, GAD-7, SBQ-R, and DERS-SF for each app.

Table 3. Pretest and posttest scores on clinical outcomes by condition.

App and time	PHQ[a]-9		GAD[b]-7		SBQ-R[c]		DERS-SF[d]	
	n (%)	Mean (SD)	n (%)	Mean (SD)	n (%)	Mean (SD)	n (%)	Mean (SD)
Beautiful Mood (n=168)								
Pretest	165 (98.2)	10.6 (6.6)	167 (99.4)	8.8 (5.7)	154 (91.7)	7.1 (3.6)	165 (98.2)	44.5 (13.0)
Posttest	165 (98.2)	9.1 (6.5)	167 (99.4)	7.8 (5.6)	154 (91.7)	7.0 (3.8)	165 (98.2)	44.6 (14.2)
COVID Coach (n=168)								
Pretest	166 (98.8)	11.2 (6.3)	168 (100)	9.2 (5.6)	159 (94.6)	6.9 (3.8)	163 (97.0)	44.6 (12.5)
Posttest	166 (98.8)	9.8 (6.7)	168 (100)	7.8 (5.6)	159 (94.6)	6.7 (3.7)	163 (97.0)	44.6 (14.0)
Calm (n=155)								
Pretest	155 (100)	10.1 (5.7)	153 (98.7)	7.9 (4.8)	144 (92.9)	6.6 (3.3)	153 (98.7)	42.9 (11.7)
Posttest	155 (100)	8.5 (5.9)	153 (98.7)	6.7 (5.1)	144 (92.9)	6.4 (3.3)	153 (98.7)	42.2 (13.1)
7 Cups of Tea (n=152)								
Pretest	151 (93.3)	11.0 (6.5)	151 (93.3)	8.9 (5.6)	139 (91.4)	7.1 (3.9)	148 (97.4)	44.6 (12.8)
Posttest	151 (93.3)	9.7 (6.6)	151 (93.3)	7.3 (5.8)	139 (91.4)	7.1 (3.9)	148 (97.4)	44.9 (13.0)

[a]PHQ: Patient Health Questionnaire.

[b]GAD: Generalized Anxiety Disorder Scale.

[c]SBQ-R: Suicide Behaviors Questionnaire-Revised.

[d]DERS-SF: Difficulties in Emotion Regulation Scale – Short Form.

Examining the –2LL, AIC, and BIC deviance statistics for each of the 4 analyses revealed that the best-fitting model was a random intercept model with a linear time slope in 2 cases: the PHQ-9 (–2LL=9118, dev_1=63.2, *P*<.001; AIC=9128, dev_1=61.2, *P*<.001; BIC=9137, dev_1=71, *P*<.001; parameters=5) and GAD-7 (–2LL=8686, dev_1=71.7, *P*<.001; AIC=8696, dev_1=69.7, *P*<.001; BIC=8720, dev_1=64.9, *P*<.001; parameters=5). From baseline to follow-up, participants improved by an estimated –1.5 points on the PHQ-9 (SE 0.2, 95% CI –1.1 to –1.8, *P*<.001) and –1.3 points on the GAD-7 (SE 0.2, 95% CI –1.0 to –1.6, *P*<.001). Models that included condition main effects centered at the follow-up time point and condition × time were not significantly better fitting than the random intercept and time model. For the other 2 analyses, the SBQ-R and DERS-SF, the best-fitting models were the null models, with no random terms or interaction variables (SBQ-R: –2LL=6695, AIC=6703, BIC=6722, parameters=4; DERS-SF: –2LL=11,078, AIC=11,086, BIC=11,105, parameters=4). Thus, there were significant mean improvements in the PHQ-9 and GAD-7 scores but not the SBQ-R and DERS-SF scores, and the app condition was not associated with differences in any of the 4 analyses.

Dosage

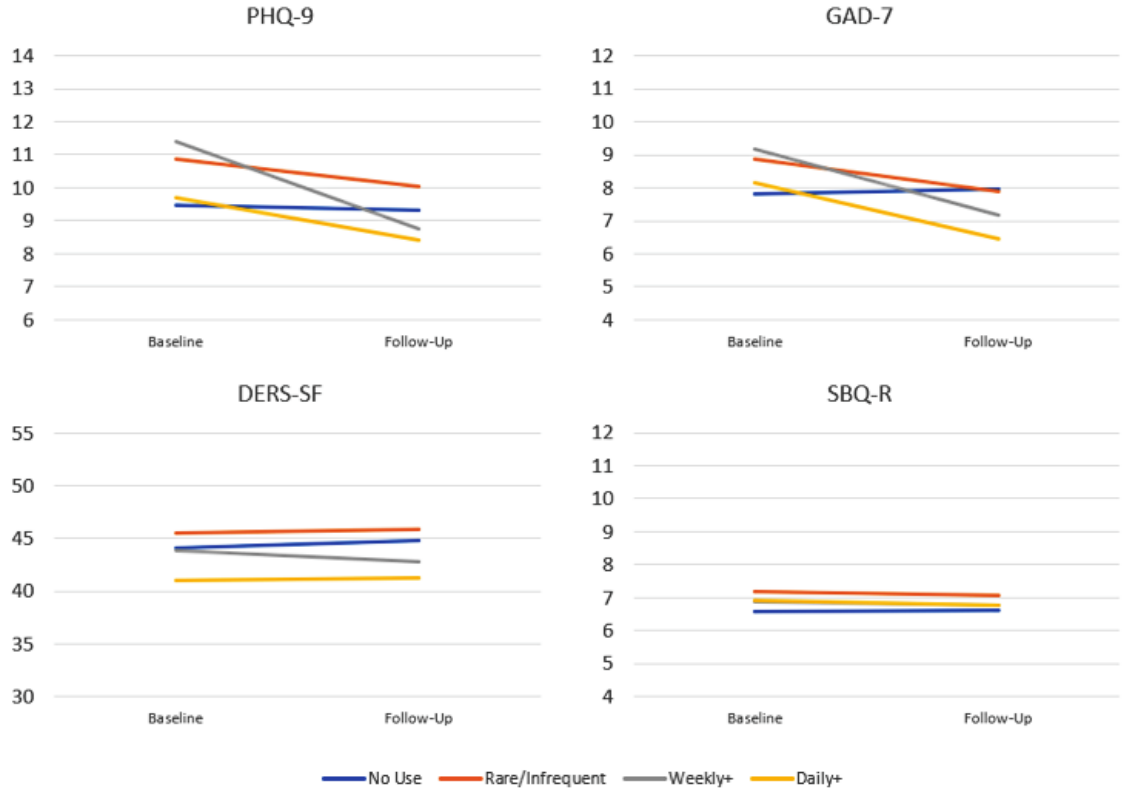
Mixed effects models were computed to examine the relation of frequency of app use with change over time on the PHQ-9, GAD-7, SBQ-R, and DERS-SF, over all conditions, controlling for the condition, for a condition × app use interaction, and for condition × time. The best-fitting model for the PHQ-9 included time, frequency of app use, and frequency × time interaction, as indicated by 2 of the 3 fit indices (–2LL=7868, dev_1=8.9, *P*=.002; AIC=7882, dev_1=6.9, *P*=.01; BIC=7914, dev_1=2.4, *P*=.12; parameters=7, *P*<.001). The BIC statistic, which penalizes for model complexity, was not statistically significant; therefore, these results should be viewed with some caution. All 3 fit statistics indicated that this same model structure was the best fit for the GAD-7 (–2LL=7481, dev_1=14.2, *P*<.001; AIC=7495, dev_1=12.2, *P*<.001; BIC=7527, dev_1=7.8, *P*=.01; parameters=7). None of the models that included condition or condition × frequency of app use was a significantly better fit, meaning we found no differences between the treatment groups on the impact that app use frequency had on change over time. For the SBQ-R and DERS-SF, none of the more complex models improved on the fit of the initial model that included the time and frequency of app use.

Salient model parameters for the best-fitting models were as follows. For the PHQ-9, when time, frequency of app use, and time × frequency interaction were included in the best-fitting model, the frequency of app use was not significant (estimate=0.05, SE 0.3, 95% CI 0.5-0.6, *P*=.86) and time was not significant (estimate=0.1, SE 0.6, 95% CI 1.0-1.3, *P*=.80), but the time × frequency interaction was significant (estimate=–0.6, SE 0.2, 95% CI 1.0 to –0.2, *P*=.003). There were similar findings for the GAD-7 such that when time, frequency of app use, and time × frequency interaction were included in the best-fitting model, the frequency of app use was not significant (estimate=0.1, SE 0.3, 95% CI 0.4-0.6, *P*=.78) and time was not significant (estimate=0.4, SE 0.5, 95% CI 0.6-1.3, *P*=.43), but the time × frequency interaction was significant (estimate=–0.7, SE –0.7, 95% CI 1.0 to –0.3, *P*<.001). Figure 2 depicts the actual mean score for each condition by frequency. For the PHQ-9 and GAD-7, those who did not use the app had no significant change on that measure over time; those who used the app more frequently improved more quickly than those who used the app less frequently. By the 4-week follow-up, however, there were no significant differences in outcome by frequency of app use (dose).

For the SBQ-R, the best-fitting model indicated that the frequency of app use was not associated with lower scores overall (estimate=–0.03, SE 0.2, 95% CI 0.4-0.3, *P*=.16), although time was significant (estimate=–0.1, SE 0.1, 95% CI 0.3 to –0.003, *P*=.05); interaction terms were not included. Therefore, when statistically controlling for the frequency of app use, SBQ-R scores decreased over time but there was no association between app frequency and change on the SBQ-R.

For the DERS-SF, the best-fitting model indicated that the frequency of app use was associated with lower scores overall (estimate=–1.5, SE 0.6, 95% CI 2.6 to –0.4, *P*=.01), but time was not significant (estimate=–0.1, SE 0.3, 95% CI 0.8 to –0.6, *P*=.84), and interaction terms were not included. Those who used their app frequently had lower scores on the DERS-SF at baseline and follow-up, with no change on the DERS-SF over time and no association between frequency of app use and change on the DERS-SF.

Figure 2. Clinical outcome means. DERS-SF: Difficulties in Emotion Regulation Scale – Short Form; GAD: Generalized Anxiety Disorder Scale; PHQ: Patient Health Questionnaire; SBQ-R: Suicide Behaviors Questionnaire-Revised.



Discussion

Principal Findings

To the best of our knowledge, this is 1 of the first pragmatic trials of free commercial apps among essential workers or those unemployed due to COVID-19 experiencing emotional distress and suicide risk. Our primary findings were that commercial mobile mental health apps are found to be usable and acceptable and have a positive impact on depression and anxiety but not emotional regulation or suicide risk. Although we did not find any significant difference between the 3 active apps on outcomes, nor between the active apps compared to the control app, we did find that the frequency of app use during the 4 weeks had a significant and positive impact on depression and anxiety outcomes. However, we offer here that 4 weeks of engagement may not be sufficient to show changes in emotional regulation or suicidal behavior or that online interventions may not be potent enough to manage these mental health challenges, given that those with greater emotion dysregulation used the apps less throughout the period. Indeed, a recent study offering online interventions aimed at suicide prevention not only found no effects but also demonstrated more adverse events in those offered online care versus those offered care as usual [78]. We also cannot rule out regression to the mean, as people who used the attention control app had outcomes similar to participants who used the active apps.

Comparison With Previous Work

Our previous work suggests that apps that focus on mindfulness, pandemic information, mood tracking, and connection with others are an acceptable means of managing stress during COVID-19 [4]. Our findings on the lack of differential clinical impact between apps is not surprising, given the data from other pragmatic trials of research-grade mobile apps. In large-scale remote, pragmatic clinical trials of mobile apps for depression, all apps found significant improvements in mood over an 8-week period but no differences between groups [17]. Our findings regarding the importance of app use on clinical outcomes have also been found in previous studies on research-grade mobile apps, where frequent use of a mobile mood app early in care resulted in better depression outcomes for those who were more severely distressed [17,79]. Although smaller, controlled trials of self-guided apps in a research context do find small but

statistically significant differences in outcomes compared to waitlist controls or no treatment [76], this study, and other pragmatic trials to date, have not demonstrated that active apps are more effective than attention control apps [7,78].

Study Strengths and Limitations

The strength of this study is in its design: It is 1 of the first studies to evaluate free commercial mental health apps prospectively and independently in a large-scale, pragmatic RCT and to assess their impact on emotional distress, emotional regulation, and suicide risk in 2 suicide-vulnerable populations at the peak of the COVID-19 pandemic. The lessons learned from this study can be useful to people seeking free and readily accessible help for emotional distress. For the field, more work is needed to understand what role commercial apps can play for emotional distress, and the data from this study serve as a good starting point for understanding what is acceptable and effective and what optimal engagement should be.

Study limitations include the following:

- Our sample consisted of participants from Prolific and thus may be most representative of essential workers or those unemployed due to COVID-19 who are proactively seeking other sources of income to offset financial stress. Although this sample may be more comfortable with technology, we believe that people seeking mobile mental health apps are also comfortable with technology, and thus the results from this study are representative of this population.
- Because we did not partner with the technology companies who created the study apps, we relied on self-reported app use, which may be subject to self-report bias. However, incentives for participating in this study were not tied to app use, and data from numerous intervention studies find that people are highly accurate in their reports of intervention adherence [80-82].
- Although we justify our timeline for measuring outcomes after 4 weeks of intervention use based on what is typical for most mental health app users, we do not have information on the lasting effects of treatment outcomes or on continued app use. Thus, although we can report on the immediate effects of the intervention, future research is needed to determine the permanence of treatment effects.
- We did not ask about potential adverse events related to app use. This is an interesting area of research that to date has not been explored. Understanding the risks of using commercial apps is as important as determining their impacts and should be explored in future studies.

Conclusion

There are several papers calling for more research to study the effectiveness of commercial mental health app interventions [7,10,83,84], specifically for COVID-19 [85-88], but published studies to date report only app downloads, aesthetics, and app use [6,83,89]. Our data suggest that essential workers and those unemployed who want self-guided mental health care found 4 commercially available apps both acceptable and usable and might receive emotional benefit from a variety of self-guided mental health apps, particularly if they use the apps frequently, but that regression to the mean cannot be ruled out, so improvement in symptoms may not be attributable to app use.

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Data Availability

The raw data supporting the conclusions of this paper will be made available by the authors, without undue reservation.

Authors' Contributions

PA, KAC, and MDP contributed to the conception and design of the study. PA, KAC, BM, MDP, and FM-G contributed to the acquisition, analysis, and interpretation of the data. MJ and MDP performed the statistical analysis. All authors contributed to writing, reviewing, and reading the manuscript, and all approved the submitted version.

Conflicts of Interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Multimedia Appendix 1
Demographics survey.
[DOCX File , 24 KB - mhealth_v10i11e41689_app1.docx]

Multimedia Appendix 2
CONSORT-eHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 1195 KB - mhealth_v10i11e41689_app2.pdf]

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Abbreviations

–2LL: –2 log likelihood
AIC: Akaike information criterion
AIM: Acceptability Intervention Measure
BIC: Bayesian information criterion
DERS-SF: Difficulties in Emotion Regulation Scale – Short Form
GAD: Generalized Anxiety Disorder Scale
HSD: honestly significant difference
IAM: Intervention Appropriateness Measure
ITT: intention-to-treat
IUS: Intervention Usability Scale
MDES: minimum detectable effect size
PHQ: Patient Health Questionnaire
RCT: randomized clinical trial
SBQ-R: Suicide Behaviors Questionnaire-Revised

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Original Paper

Examining the Use of Mobile Technology to Deliver Tailored Sexual Assault Prevention in a Classroom Environment in the Military: Development and Usability Study

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Abstract

Background: Advances in mobile technology over the last 10 years have expanded its use in scientific research. However, there are challenges in creating a reliable system for intervention content delivery and data collection in an environment with limited internet connectivity and limited staffing capacity. The Sexual Communication and Consent (SCC) study used tablets to provide individualized Sexual Assault Prevention and Response training in a classroom environment that was both technologically and support staff limited.

Objective: We developed the SCC Basic Military Training app and a separate Sexual Assault Response Coordinator app to support individualized training within the new SCC program. This paper presents the functionality, protocols, challenges, and feasibility of deploying mobile technology in an educational environment in the military with limited resources.

Methods: We developed both mobile apps targeting the Apple iOS ecosystem. The Basic Military Training app provided a screening instrument that routed the trainee into 1 of 5 specific intervention programs. Over 2 days of basic military training set 2 weeks apart, trainees received a combined 6 hours of program-specific tablet training, combined with universal, interactive classroom training, led by qualified instructors. The Sexual Assault Response Coordinator app, used to deliver supplemental content to a subgroup of trainees, was made available for voluntary and private use at the Sexual Assault Response Coordinator's office on base. All anonymous data were manually transferred onto laptops, where the data were aggregated into files and securely transferred to the project staff for analysis. The study was conducted at the Lackland Air Force Base, Joint Base San Antonio, with 9196 trainees providing the data.

Results: A total of 7742 trainees completed both the sessions of the SCC program and a series of evaluative assessments. Some trainees did not receive day 2 training, and only received day 1 training because the COVID-19 pandemic shortened the study period. Of the 190 SCC classes taught, only one class was unable to complete tablet training because of Apple licensing–related technology failure. The 360 study tablets were distributed across 3 classrooms (120 per classroom) and were handled at least 16,938 times with no reports of breakage or requiring replacement. Wi-Fi access limitations exacerbated the complexity of Apple licensing revalidation and the secure transfer of data from the classroom to project personnel. The instructor staff's limited technical knowledge to perform certain technical tasks was challenging.

Conclusions: The results demonstrated the feasibility of deploying a mobile app for tablet-based training in a military educational environment. Although successful, the study was not without technical challenges. This paper gives examples of technical lessons learned and recommendations for conducting the study differently, with the aim that the knowledge gained may be helpful to other researchers encountering similar requirements.

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KEYWORDS

research techniques; mobile technology; tablet; iPad; restricted; resource limited; Wi-Fi; tailored learning; military; data security

Introduction

Background

Sexual assault continues to significantly impact military force readiness and lethality [1]. The 2018 Workplace and Gender Relations Survey reports an increase in sexual assault from 2016, with 20,473 active-duty service members experiencing sexual assault between October 1, 2017, and September 30, 2018 [2]. In addition to an estimated 16,000 manpower years lost because of sexual assault and sexual harassment each year [3], victims of sexual violence may experience repeat victimization, posttraumatic stress disorder, depression, and anxiety [4,5].

In the military, other service members perpetrate most sexual assaults; both men and women are sexual assault victims, and revictimization is more likely if individuals are sexually victimized before joining the military [2,6-8]. Scientific studies have shown better outcomes from personalized and tailored instruction over one-size-fits-all content [9], including enhanced sexual assault intervention effectiveness [10]. However, tailored programs that address military-specific risk factors do not exist.

The Sexual Communication and Consent (SCC) project aimed to develop a tailored approach to sexual assault prevention with the goal of improving the existing one-size-fits-all approach at the US Air Force Basic Military Training (BMT). The SCC project used modern mobile technology and digital content to provide a tailored learning experience to trainees [11]. With the prevalence of mobile technology in use today, it is only natural to see increased adoption in learning institutions, especially as new learning innovations and technologies emerge [12].

Similar to higher education institutions that are embracing these new learning innovations and technologies, federal institutions such as the military must also begin to do so. The world at present is accustomed to constant digital connectivity, with information accessible anytime and anywhere. By design, mobile technology is expected to be connected to facilitate information sharing even if the information is sensitive and protected. The military has embraced the use of mobile technology in some areas such as resilience strategies [13]; however, these mobile apps run on personal mobile devices. The use of mobile technology within an organization is governed by the rules of that organization. In addition, technologies that consumers take for granted are restricted in some organizations, such as the military, in the interest of national security.

This paper focuses on the lessons learned using modern mobile technology in a restricted learning environment and does not discuss the science behind the SCC study. Broader descriptions of intervention content development, SCC implementation feasibility, and preliminary program outcomes are forthcoming.

An Overview of the SCC Project

The SCC training included a mixed classroom experience combining instructor-led sexual assault educational activities and discussion with a tailored learning experience using mobile technology to be used during BMT conducted at the Lackland Air Force Base, Joint Base San Antonio, Texas. Early in the development of this training approach, we learned that new trainees were not allowed to access personal mobile devices during basic training, and the training rooms had limited internet access. To facilitate the delivery of tailored training components, we developed 2 offline mobile apps, that is, the BMT app and the Sexual Assault Response Coordinator (SARC) app, which trainees would access on project-provided classroom sets of tablets [11].

The BMT app is the primary app used in the BMT classroom setting. With over 100 trainees per class, and the training split across 2 days, each trainee used the BMT app to first determine their sexual assault risk profile, which was identified from their responses to an anonymous screening assessment. On the basis of their sexual assault risk profile, the trainee then received tailored content from 1 of 5 programs: Revictimization Prevention (separate programs for male and female), Primary Prevention and Situational Awareness Enhancement (separate programs for male and female), and Healthy Relationships and Airmen Intervention (for males with no victimization history or risk). The tailored training was delivered confidentially using the BMT app, and tablet privacy screens and headphones were provided to ensure privacy. The tailored content included videos depicting scenarios in which sexual assault can occur and modeled behavioral strategies that can be used to decrease the risks associated with such situations.

The tailored tablet training was combined with interactive classroom training instruction and activities, led by 2 trained instructors in a 120-minute block on day 1 and a 240-minute block on day 2, for a total of 6 hours of training for each trainee. On day 1, a total of 93 minutes were programmed for time spent using the tablet, and 109 minutes were programmed on day 2. The integration of individualized, tablet-based training into the BMT classroom environment provided a unique opportunity to reach at-risk groups with tailored content (eg, women and individuals who experienced sexual assault before enlistment), while protecting their privacy and providing consistent messaging to the larger group [14].

A separate SARC app containing individualized, tablet-based content for sexual assault survivors, which is too sensitive to deliver in a classroom setting, was made available for voluntary, confidential viewing in the SARC office following group training. Trainees followed BMT confidentiality processes to ensure they were not outed as a survivor if they voluntarily chose to receive this additional training.

In parallel with the training development process, we worked with partners at the BMT and Headquarters Air Force to

determine the best approach for implementation and feasibility testing. The resulting plan included a gradual three-phase implementation that occurred over 26 weeks. Overall, 25% of incoming trainees received the SCC program, while the remaining 75% received the current BMT training in phase 1 (10 weeks). Moreover, 50% of incoming trainees received SCC during phase 2 (10 weeks), and 100% of incoming trainees received SCC during phase 3 (6 weeks).

All study procedures were subject to several rounds of Department of Defense (DoD) programmatic, legal, and human subjects protection review.

Requirements of the Training Environment

Individualized, tailored trainings were at the forefront of both the application and technology design considerations when implementing the SCC project. Early in the development of the training approach, we learned that the trainees would have no access to personal or government-provided technology other than what was provided in the classroom. The nature of the SCC project was to do better than a *one-size-fits-all* solution; each trainee would receive tailored training targeted at them. The only 2 choices were web-based applications or mobile-based apps accessible by either tablets or laptops; the Air Force directed the use of Apple iPads and MacBooks.

Regardless of the technology, the trainees were to be restricted in what they could do with it. For example, during class, they were not permitted to access emails or surf the web. The device must only provide access to the apps pertaining to the classroom materials. This is analogous to *kiosk* or *single-app mode* where access to any other app is prevented.

In addition, we were informed that a Wi-Fi network providing access to the internet would not be available for our use; therefore, with no access to the internet, anything web-based was ruled out, including the use of a Mobile Device Management (MDM) system. An MDM allows administrators to remotely control and secure mobile devices such as tablets used in a classroom [15]. The lack of a network connection meant that there was no real-time access to a back-end storage server, such as SQL Server. As this more typical method of data collection and storage was not available, a nonstandard approach was required. Three months before the main study started, the project team was informed that limited Wi-Fi access was available, which resulted in a few minor changes to the system, but it was too late for the major changes required to take advantage of a networked system. Originally, because a network was not available, Verizon mobile hotspots [16] were incorporated into the system design to facilitate data transfer. With limited Wi-Fi access permitted, instead of using the Verizon mobile hotspot, the system was changed to permit MacBooks to connect directly to the limited Wi-Fi network as needed for data transfer. Modifying the BMT app to use a Wi-Fi internet connection was not realistic, given the project schedule.

The iPads were intended to remain in the classroom for reuse by other trainees undergoing the same SCC training. With classes in both the morning and afternoon, the devices had to maintain battery charge through the course of the day, with a full charge taking place overnight to be ready for the next day's classes.

The SCC training was spread out over 2 days, with day 1 of SCC training occurring during week 2 of basic training and day 2 of SCC training occurring during week 4 of basic training. There was no guarantee that a trainee would be in the same classroom for their second day of training, and attempting to provide trainees with the same device they had from day 1 training was too high a burden on the instructional staff in addition to their other duties. Thus, 12 GB of content comprising all intervention programs had to be present on every device, as each use of the device could result in a different intervention program assignment for a trainee. Furthermore, with no real-time ability to access a back-end storage server such as an SQL Server database and all saved data needing to be anonymous to protect trainee privacy, a new approach was required for data collection and storage to link data over time and ensure trainees received the same program from day 1 to day 2.

Objective

The aim of this study was to evaluate the efficacy and effectiveness of the technical implementation of the SCC program in a restricted educational setting with limited internet connectivity and the resulting ramifications. This is addressed by (1) how the technical solution met the requirements and (2) how it was implemented. We then review the technological feasibility results, discuss the lessons learned, and provide suggestions for different implementation strategies. The findings will provide guidance for future similarly restricted projects to focus on possible problems and alternative solutions.

Methods

Hardware

With guidance from the Air Force project team members, 364 iPads were purchased; 120 iPads were distributed to each of 3 classrooms. The remaining 4 iPads were distributed to the SARC office. Although each classroom has a capacity for 120 trainees, the average class size was less than 110, leaving at least 10 spare iPads per classroom to serve as backups in case something went wrong. In addition, 3 MacBooks were purchased, with 1 MacBook distributed to each classroom. To facilitate the charging and management of the iPads, we purchased 9 Evo 40 Cart [17]—Sync and Charge carts. Each cart connects, stores, and secures up to 40 iPads while also acting as a giant USB hub capable of providing simultaneous charging and synchronization, and 3 carts were stored in each classroom.

In the absence of Wi-Fi and consequently the inability to use an MDM, a rudimentary desktop MDM application, the Apple Configurator [18] was used to facilitate tablet management using Apple hardware. By physically connecting a classroom's MacBook to the Evo 40 Cart, technical staff were able to configure and update the cart's 40 iPads simultaneously before moving on to the next cart. After all, 3 classrooms were completed, 1 MacBook's 4 USB ports were used to physically connect to, configure, and update the 4 iPads kept in the SARC office for voluntary supplementary training. In this way, while still a manual process, we were able to efficiently manage the

360 classroom iPads, replicating what could be done with an MDM if Wi-Fi had been available.

For security, each cart was physically locked, with the key stored in a combination lockbox accessible only by the project staff. The instructors distributed the required number of iPads based on the classroom roster before the class started. Distribution included headphones with disposable ear covers and single-use sanitization wipes to be used at the end of each training session. The iPads were already in single-app mode, also known as kiosk mode, preventing the trainee from accessing any other part of the iPad. Placing an iPad in a single-app mode was a task performed when the apps were installed or updated with a newer version.

To protect the MacBooks from unauthorized access, 2-factor authentication (2FA) was enforced. 2FA requires 2 methods to verify one's identity: (1) something one knows, such as a username, a password, or a pin, and (2) something one has, such as a Personal Identity Verification, a security token, or a biometric factor [19]. As the system was not connected to the internal Air Force network, a government-provided Common Access Card (CAC) could not be used. Instead, a YubiKey [20] hardware security key was used as a physical authentication token.

Custom Software

With the equipment design and setup complete, many of the technical requirements were met. To resolve the remaining technology requirements, we wrote custom software. Overall SCC program development, including content development, review, video production, and technical development and testing, took over 3 years.

Ensuring that the trainees received the appropriate tailored training on both days was challenging but key to the SCC project. With no way to ensure that a trainee would use the same iPad on both days, and no identifying data being recorded into a data storage mechanism, the project solved the problem of delivering the appropriate training on day 2 by implementing a *continuation code*. On day 1, upon completion of the screener instrument, the screening algorithm generated a 12-digit code. It was an obfuscated set of numbers (eg, 458-857-018-173) that embedded the information about their assigned intervention program. Trainees were instructed to write this continuation code in their BMT Study Guide. At the start of day 2 of the SCC program, trainees entered their continuation code to resume training. If a trainee did not have their continuation code (ie, they lost it, forgot their Study Guide, or never wrote it down), the app, with assistance from the instructor as necessary, directed the trainee to a *short screener*, a brief screening instrument that routed them to a self-identified sex-specific program that was least likely to be harmful and most likely to be appropriate.

To further protect trainee privacy during the class and because the single-app mode precluded the normal iPad lockout functionality, the SCC mobile apps implemented a custom lockout at the application level. Trainees were instructed to create their own 4-digit personal identification number (PIN) that could be used to lock and unlock the app throughout training. PINs were temporary and not saved with trainee data. The trainees created a new PIN for the day 2 class.

The use of the SCC apps resulted in deidentified data saved locally to each iPad. The Apple Configurator only provided the ability to manage iPads and update SCC apps with new versions and content. It did not provide the ability to extract data generated using SCC apps. Instead, custom software, designated the Data Aggregator, was written to connect and extract the data from the iPads to the MacBook and then aggregate the data into a format suitable for analysis. The use of the Data Aggregator is described in the Procedures Requiring Unique Skills section.

Procedures Requiring Unique Skills

We tracked any classroom and system issues manually by reporting weekly with on-premises staff and via instructor and observer logs. In addition, use data were captured via the app, tracking how the trainee was using the app, which screens, the order of the screens, and how much time they spent on each screen they accessed within the app.

Daily Tasks

Before the start of each class, instructors placed iPads, headphones, disposable headphone covers, sanitization wipes, and classroom materials in each seat. At the end of each class, trainees wiped iPads with the provided sanitization wipes and disposed headphone ear covers. At the end of each class or training day, instructors collected the iPads, returned them to the carts, and connected the cables for each iPad to recharge for the next class.

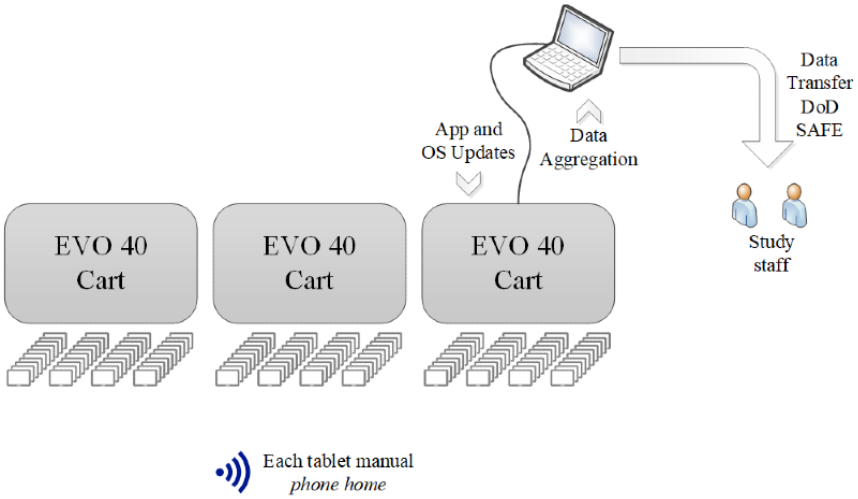
Weekly Tasks

Every Friday, trained instructors connected the classroom's MacBook to a cart and ran the Data Aggregator to pull the week's data from iPads onto the MacBook (Figure 1). After repeating these steps for the remaining 2 carts in the classroom, the aggregated data were transferred to the project staff for study analysis via the DoD SAFE secure file transfer system.

The data collection steps were repeated in the other 2 classrooms. For the 4 iPads in the SARC office, because Wi-Fi was not available in the SARC office, 1 MacBook was brought to the SARC office, and all 4 iPads were connected directly to the MacBook. The same data synchronization steps were performed as in the classroom, and the iPads were then plugged back into their individual chargers, plugged into a wall power outlet. On returning to the classroom, the SARC app data were transferred to the project staff via DoD SAFE.

Backups of the data were kept on the MacBooks until it was deemed that the DoD SAFE transfer was successful and the data were processed. At that time, we deleted data from MacBooks.

Figure 1. The classroom configuration of 3 Evo 40 carts, each cart containing 40 iPads. This figure illustrates some of the tasks performed by staff. This configuration was repeated in 2 other classrooms. DoD: Department of Defense; OS: operating system.



Monthly and As-Needed Tasks

Apple requires software developers to use 1 of 2 Apple Developer programs. As these apps were internal Air Force apps, used only by Air Force personnel and not for distribution via the Apple App Store, we used the Apple Enterprise Developer Program [21] to generate distribution certificates. As part of fraud prevention, Apple requires each app to connect with Apple servers (ie, to "phone home"; Figure 1) to validate the authenticity of each app's signing certificate. Under normal circumstances, mobile devices are regularly connected to the internet. With data plans, phones are permanently connected unless the user actively puts the phone in Airplane mode or turns off Wi-Fi and cellular data. On a tablet without a data plan, access to the internet is via Wi-Fi; this is how tablets are typically used. The required "phone home" for app certificate validation occurs behind the scenes, without the need for user intervention or notification. However, in this classroom setting, the lack of Wi-Fi access effectively prevented the phone home from automatically happening on the study tablets.

Operating System Updates

As per the instructions in the Authorization to Operate (described below), iPads and MacBooks required periodic operating system (OS) updates. All OS updates were first tested on the development test equipment to ensure field operability. Technical staff then traveled to the BMT to perform technical updates. The MacBook OS updates were performed first, followed by iPad OS updates (Figure 1).

With iPad OS updates, a phone home was also performed. Instead of each iPad downloading the OS update individually, an Apple Configurator was used to push the new OS to the iPads simultaneously. The classroom MacBook was first connected to an Evo 40 Cart. Using the Apple Configurator, the iPads were removed from the single-app mode and refreshed with the latest OS. The benefit of using the Apple Configurator for pushing the OS to the iPads was that the OS was downloaded only once per MacBook instead of 364 times (once per iPad). Once the iPads were updated, the OS setup was completed on each iPad. If required, a new version of the SCC app was pushed, and finally, a phone home was performed before putting the iPads back into single-app mode.

Military Cybersecurity

Per US Air Force cybersecurity requirements, an Authorization to Operate (ATO) was required. An ATO is permission to use an information technology system. Working with Air Force cybersecurity personnel, appropriate security controls were identified that required documentation and possible software adjustments. Updates were entered into the Enterprise Mission Assurance Support Service (eMASS), a web-based application providing comprehensive cybersecurity management. Various cybersecurity-directed changes also needed to be applied to both iPads and MacBooks, such as turning off Bluetooth and enforcing 2FA.

Conducting the Study

Although each technical task was meticulously documented and instructional staff received training in these tasks, the complexity and volume of the technical tasks, combined with the fact that the project technical team was off-site in another state, called for additional specialist safeguards. As such, BMT IT staff were also trained on technical tasks to provide on-premise support. The off-site technical project staff were on call during classroom sessions for troubleshooting and worked with on-premise IT staff to support the various technical tasks related to this project.

The feasibility study ran from September 2019 to March 2020, which was shortened by 4 weeks due to the onset of the COVID-19 pandemic. Approximately 800 new trainees start BMT every week, enabling a quick rollout of SCC to trainees. We received a non–human subjects research determination from the research team's institutional review board, as the DoD deemed that the feasibility study was not research.

Results

Technology System

The technology system was tested with 190 classes, with 9196 trainees providing data on day 1 and 7742 providing data on day 2, resulting in at least 16,938 iPad uses. Owing to the

COVID-19 pandemic, the study ended early; as a result, some day 1 trainees had never received day 2 training. None of the iPads broke or required Apple Care replacement; however, many headphones broke during repeated use (Table 1). Of the 7742 day 2 trainees, 758 did not have a working continuation code. More than 1000 unique data points were captured per trainee for scientific analysis with results forthcoming in future publications.

iPad issues during training, such as not turning on, freezing, needing to be restarted, or trainees being in the incorrect place in the training schedule, were noted by instructors for less than 14% of all class sessions. If a challenge was discovered during room setup, instructors borrowed unused tablets from the open classroom to ensure that all trainees would be able to participate in tablet content. Challenges that occurred during group instruction were managed by the co-instructor, while the primary instructor was able to continue instruction for the rest of the classroom; this was rendered more difficult if multiple trainees were having issues simultaneously. There were no difficulties with tablet accountability, distribution, recovery, storage, or data transfer.

Of the 190 classes conducted throughout the trial, there was only one issue that disrupted instruction. During the class, 80 tablets appeared to be "bricked," completely unable to function. Confusing the issue was that of all the iPads, only 80 were nonfunctional. This disruption was compounded by a base-wide Wi-Fi outage that lasted several days, preventing the local BMT support team from troubleshooting potential solutions under the guidance of a remote technical team. On the day this problem was discovered, one class was unable to receive SCC training and subsequent classes. As the study was not yet running at 100%, we were able to borrow iPads from other classrooms until this issue was resolved. After a week of troubleshooting, we determined the malfunction was the result of Apple requiring a more frequent "phone home" than the 90-day frequency Apple recommended us to use. Detailed analysis showed that beginning approximately 6 weeks after the phone home, the iPads started to become unresponsive. However, not all 360 iPads became unresponsive on the same day. Rather, each day, a few iPads would randomly become unresponsive, until after a few weeks they were all unresponsive. Our tests could not establish a predictable pattern, and therefore, we performed the phone home connection every 28 days, thus guaranteeing that the iPads did not become unresponsive because of the inability to verify the certificate. We chose every 28 days to give us a 2-week buffer to the 6-week mark when we first noticed an unresponsive iPad in troubleshooting. We felt that this 2-week buffer was sufficient time to resolve any unforeseen technical issues, such as a Wi-Fi outage. The one class that did not receive the SCC training instead received the prior Sexual Assault Prevention and Response training that was already in place at BMT.

Table 1. The Sexual Communication and Consent technical issues tracked by the app and the instructor and observer logs.

Measure	Outcome	
	N	n (%)
Proportion of classes unable to continue because of tablet issue or systemic IT issue	190	1 (0.52)
Broken headphones	360	111 (30.83)
Did not have continuation code in day 2	7742	758 (09.79)

Technical Activities

No analysis was performed to determine if the staff felt the system was too burdensome to maintain; rather, based on manual reports, we calculated the amount of time spent performing these technical activities. The instructors and BMT support staff engaged in the technical activities described in Table 2.

Table 2. The technical activities staff performed and the burden of each activity.

Activity	Commitment
Training and ongoing technical assistance	
New instructor technical training	2 hours
Technical support with research team	1 hour per week; usually supporting data transmissions
Daily instructional time	
Setting up the classroom (including iPad distribution)	Up to 1 hour per class
Tearing down the classroom (including returning iPads to carts)	Up to 30 minutes per class
Classroom and tablet maintenance	
Weekly data transmissions to research team	Requires 1 person<30 minutes per classroom (3 classrooms total plus SARC[a] office); dependent upon Wi-Fi
Monthly Apple license update (“phone home”)	6 hours; requires 2 people up to 2 hours each, per classroom (3 classrooms total plus SARC office); dependent upon Wi-Fi
Operating system updates (include app update and “phone home”)	Requires 2 people 6 hours per classroom (3 classrooms plus SARC office total); dependent upon Wi-Fi

[a]SARC: Sexual Assault Response Coordinator.

Discussion

Principal Findings

This study showed that a modern, tablet-based, Wi-Fi–restricted classroom environment does work. We successfully implemented a tailored prevention program and collected data from over 7700 trainees over 2 training periods. With almost 17,000 uses, none of the 360 iPads broke or required a replacement from Apple via their Apple Care insurance. The SCC program was mentioned in the Fiscal Year 2020 Annual Report on Sexual Assault in the Military: Department of the Air Force as an innovative evidence-informed sexual assault prevention training as a new initiative to evolve the Department of the Air Force’s integrated prevention and response efforts [22].

Despite the promise of this innovative approach, we encountered several challenges that forced us to ask whether it is *worth it* to create such a custom environment. There is no disputing the importance of technological integration with scientific research, and with knowledge, we have gained better insights. In retrospect, the technology team should have pushed it harder for Wi-Fi access. As the SCC was custom, no other trainings could use the investment in the hardware the SCC required. In addition, the large cost investment in dollars and labor hours spent creating this custom solution are not feasible in most other environments. Understanding that importance is subjective, we present the following lessons learned in order of importance to SCC study.

Lack of Wi-Fi

The number one issue that impacted many different parts of the system was the permanent access to Wi-Fi. Even with the rapid pace of innovation using technology, technology itself continues to be a barrier, with an internet connection being the largest [23].

Tight control over what and who accesses a network is integral to security. One approach to mitigate potential security concerns associated with allowing training iPads to access Wi-Fi would be to white list them, a mechanism that grants the IP address of each iPad explicit access to the Wi-Fi network. With permanent Wi-Fi access to the internet, the *phone home* challenge and related ramifications were eliminated. The hours spent troubleshooting why the iPads bricked in the first place before the 90-day marker and all the hours spent doing the *phone home* process every 28 days to 364 iPads would have been avoided. The study benefited from having a large total sample and missing one class, which did not affect the analysis, but if the N was much smaller, losing even one class could influence the data analysis. The *phone home* process was time consuming, averaging 6 hours to complete, and not without its own issues. Although the re-engineered process worked, manually connecting to Wi-Fi did not always work for the first time and sometimes required multiple attempts to forget and reconnect to the Wi-Fi network. White listing the iPads would have also prevented the need for multiple Wi-Fi connection attempts.

Access to Wi-Fi would have also permitted the mobile apps to save the data directly to a back-end cloud database storage server [24] for immediate access by project team members, a more standard architectural design for mobile app development. Instead, custom software had to be written, and trained staff had to be physically in the room to manually transfer the data from the iPads to a MacBook and then manually transfer the data to project team members via a secure file transfer mechanism.

Access to Wi-Fi would have also permitted the use of an MDM system such as IBM’s MaaS360 solution [25]. Instead of having trained staff physically in the room using MacBook client software manually connected to the iPads to manage them, an MDM solution would have permitted remote management of the iPads for OS updates and SCC app and content updates. MacBooks would have been used for emergency backup

purposes only, as everything would be done remotely. Project staff, if remote, can multitask and perform other tasks while an update is being pushed. Without Wi-Fi, staff members were required to be in the classroom to monitor when the update was completed, sometimes waiting over an hour while the update was being performed.

Moving to a web-based solution for the training still requires Wi-Fi but eliminates the need for MDM to manage this specific class. This structure of this study was for the trainees to only use the iPad during the SCC class in a classroom setting. The iPads were stored in the classroom and were only accessed within the classroom. The SCC training was only one class of many as the trainees went through basic military training. If the overall education system for basic training is invested in Wi-Fi infrastructure and more permanent use of technology by trainees, SCC could become part of that ecosystem, eliminating the need for a stand-alone system that cannot be used by any other training. Although an MDM would still be needed for the overall management of the device, it would be integrated into the overall educational ecosystem and no longer be SCC-specific.

Procedures Requiring Unique Skills

As the study progressed, the instructors and BMT IT staff became more comfortable performing technical activities (Table 2) required of them.

Troubleshooting via text messaging and videoconferencing between BMT IT and instructor staff with remote research and technical staff was very efficient. Although the cellular connection was not always stable, the ability to *see* what was happening from a remote location streamlined troubleshooting greatly. Remote staff can direct the premises staff much more easily and make real-time suggestions instead of waiting for emails to go back and forth. There was a need for an IT person to be *available* while classes were in session should something go awry. During the study, the remote project staff maintained an on-call approach, which was very useful. During the study, instructors completed many of these IT tasks and became proficient in the procedures and self-sufficient within a few weeks in the field. Instructors who were already familiar with the Apple ecosystem became especially proficient. On the basis of SMS text message and FaceTime history, there appeared to be a decrease in both forms of communication as the study progressed.

Each class required 1 hour and 30 minutes of setup and teardown time. Having dedicated classrooms permanently provisioned to avoid setup and takedown procedures could significantly reduce the daily manpower requirements. Instructors and IT staff could divide classroom and tablet maintenance tasks to disperse the associated manpower requirement.

Every 28 days, staff members were required to perform the monthly Apple license update (“phone home”) task. The regularity with which this task needs to be performed is not found in public Apple documentation. If the application does not connect, it becomes unavailable for use on the device. As the iPads were in single-app mode, the result of this unavailability manifests as an unresponsive tablet with a blank screen and no error messaging.

To avoid this, and because the tablets could not automatically phone home, instructors were trained to perform this license validation task manually on each iPad. Per Apple direction, we trained instructors to perform this certificate validation task every 90 days.

Critical to the study’s success were other skill sets, including staff with expertise in the Apple ecosystem, including MacOS, iPadOS, MacBook, and tablet maintenance; software development skills for app updates and OS updates; and Air Force cybersecurity requirements to maintain the ATO. When implementing this program, or others like it, in the future, staff will need to commit sufficient time to ensure that the program runs smoothly on the tablets (eg, by conducting quality checks after each device or app update). Software development troubleshooting skills are highly recommended because of the nature of mobile software updates [26].

Owing to their intimate knowledge of the study’s technical ecosystem, having a software developer as part of the support team was key. In addition to maintaining the annual Apple Developer Enterprise Program License yearly, they were able to troubleshoot app issues that may be introduced through iOS updates (eg, someone who knows what to do if the keyboard comes upside down on the tablets after an automatic system upgrade) and rebuild and redeploy the app to all iPads when needed.

The instructors, through training and use of the system, became technical experts on the system. They needed ample lead time in the classroom and support to work with the technology and became well versed in addressing problems that arose with iPads and the app during classes. Building trust among all staff members is important when conducting research using unfamiliar technology. Unfamiliarity can breed uncertainty, and SCC benefited from open, early, and frequent communication among all team members. Weekly technical assistance calls were set up to address any questions or concerns that the instructors had. Instructors should not have to become technology experts in their classroom; rather, they should be able to use the technology and focus on engaging with students, especially in sensitive topic areas, such as sexual assault, which can trigger an unexpected emotional response.

Broken Headphones

Headphones breaking over time was reported as an issue. Headphone reuse and sanitation worked for this class, but due to the constant bending of headphones to place over the ears almost 17,000 times, approximately one-third of the headphones needed to be replaced (Table 1). The dilemma was whether to purchase many cheap headphones frequently or more expensive headphones that were more durable and lasted longer. No determination was made in this study that comparing cheaper quality versus higher quality headphones other than projects using headphones should plan to replace headphones over time.

Hardware Choices

What about using Google Android instead of Apple iOS or iPadOS in the future? Using non-Apple equipment was not an option; the requirement was to use technology from the Apple ecosystem, following the trend of other Air Force projects using

Apple technology. However, switching to an Android ecosystem would only, perhaps, save on the phone home. Our experience on other projects using Android indicates that there are no phone home requirements for Android applications. Although avoiding the phone home issue would have saved labor and time, all the other issues would have remained as the issue was around Wi-Fi access, not what OS the mobile device was running.

If trainees had iPads assigned to them, perhaps at the start of BMT, the need for a continuation code could have been avoided. The continuation code, a set of obfuscated numbers that embedded information about an assigned intervention program, was more an annoyance than a problem. All data were deidentified, and with no back-end system to query, it was impossible to know what intervention program the trainee was assigned to. This was crucial to the study design for trainees to receive correct tailored training.

The Evo sync-n-charge cart is indispensable for efficiently managing manual technical tasks and charging. In addition to charging the iPads, when a MacBook was connected to the cart, all 40 iPads were available for bulk updating via Apple Configurator software. The Apple Configurator worked well as a manual MDM, with the only downside being a lack of detailed progress. For example, when pushing 12 GB of SCC content to 40 iPads, there was no indicator of how much content was pushed to the number of iPads. Only through trial and error did we determine that the software was not hung up but rather, with *started* and *completed* status updates as our guides, we learned it took 3 to 4 hours to update 40 iPads with all the SCC content.

Lack of Data Storage Lookup Mechanism

As the system had no back-end data storage mechanism, there was no automated solution to look up a trainee's assigned intervention program. The continuation code solution was an annoyance because trainees had to write down a long, 12-digit number and then key it into the app on day 2. Of the 7742 day 2 trainees, 758 did not have a working continuation code (Table 1). If the trainee did not have the code from day 1, they would complete a short questionnaire asking for self-identified sex only. On day 1, the full screener placed the trainee in 1 of 5 different intervention programs. This shortened questionnaire would place the trainee into 1 of 2 intervention programs as time did not permit the trainee to go through the entire screener again. The potential risk is that the trainee would not receive the same tailored program.

If trainees had iPads assigned to them, perhaps at the start of BMT, the need to have a continuation code could have been avoided. The data would be saved locally on their assigned iPad, including the correct intervention program assignment. In mobile apps, extra software development for the error handling of a lost continuation code could have been reduced. More importantly, this would also reduce the risk of trainees receiving a different intervention program.

Military Cybersecurity

The use of mobile technology was new to the BMT classroom at the time, and for security purposes, the military was rightly cautious in its adoption of new technologies. Conducting research with the military provides its own set of unique challenges with many required signoffs. Research using IT should plan on a Certified Information Security Manager (CISM) to assist with ATO. The CISM interfaces with the cybersecurity team at the military and submits all documentation into eMASS. An experienced IT technical team works with CISM to determine relevant security controls and Security Technical Implementation Guides to implement. The IT team needs to plan for extra time to update the design and implement changes in the system as per the Security Technical Implementation Guides.

Owing to the nature of the unique SCC system being a closed system with no cloud access, many of the security controls were not applicable, which prompted some discussion on how to accurately record the correct response within the eMASS system. This study broke new ground, and electronic systems were not set up to track cybersecurity details efficiently. Additional details are required and documented in the security control documentation because of the custom solution of the SCC system.

The SCC operated under an interim authority to test, then a 1-year ATO, and then a 3-year ATO was issued. Project planning should account for the appropriate time in the schedule to perform ATO-related tasks: where the system will be hosted, updating the system with the required changes, and documenting the security controls in eMASS.

Finally, projects should plan for staff members to pass a security clearance and obtain CAC and government-issued computers to access eMASS. A CAC is a smart card and the standard identification used by the DoD for physical access to buildings, controlled spaces, and access to computer networks and systems. Owing to circumstances beyond our control, it took 13 months for the project staff to receive their CACs after the initial security clearance submission.

Next Steps

The SCC project team has since developed a web-based version of the SCC program to resolve many of the challenges faced in this initial study. We are currently testing and evaluating this version of the program in a military setting that is Wi-Fi enabled. In addition, we plan to evaluate the integration of the SCC program into standardized web-based e-learning systems in other military locations.

Conclusions

The use of mobile technology in a classroom setting allows for new ways of teaching, especially delivering training tailored to a specific student. Although the use of technology in new ways is exciting, it presents new challenges and requires new skills. The SCC project shows that mobile technology in a unique, Wi-Fi–restricted classroom setting does work, but that improvements are needed before it will be sustainable or scalable. Testing any system in its intended environment is critical for increasing its acceptability, feasibility, and usability [27]. Advances in technology allow for new and creative ways of conducting scientific research, and we encourage researchers and technologists to explore new uses of technology. Considering the constraints and lessons learned in this study will impact overall technical implementation.

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Conflicts of Interest

None declared.

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Abbreviations

ATO: Authorization to Operate
BMT: Basic Military Training
CAC: Common Access Card
CISM: Certified Information Security Manager
DoD: Department of Defense
eMASS: Enterprise Mission Assurance Support Service
MDM: Mobile Device Management
OS: operating system
PIN: personal identification number
SARC: Sexual Assault Response Coordinator
SCC: Sexual Communication and Consent

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Original Paper

Efficacy of the Mental Health App "Intellect" to Improve Body Image and Self-compassion in Young Adults: A Randomized Controlled Trial With a 4-Week Follow-up

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Abstract

Background: Body image concerns are prevalent among young adults, who may be vulnerable to developing body image concerns because of particular risk factors associated with this life period. With technological advancements, digital mobile health (mHealth) apps are cost-effective and scalable interventions. Thus, mHealth apps can be explored as a form of prevention effort to alleviate body image concerns in young adults.

Objective: In this randomized controlled trial, we examined the effectiveness of a self-guided mHealth app in improving body image and self-compassion in a sample of university students.

Methods: Participants (N=310) were randomized to a 9-day self-guided body image and self-compassion mHealth app (n=149) and to an active waitlist control group (n=161), where they completed a similarly structured 9-day program on cooperation. Both programs consisted of content learning and activities such as quizzes, with the number and length of activities matched for both programs. Measures were obtained at baseline, upon completion of the programs (after the intervention), and at 4-week follow-up.

Results: The intervention group for female participants reported significant reduction in body dissatisfaction (P<.001) and improvements in body appreciation (P<.001) and self-compassion (P=.001) compared with the active waitlist control group after the intervention. Similarly, for male participants after the intervention, a significant reduction was found in the intervention group in body dissatisfaction (P<.001) after the intervention as well as improvements in body appreciation (P=.02) and self-compassion (P=.047). The effects were maintained at 4-week follow-up for female participants on body dissatisfaction (P<.001), body appreciation (P<.001), and self-compassion (P=.02) but not for male participants. On body image risk factors, significant reductions were found for female participants after the intervention for thin-ideal internalization (P<.001), peer pressure (P=.002), and media pressure (P<.001) after the intervention, while the effects were only maintained for thin-ideal internalization (P=.008) and media pressure (P=.01) at 4-week follow-up, compared with the active waitlist control group. As for male participants, no intervention effects were found both after the intervention and at follow-up for all body image risk factors of muscularity internalization, peer pressure, and media pressure. Both apps were acceptable and participants engaged equally across the intervention and active waitlist control groups, as indicated on a measure of app engagement (P=.76).

Conclusions: This study provides preliminary evidence for a self-guided mHealth app in improving body image concerns and self-compassion in young adult university students. Future studies should include longer follow-ups, and examine its effects with the wider populations of young adults.

Trial Registration: ClinicalTrials.gov NCT04977973; https://clinicaltrials.gov/ct2/show/NCT04977973

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KEYWORDS

body image; body image program; mobile health app; mHealth app; mobile-based interventions; dissonance-based interventions; self-compassion

Introduction

Background

Body image problems are highly prevalent among adolescents and young adults and have been frequently implicated in the development and maintenance of problematic eating behaviors [1,2] and body dysmorphic disorder [3,4]. Young adults may be particularly vulnerable to developing body image problems because of particular risk factors associated with this life period [5,6]. As young people transition through this developmental period, their bodies change in height, weight, and proportion while being exposed to social pressures associated with physical appearances [7]. Sociocultural factors play an important role in the development of body image concerns. According to the tripartite influence model, media, peers, and parents are the main sources of social influence on an individual's body image [8]. These influences largely take place through appearance-ideal internalization and appearance comparisons [9]. Research has shown that women tend to desire the thin-ideal, whereas men desire muscularity and weight [10]. Appearance-ideal internalization was found to mediate the relationship between sociocultural influences and body dissatisfaction [11,12], with greater internalization exacerbating body dissatisfaction [9]. This suggests that reducing the internalization of appearance ideals likely decreases body dissatisfaction.

Individuals tend to engage in upward appearance comparison, whereby they compare their appearance to others whom they perceive to be more attractive [13]. Consequently, they experience lower body esteem and higher body dissatisfaction, which perpetuate further appearance comparison [9,14].

Exposure to media contributes to appearance-ideal internalization and appearance comparison. Media and social networking platforms are filled with ideal-looking images of the self and others which are often skewed representations of reality [15,16]. Through social learning, individuals tend to normalize such content and internalize them as reality [15,17]. Moreover, individuals with vulnerability factors such as preexisting body image concerns, low self-esteem, depression, perfectionism, or overvalued appearance ideals are more likely to engage in appearance comparison to seek assurance and validation [18]. Altogether, appearance comparison on media platforms contributes to the development and maintenance of body dissatisfaction [9], highlighting the importance of addressing media literacy in reducing body image concerns.

Among peers, appearance-focused comparison and appearance-related conversations and activities may also increase body dissatisfaction as they increase individuals' awareness of their bodies, strengthen the internalization of appearance ideals, and negatively alter personal attitudes and beliefs in relation to beauty standards [19].

Apart from sociocultural influences, ruminative cognitive styles have been associated with greater body dissatisfaction [20]. Rumination is a response style to distress wherein individuals focus on repetitive thoughts and feelings about the distress [21]. As such, distress arising from negative body image may elicit rumination about one's appearance, which in turn contributes to body dissatisfaction [20].

Positive Body Image and Self-compassion

Positive body image is characterized as being accepting, appreciating, and respecting of our bodies through attending to the body's needs, protecting ourselves against unrealistic body ideals, having broader conceptualizations of beauty, and filtering information in a body-protective manner [22,23]. In qualitative studies, participants with positive body image actively rejected unrealistic media images to protect their body image [24,25]. Growing literature highlights that self-compassion contributes to a positive body image [26]. Self-compassion has been found to buffer the impact of media pressure on thin-ideal internalization in women [23], and to reduce body image distress and body dissatisfaction, reduce rumination, and increase body appreciation [23,27,28]. Homan and Tylka [29] highlighted that women who were high in self-compassion maintained high levels of body appreciation in the face of body-related comparisons. Thus, enhancing individuals' self-compassion may reduce the effects of negative body image and promote positive body image.

Intervention programs targeting body image risk and protective factors have been developed in the last 2 decades. Psychoeducational and cognitive behavioral programs have been effective in improving body image concerns, reducing disordered eating behaviors and attitudes, thin-ideal internalization, and dieting in adolescents and young adults [30,31]. Dissonance-based interventions are also increasingly adopted to address health and social behaviors [32]. For example, the *Body Project* adopted dissonance-based approaches in a group setting by having participants voluntarily critique and take a counterattitudinal stance against the thin-ideal in verbal, written, and behavioral activities [33]. It was theorized that the discrepancy generated between participants' personal beliefs (eg, thinner is better) and the counterattitudinal arguments made against pursuing thinness would elicit discomfort, and the discomfort would be alleviated by adjusting their personal beliefs to be more in line with the anti–thin-ideal statements [33]. Efficacy trials of the *Body Project* showed reduced eating disorder risk factors (eg, thin-ideal internalization and body dissatisfaction) and fewer eating disorder symptoms in female adolescents and young adults with body image concerns compared with assessment-only control conditions or alternative interventions, with numerous effects sustained up to 3-year follow-ups [34,35]. The *Body Project M* designed for male participants found that cognitive dissonance approach improved outcomes related to male participants' dissatisfaction with body fat and muscularity, body appreciation, muscularity-enhancing behaviors, appearance comparison, and internalization after the intervention, with all outcomes except dissatisfaction with muscularity and internalization being

sustained at 3-month follow-up [36]. Encouraging findings were also found for the *Body Project: More Than Muscles*, wherein significant reductions were observed for several eating disorder risk factors and muscularity and body fat dissatisfaction in male participants, with some outcomes maintained at the 4-week follow-up [37]. A further extension of the *Body Project*, the *Body Project 4 All*, evaluated the effectiveness of a mixed-sex program which found gains to be sustained over a 6-month follow-up [38]. Meta-analyses confirmed the effectiveness of dissonance-based programs [39,40]. Altogether, these studies suggest that dissonance-based interventions are promising in improving body image concerns in male and female participants.

The direct challenging of the thin-ideal within dissonance-based interventions differs somewhat from a self-compassion approach, which aims to promote greater awareness of adverse outcomes created by the thin-ideal. In response to this awareness, self-compassion interventions engender a mindset that promotes self-kindness and connection with others in the face of body image concerns. In other words, self-compassion approaches seek to alter the way in which individuals cope with the distress associated with negative body image [27,28] rather than changing body image itself.

Self-compassion interventions are gaining empirical support in alleviating body image concerns. Self-compassion meditation and single-session self-compassion writing tasks can reduce women's body dissatisfaction and body shame and improve self-compassion and body appreciation [27,41]. A recent randomized controlled trial (RCT) by Toole et al [42] found self-compassion and dissonance-based interventions for young women with body image distress to be comparable with and more effective than waitlist control and suggested that integrating both self-compassion and dissonance-based approaches in interventions for body image may increase the acceptability of the interventions and reap more beneficial outcomes.

Self-guided, mobile-based body image programs have been developed and evaluated in light of technological advancements [43-45]. The 7-day mobile app study by Kosinski [44] led to a decrease in participants' body dissatisfaction, drive for thinness, and increase in self-esteem. Cerea et al [43] adopted a cognitive behavioral training approach with short, daily, cognitive training exercises for 16 days and found that it reduced body dissatisfaction in female university students. Finally, *BodiMojo*, a 6-week program, which involves sending daily intervention messages on body image and self-compassion–related content, increased appearance esteem and self-compassion in adolescents [45]. In a sample of high school and college students, *BodiMojo* improved participants' body image and self-compassion [45].

This Study

Emerging adulthood often marks the onset of body image concerns [35]. Presently, most intervention programs are designed for female participants and are conducted in Western populations. The *Body Project* was only recently modified to cater to male participants and mixed-sex groups [36-38]. However, these programs are conducted face-to-face and not on mobile platforms. Evidence is emerging that mobile apps can provide convenient, effective, and cost-friendly mental health interventions [46]. Therefore, this study evaluated the effectiveness of a self-guided mobile health (mHealth) body image app for both female and male participants. The app adopted both cognitive dissonance and self-compassion approaches, covering the following 3 topics: media literacy, appearance comparisons, and self-compassion. These topics were selected because of the robust empirical evidence that has been found for their role as risk and protective factors of body image concerns. The content was adapted from existing evidence-based interventions for body image, eating disorders, and self-compassion [47-51]. We predicted that the intervention would lead to significant improvements on measures of body image and self-compassion after the intervention and 4-week follow-up, compared with an active waitlist control group.

Methods

Participants

The sample consisted of 310 female (age: mean 21.12, SD 2.07 years) and male (age: mean 22.68, SD 2.10 years) adults aged between 18 to 30 years, recruited from the department of psychology's research participant pool and the research recruitment platform of the National University of Singapore. A poster advertisement was uploaded on the respective recruitment platforms, wherein interested students were able to directly access a web-based link to participate in the study. Participants received either course credits or a reimbursement of SGD $ 15 (US $10.63). A power analysis with G*power 3.1 [52] revealed a minimum number of 128 participants, using a moderate effect size as found in relevant mobile-based body image studies [45,53,54]. We aimed for a total of 308 participants to account for a potential attrition of 20% [45].

Intervention Conditions

Body Image Program

This 9-day program adopted cognitive dissonance and self-compassion approaches designed around the following 3 topics: media literacy, appearance comparison, and self-compassion. At the start of each 3-day period, the participants underwent a 5-minute content learning and dissonance-based or self-compassion activity related to the topic (Textbox 1). The dissonance-based activity involved participants challenging sociocultural influences regarding media messages, appearance ideals, and appearance comparison. Participants typed their answers to questions which guided them in challenging sociocultural ideals. Self-compassion interventions involved psychoeducation and experiential activities. Participants were also given a cognitive or behavioral task, which encouraged noticing and challenging sociocultural influences in their daily lives, or practicing self-compassion.

Daily body image and self-compassion–focused messages were sent through the app to participants thrice a day, messages modeled after the *BodiMojo* mobile app (Table 1) [45]. These intervention messages included psychoeducation, affirmations, behavioral tips, short activities, and quizzes to reinforce participants' learning (Figure 1).

Textbox 1. Overview of the body image program content.

Topics and content

- Topic 1: appearance ideal and media literacy
  - Introduce the concepts of body image and appearance ideals
  - Highlight how the media influences our appearance ideals and raise awareness of media manipulations
  - Elicit discrepancies between participants' existing beliefs and behaviors about media influences
  - Develop participants' skills in identifying media influences on appearance ideals
- Topic 2: appearance comparison
  - Introduce the concept of appearance comparison
  - Highlight areas of common appearance comparisons for female and male participants
  - Highlight disadvantages and consequences of appearance comparison
  - Elicit discrepancies between participants' existing beliefs and behaviors about appearance ideals and comparison
  - Develop participants' ability to manage situations when appearance comparison arises
- Topic 3: self-compassion
  - Introduce the concepts of self-compassion and appearance rumination
  - Highlight the disadvantages and consequences of appearance rumination
  - Introduce skills to develop participants' ability to engage in self-compassion to manage negative thoughts and feelings about their body

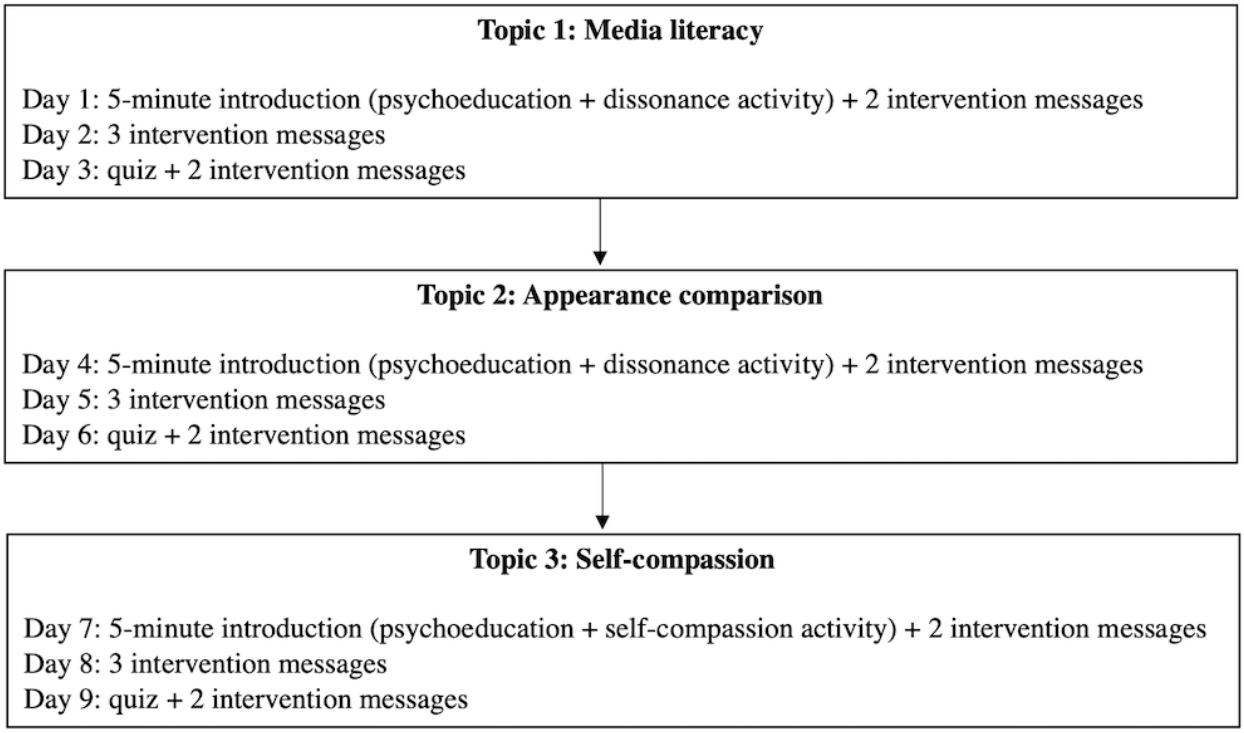
Table 1. Body image and self-compassion–focused intervention messages.

Intervention messages	Examples
Body image	• Did you know, media images are often edited after a photoshoot? For example, complexions are cleaned, eyelines are softened, thighs and stomachs are thinned. Hence, it is not wise to match yourself to these appearance ideals. Can you think of other ways in which media images are edited?

Mindfulness	• I hope you have not been too hard on yourself this week. Every time you catch yourself being judgmental or critical about yourself or your body
	  • Gently acknowledge and hold the thought in your mind.
	  • Breathe slowly, and allow yourself to notice the emotional pain or sensations.
	  • Remember, it is perfectly ok for your mind to wander.
	  • Simply notice it and gently guide your attention back to your body.
	  • Slowly, give yourself compassion by reframing the inner dialogue into something encouraging and supportive.
	  • Remember, you can always think of how a wise, nurturing friend, parent, teacher or mentor would say to encourage and support you.

Common humanity	• Sometimes, our self-critical voice can be so common that we do not even notice when it is present. Many others have felt this way before too. Have you ever noticed what you say to yourself when you are feeling bad about yourself? Let's try to soften this self-critical voice with compassion.
Self-kindness	• Be kind to yourself and your body. Do not say things about your body and self that you would not say to a friend.
Behavioral tips	• Try not to check yourself on reflective surfaces when you are up and around! Enjoy your surroundings! :)
Affirmations	• Hey! You are a limited edition and one of a kind! Appreciate all the good things that you and your body can do! :)

Figure 1. Flow of Body Image Program.



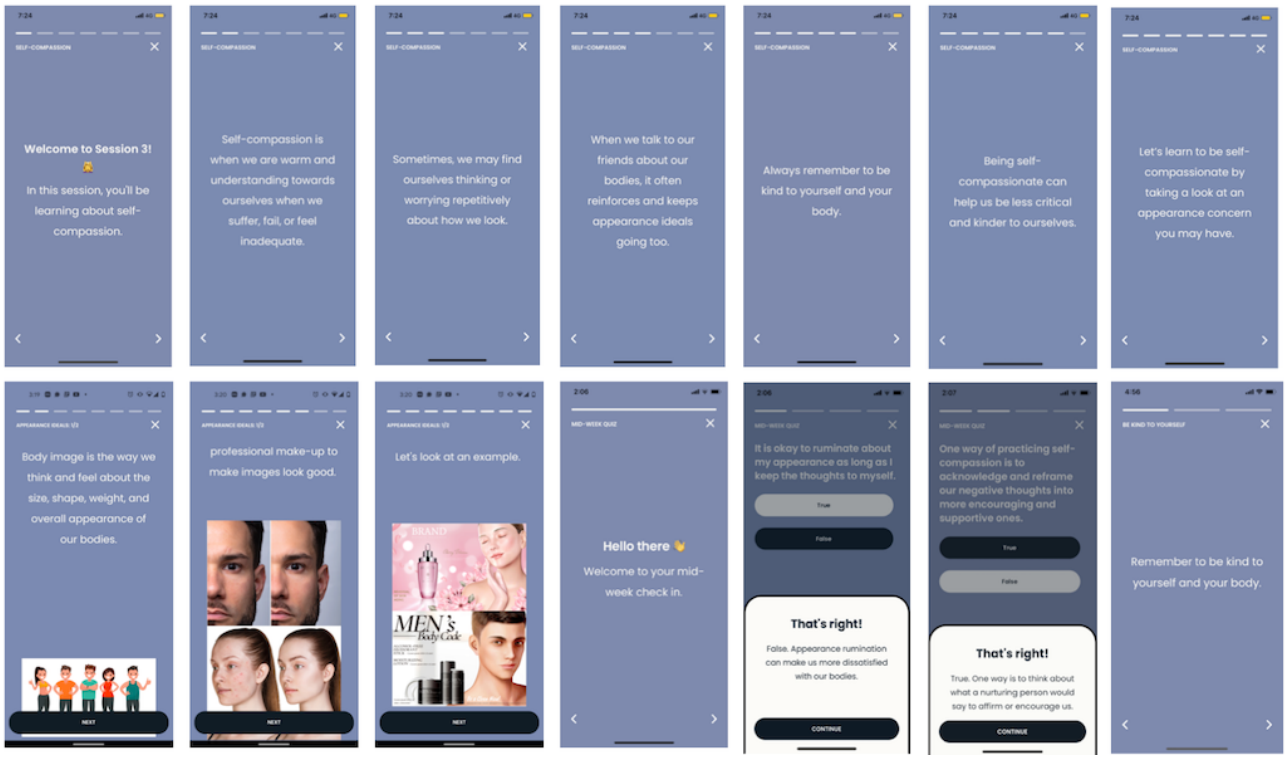
Cooperation Learning Program

Participants in the active waitlist control group engaged in a self-guided learning program on cooperation. The active waitlist control group was chosen instead of a waitlist control as it serves as an attention control to create similar experiences for participants in both groups to control for nonspecific factors that may influence the study outcomes [55]. This 9-day learning program develops participants' skills to improve group morale and relationships. It consists of content learning once a day and activities such as quizzes, and the number and length of activities were matched to the body image app.

Ethics Approval

Ethics approval for this study was obtained from the National University of Singapore's institutional review board (NUS-IRB-2021-85), and it was preregistered with ClinicalTrials.gov (registration number: NCT04977973). The methods and results described complied with the CONSORT (Consolidated Standards of Reporting Trials; 2010) guidelines for reporting RCTs (Figure 2) [56]. Data collection took place in Singapore in an entirely web-based setting.

Figure 2. Screenshots of the body image program.



Procedure and Participant Flow

Participants first read the Participation Information Sheet on Qualtrics. After providing informed consent, participants completed measures on body image, body image risk factors, and self-compassion to obtain baseline ratings. Thereafter, participants were randomized to 1 of 2 conditions, intervention or active waitlist control, using simple randomization procedures. In this study, blinding of participants was marginally feasible as the content of the intervention programs that the participants engaged in were different in nature. However, participants were not outwardly informed of the real function of each intervention condition or of the real nature of the study being to evaluate the effectiveness of the body image program. The title of the study made known to participants was kept general (*The effectiveness of a self-guided mobile phone application in improving the way we see ourselves and our bodies*) to reduce the demand characteristics of the participants.

Next, the participants downloaded the mobile app and were guided on how to navigate the app. Participants in the intervention group underwent 9 days of body image training, while participants in the active waitlist control group underwent 9 days of the cooperation learning program. The anticipated time participants spent on each program was comparable (<5 minutes per day).

Participants filled out the same questionnaires upon program completion (postintervention measure) and after 4 weeks (follow-up measure). The feedback questionnaire was administered only after the intervention.

After the 6-week data collection period, participants were debriefed about the purpose and real intent of the study. Participants in the active waitlist control group were given access to the body image program.

Outcome Measures

Overview

Body Image Ideals Questionnaire (BIQ [57]) is a 22-item scale that assesses body image satisfaction-dissatisfaction by measuring the degree of congruence or discrepancy in one's perceived and idealized physical attributes. On a scale ranging from 0 (exactly as I am) to 3 (very unlike me), participants rated the degree to which they resembled their physical ideal on 11 physical attributes. Next, participants rated the importance that they assigned to attaining their ideal on each physical attribute. The cross-products of the discrepancy and importance ratings for each physical attribute were obtained and a composite BIQ score was computed. Higher scores indicated greater disparity between one's perceived and ideal physical attributes, suggesting higher levels of body dissatisfaction. The BIQ showed good internal consistency, with a Cronbach α of .81 for male participants and .76 for female participants.

The Body Appreciation Scale-2 [58] is a 10-item scale that assesses individuals' positive attitudes toward their bodies. The items are scored on a scale from 1 (never) to 5 (always). Scores on all items are averaged with higher scores indicating greater body appreciation. The Body Appreciation Scale-2 has excellent internal consistency, with a Cronbach α of .96 for male participants and .97 for female participants.

The Sociocultural Attitudes Toward Appearance Questionnaire-4 Revised [59] measures internalization ideals and appearance-related sociocultural pressures. The 7 subscales consist of 31 items for female participants and 28 items for male participants on a scale ranging from 1 (definitely disagree) to

5 (definitely agree). Higher scores on each subscale indicate higher levels of internalization and sociocultural pressure. In this study, the subscales of Internalisation: Thin/Low Body Fat (for female participants), Internalisation: Muscularity (for male participants), and Pressures: Peers and Media were used. The internal consistencies of the subscales are good, with Cronbach α of ≥.82 in a sample of university female participants and Cronbach of ≥.75 in a sample of university male participants.

Self-Compassion Scale-Short Form [60] is a 12-item scale that measures self-compassion on 6 subscales. Each item is scored from 1 (almost never) to 5 (almost always). A total self-compassion score is the mean of all 6 subscales, with higher scores indicating higher levels of self-compassion. The internal consistency of the scale is excellent, with a Cronbach α of .86.

App Engagement

App Engagement Scale [61] is a 7-item scale that measures participants' engagement on the phone app with scores ranging from 1 (definitely disagree) to 5 (definitely agree). A total score is derived by adding the scores from each item. Internal reliability of the scale is good, with a Cronbach α of .84.

Analytic Approach

Statistical analyses were conducted using SPSS (version 26.0; IBM Corp). As previous research has found that female and male participants' body image are dissimilar and that they respond differently to intervention programs [62,63], analyses for this study were conducted separately for female and male participants. Intent-to-treat analyses were conducted to address loss of participant data because of participant withdrawal or technical difficulties, by carrying forward the participants' last reported score. Independent 2-tailed *t* tests were also conducted to determine if participants who withdrew or could not continue because of technical difficulties differed significantly from those who remained in the study on any demographic and outcome measures. This informed of attrition-related bias, if any. Finally, missing scores on the App Engagement Scale (AES) were substituted using mean substitution [64].

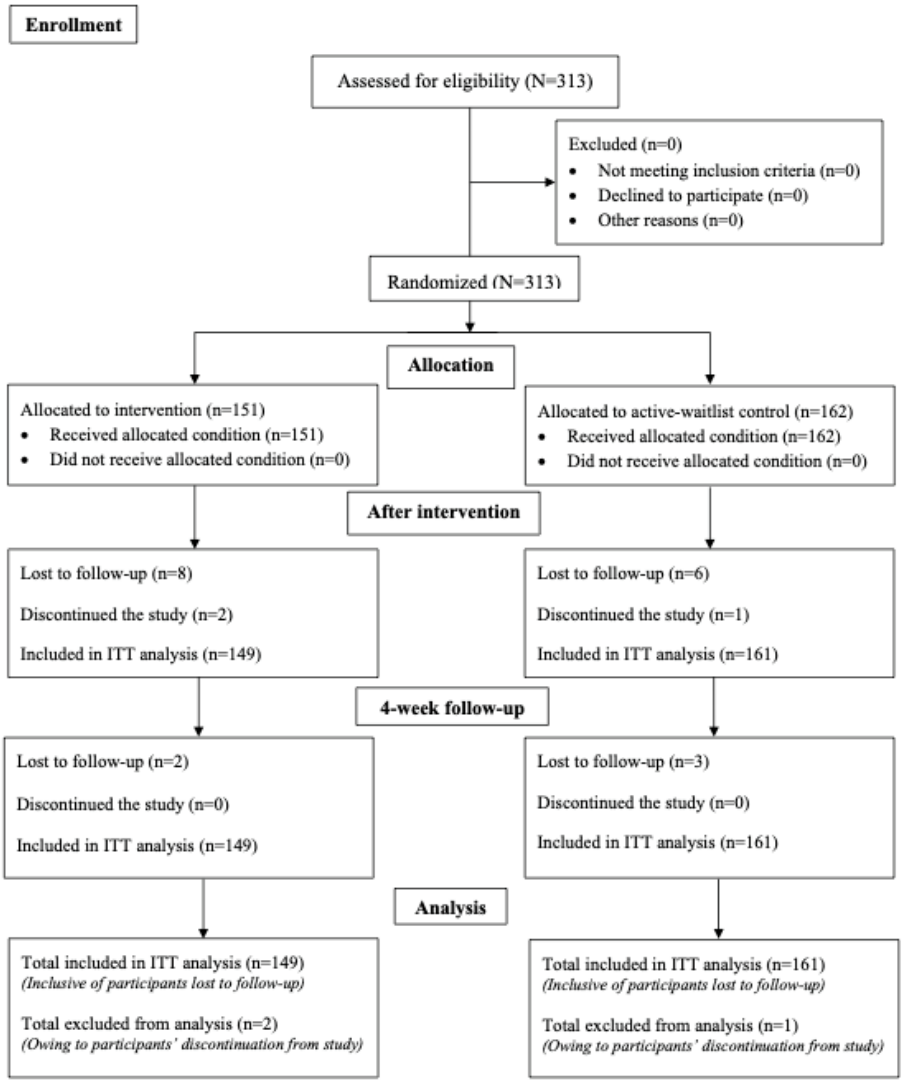
An analysis of covariance (ANCOVA) examined if changes in outcome measures after intervention and at follow-up were significantly different in the intervention group compared with the active waitlist control group. ANCOVA is the recommended analysis for the inferential test of intervention effects [65]. By controlling for baseline scores, any baseline differences that may account for effects in the groups were removed, ensuring that the results after the intervention and at follow-up were because of intervention effects [66]. To compare the intervention and active waitlist control groups after the intervention, ANCOVA was conducted on postintervention scores, with baseline scores of the relevant outcome measures entered as the covariate. The α level was set at $P<.05$. Partial eta squared (η_p^2) was the effect size reported for ANCOVA, while eta squared (η^2) was the effect size reported for 2-tailed *t* tests and ANOVA.

Results

Participant Characteristics

A total of 313 participants completed questionnaires at baseline, 296 (94.57%) participants completed questionnaires after the intervention, and 291 (92.97%) participants completed questionnaires at follow-up (Figure 3).

Figure 3. CONSORT (Consolidated Standards of Reporting Trials) flow diagram. ITT: intention-to-treat.



Preliminary Analyses

The intervention and active waitlist control groups did not differ significantly on demographic variables and most outcome measures at baseline (Tables 2, 3, and 4). The only outcome measure with a significant baseline difference was BIQ for male participants (P=.03). AES rated after the intervention did not differ significantly between female and male participants (P=.51) and between the intervention and active waitlist control groups (P=.76).

Intent-to-treat analyses were conducted for participants who were lost to follow-up by carrying forward their last reported scores. Missing scores for AES were substituted with the mean score. Independent 2-tailed t tests did not reveal any attrition-related biases across demographic and outcome variables (P>.10).

Table 2. Descriptive statistics for demographic variable of sex by condition.

Demographic variable	Intervention condition (n=149), n (%)	Active waitlist control condition (n=161), n (%)	*P* value
Sex			.32
Female	98 (65.8)	115 (71)	
Male	51 (34.2)	46 (29)	

Table 3. Descriptive statistics of baseline demographic and outcome variables by condition for female participants (N=213).

Variable	Intervention condition	Active waitlist control condition	*P* value
Age (years), mean (SD)	21.05 (1.96)	21.18 (2.17)	.65
BMI (kg/m^2), mean (SD)	20.20 (2.59)	20.85 (3.32)	.14
Race, n (%)			.13
Chinese	94 (95.9)	102 (88.7)	
Malay	0 (0)	1 (0.9)	
Indian	1 (1)	8 (7)	
Others	3 (3.1)	4 (3.5)	
BIQ[a] score, mean (SD)	2.14 (1.21)	2.10 (1.17)	.80
BAS[b] score, mean (SD)	3.44 (0.77)	3.50 (0.75)	.54
SCS-SF[c] score, mean (SD)	2.88 (0.63)	2.98 (0.55)	.23
SATAQ-4R[d]: Internalisation Thin/Low Body Fat score, mean (SD)	3.15 (0.86)	3.03 (0.89)	.32
SATAQ-4R: peer pressure score, mean (SD)	2.23 (1.00)	2.14 (0.98)	.50
SATAQ-4R: media pressure score, mean (SD)	3.26 (1.04)	3.18 (1.23)	.61

[a]BIQ: Body Image Ideals Questionnaire.

[b]BAS-2: Body Appreciation Scale-2.

[c]SCS-SF: Self-Compassion Scale-Short Form.

[d]SATAQ-4R: Sociocultural Attitudes Toward Appearance Questionnaire-4 Revised.

Table 4. Descriptive statistics of baseline demographic and outcome variables by condition for male participants (N=97).

Variable	Intervention condition	Active waitlist condition	*P* value
Age (years), mean (SD)	23.06 (2.33)	22.26 (1.76)	.06
BMI (kg/m^2), mean (SD)	22.19 (3.59)	22.79 (3.17)	.39
Race, n (%)			.07
Chinese	50 (98)	39 (84.8)	
Malay	0 (0)	1 (2.2)	
Indian	0 (0)	5 (10.9)	
Others	1 (2)	1 (2.2)	
BIQ[a] score, mean (SD)	2.12 (1.17)	1.59 (1.12)	.03[b]
BAS[c] score, mean (SD)	3.45 (0.73)	3.55 (0.68)	.48
SCS-SF[d] score, mean (SD)	3.01 (0.52)	3.05 (0.49)	.67
SATAQ-4R[e]: muscularity internalization score, mean (SD)	3.44 (0.74)	3.17 (0.82)	.32
SATAQ-4R: peer pressure score, mean (SD)	2.79 (1.14)	2.78 (1.10)	.94
SATAQ-4R: media pressure score, mean (SD)	2.70 (1.10)	2.71 (1.05)	.96

[a]BIQ: Body Image Ideals Questionnaire.

[b]$P<.05$.

[c]BAS-2: Body Appreciation Scale-2.

[d]SCS-SF: Self-Compassion Scale-Short Form.

[e]SATAQ-4R: Sociocultural Attitudes Toward Appearance Questionnaire-4 Revised.

Main Analyses

Overview

Most outcome variables met the assumption tests for ANCOVA. The homogeneity of variance assumption was violated for a small number of outcome measures. However, because of the robustness of ANCOVA when sample sizes in each group are relatively equal [67], analysis using ANCOVA proceeded. The assumption of independence between independent variable and covariate was met for all outcome measures (P>.20), except BIQ for male participants. The assumption of homogeneity of regression slopes were violated in 2 variables for female participants (postintervention BIQ; postintervention SATAQ-4R Internalisation: Thin/Low Body Fat). For these variables, 1-way ANOVA was conducted using differences in scores between baseline and after the intervention and baseline and follow-up, respectively.

Female Participants

On body image measures, the intervention group reported significantly lower body dissatisfaction, and significantly higher body appreciation, after the intervention and at follow-up, compared with the active waitlist control group. The effect sizes were between moderate to large at both postintervention and follow-up. On thin-ideal internalization, the intervention group reported significantly lower internalization of thin-ideal scores after the intervention and at follow-up, compared with the active waitlist control group, with small to moderate effect sizes after the intervention and at follow-up. Significant score reductions were found on measures of peer and media pressure after the intervention in the intervention group, compared with the active waitlist control group, with small to moderate effect sizes. At follow-up, a significant difference was only found for reduction in media pressure, and no significant difference was found for peer pressure. Finally, significant differences were found for the self-compassion measure after the intervention and at follow-up, compared with the active waitlist control group (Table 5).

Table 5. Means (SDs), univariate F test values, and effect sizes for outcome variables in female participants.

Variable	Scale range	Baseline, mean (SD)		After the intervention					Follow-up				
		Intervention	Control	Intervention, mean (SD)	Control, mean (SD)	*F* test (*df*)	*P* value	Effect size[a]	Intervention, mean (SD)	Control, mean (SD)	*F* test (*df*)	*P* value	Effect size[a]
Body Image Ideals Questionnairescore[b]	−3 to 9	2.14 (1.21)	2.10 (1.17)	1.30 (0.99)	1.94 (1.20)	26.02[c] (1)	*<.001*[d]	0.11	1.42 (0.09)	1.91 (0.087)	17.48[c] (1)	*<.001*	0.077
Body Appreciation Scale-2 score[e]	1 to 5	3.44 (0.77)	3.50 (0.75)	3.79 (0.48)	3.57 (0.44)	37.80[c] (1)	*<.001*	0.27	3.73 (0.05)	3.60 (0.045)	38.00[c] (1)	*<.001*	0.27
Self-Compassion Scale-Short Form score[e]	1 to 5	2.88 (0.63)	2.98 (0.55)	3.28 (0.04)	3.09 (0.041)	10.82[f] (1)	*.001*	0.049	3.20 (0.47)	3.05 (0.043)	5.92[g] (1)	*.02*	0.027
SATAQ-4R[h]: Internalisation Thin/Low Body Fat[b] score	1 to 5	3.15 (0.86)	3.03 (0.89)	2.77 (0.85)	3.03 (0.92)	18.49[c] (1)	*<.001*	0.081	2.79 (0.06)	3.00 (0.053)	7.21[f] (1)	*.008*	0.033
SATAQ-4R: peer pressure[b] score	1 to 5	2.23 (1.00)	2.14 (0.98)	2.00 (0.07)	2.28 (0.065)	9.73[f] (1)	*.002*	0.044	2.12 (0.08)	2.30 (0.073)	2.93 (1)	.09	0.014
SATAQ-4R: Media pressure[b] score	1 to 5	3.26 (1.04)	3.18 (1.23)	2.77 (0.09)	3.27 (0.080)	18.08[c] (1)	*<.001*	0.079	2.80 (0.09)	3.12 (0.085)	6.49[a] (1)	*.01*	0.031

[a]Effect sizes of 0.01=small, 0.06=moderate, and 0.14=large [68].

[b]Lower scores are more desirable.

[c]*P*<.001.

[d]Italicized values indicate a significant *P* value at .05.

[e]Higher scores are more desirable.

[f]*P*<.01.

[g]*P*<.05.

[h]SATAQ-4R: Sociocultural Attitudes Toward Appearance Questionnaire-4 Revised.

Male Participants

Male participants in the intervention group reported significantly lower scores on body dissatisfaction after the intervention, compared with the active waitlist control group, with a large effect size. Male participants in the intervention group also reported significantly higher scores for body appreciation and self-compassion after the intervention, compared with the active waitlist control group, with effect sizes ranging from small to moderate. No intervention effects were found after the intervention for muscularity internalization, peer pressure, and media pressure, and at follow-up for all measures (Table 6).

Table 6. Means (SDs), univariate F values, and effect sizes for outcome variables in male participants.

Variable	Scale range	Baseline, mean (SD)		After the intervention					Follow-up				
		Intervention	Control	Intervention, mean (SD)	Control, mean (SD)	*F* test (*df*)	*P* value	Effect size[a]	Intervention, mean (SD)	Control, mean (SD)	*F* test (*df*)	*P* value	Effect size[a]
Body Image Ideals Questionnaire[b]	−3 to 9	2.12 (1.17)	1.59 (1.12)	1.24 (0.95)	1.53 (1.20)	16.07[c] (1)	*<.001*[d]	0.15	1.69 (1.23)	1.32 (1.24)	0.69 (1)	.41	0.007
Body Appreciation Scale-2[e]	1 to 5	3.45 (0.73)	3.55 (0.68)	3.83 (0.065)	3.61 (0.068)	5.71[f] (1)	*.02*	0.057	3.75 (0.07)	3.60 (0.073)	20.32 (1)	.13	0.024
Self-Compassion Scale-Short Form[e]	1 to 5	3.00 (0.60)	3.15 (0.64)	3.33 (0.054)	3.17 (0.057)	4.039[f] (1)	*.047*	0.041	3.24 (0.06)	3.12 (0.060)	10.79 (1)	.18	0.019
SATAQ-4R[g]: Muscularity internalisation[b]	1 to 5	3.44 (0.74)	3.28 (0.81)	3.17 (0.092)	3.20 (0.097)	.070 (1)	.79	0.001	3.27 (0.09)	3.25 (0.093)	0.018 (1)	.89	0.000
SATAQ-4R: Peer pressure[b]	1 to 5	2.79 (1.14)	2.78 (1.10)	2.57 (0.12)	2.85 (0.12)	2.72 (1)	.10	0.028	2.48 (0.10)	2.63 (0.11)	0.99 (1)	.32	0.01
SATAQ-4R: Media pressure[b]	1 to 5	2.70 (1.10)	2.71 (1.05)	2.54 (0.13)	2.62 (0.13)	0.17 (1)	.68	0.002	2.78 (0.12)	2.65 (0.12)	0.61 (1)	.44	0.006

[a]Effect sizes of 0.01=small, 0.06=moderate, and 0.14=large [68].

[b]Lower scores are more desirable.

[c]*P*<.001.

[d]Italicized values indicate a significant *P* value at .05.

[e]Higher scores are more desirable.

[f]*P*<.05.

[g]SATAQ-4R: Sociocultural Attitudes Toward Appearance Questionnaire-4 Revised.

Discussion

Principal Findings

This RCT evaluated the effectiveness of a self-guided mHealth app in improving body image and self-compassion in a sample of Asian university students. Our study extended the findings of previous studies by showing that cognitive dissonance and self-compassion approaches delivered on a mobile-based platform can be beneficial in improving body image and self-compassion in young adults.

Our hypotheses for female participants were largely supported. Except for peer pressure whereby intervention effects were not found at follow-up, the intervention group reported significant improvements on body image, body image risk factors, and self-compassion at both postintervention and follow-up, compared with the active waitlist control group. Consistent with past research on longer web-based or face-to-face interventions, our findings showed that a 9-day mobile-based program using cognitive dissonance and self-compassion approaches can reduce body dissatisfaction and its risk factors, improve body appreciation, and improve self-compassion after the intervention and at follow-up in female adults [33,34,42,43,44,51,69]. The moderate to large effect sizes for improvements found on body image and risk factor measures in our body image program are comparable with the average effect sizes found in *eBody Project* after the intervention [54]. Furthermore, our study extended the study by Toole et al [42] by demonstrating that integrating dissonance-based and self-compassion approaches and conducting the intervention on a mobile-based app can be beneficial for body image interventions. Comparable with the study by Toole et al [42], the effect sizes for female participants in our study were also moderate to large for body dissatisfaction, body appreciation, and thin-ideal internalization after the intervention.

Our hypotheses for male participants were partially supported. Unlike findings from *Body 4 All* and *Body Project M*, which found significant improvements in male participants on body satisfaction, body appreciation, dissatisfaction with fat and

muscularity, appearance comparison, and internalization of cultural appearance ideals, with some effects sustained at their respective follow-ups [37,38], our study only revealed significantly lower body dissatisfaction, higher body appreciation, and higher self-compassion in the intervention group after the intervention relative to the active waitlist control group. In particular, the effect size for body dissatisfaction was large. Although the results for internalization of muscularity (P=.79 and P=.89), peer pressure (P=.10 and P=.32), and media pressure (P=.68 and P=.44) did not reach statistical significance after intervention and at follow-up, there was a trend observed toward male participants in the intervention group reporting lower scores of muscularity internalization and media and peer pressure after the intervention.

Overall, our findings provide preliminary support for the use of cognitive dissonance and self-compassion approaches on an mHealth app to reduce body image concerns and improve self-compassion in students. On the basis of the cognitive dissonance theory and the dual pathway model [33,70], guiding participants to challenge ideal appearances likely led to the participants' reduced subscription to appearance ideals, which decreased body dissatisfaction. The 4-week follow-up effects found in female participants for all measures except for peer pressure were encouraging. In particular, the large effect sizes maintained for female participants on the improvements on both body dissatisfaction and body appreciation both after the intervention and at the 4-week follow-up are noteworthy. In addition to the use of cognitive dissonance techniques in our body image program to challenge appearance ideals directly, the integration of self-compassion components may have contributed to female participants' enhanced self-awareness of appearance ideals, elicited a compassionate view of themselves and their bodies, and helped them to cope with the body image distress by fostering self-kindness and connection with others. Altogether, these may have translated to greater intrinsic self-worth and enhanced acceptance and appreciation of their bodies [27,42]. In addition, a self-compassion approach for the body image program may have been more appealing for young female adults, and increased their acceptance of the program [42].

Consistent with *BodiMojo's* 6-week mobile-based intervention, our 9-day mobile-based intervention revealed comparable small to moderate effect sizes in self-compassion after the intervention for female and male participants. Compared with *BodiMojo* and the face-to-face programs of the *Body Project*, our study found similar or larger effect sizes for body image in both sexes after the intervention [36,45,71]. These suggest that beneficial effects for body image and self-compassion can be obtained much faster than through longer web-based or face-to-face programs in reducing body image concerns and improving self-compassion in young adults. Although longer programs may provide more opportunities for users to learn and practice skills to elicit behavior change [72], briefer interventions could also be of value in sustaining users' engagement and reducing attrition rates.

Although significant improvements in self-compassion were found for male participants after the intervention, the effect was weaker, and not significant at follow-up. As self-compassion has been identified as a crucial factor in reducing body dissatisfaction and enhancing body appreciation in female and male participants [29,73,74], the weaker effects observed for self-compassion in male participants may have had a downstream effect and explained the lack of follow-up effects for male participants' body dissatisfaction and body appreciation.

Sex differences in self-compassion may explain the lack of follow-up effects for self-compassion in male participants. A meta-analysis conducted by Yarnell et al [75] suggested that self-compassion approaches may be more effective for women than men, as feminine gender role norms associated with nurturance, self-sacrifice, and caregiving may facilitate the fostering of compassion toward the self. On the contrary, masculine gender norms, which tend to be associated with being strong, unemotional, pragmatic, and independent may form barriers to men being tender and caring toward themselves in times of need [76,77]. Hence, men with higher masculine norm conformity may find it challenging to acquire self-compassion [78]. Nonetheless, individuals may not necessarily conform to traditional gender role orientations [78], and our study did not explore participants' conformity to gender norms. As literature in this area remains relatively new, further research is required to improve our understanding of gender role norms in self-compassion, to effectively tailor self-compassion approaches for female and male participants.

Several reasons are conceivable why peer pressure did not reveal differential effects for male participants and for female participants at follow-up. During this developmental phase as a young adult, interpersonal relationships are crucial for female and male participants [79,80]. Female participants tend to experience greater sensitivity and stress because of interpersonal rejection [81,82]. Coupled with female participants' tendency to associate body image with the perception of peer acceptance and the lack of effective coping strategies, female participants may have found it challenging to manage peer pressures [83,84]. Thus, equipping female participants with stress and communication management skills may be a more targeted approach for enhancing female participants' capacity to reduce peer pressures [84]. The lack of significant findings for peer pressure in female participants at follow-up may also be because of a floor effect, as participants in both intervention and active waitlist control groups had low ratings on the measure at baseline, thus limiting intervention effects at follow-up. As for male participants, studies found that greater body dissatisfaction was related to peer stressors focused on personality characteristics or achievements [81,84]. Thus, targeting body image and its risk factors may be less effective in reducing peer pressures for male participants.

The lack of significant reduction in the internalization of muscularity after the intervention and at follow-up may be accounted for by at least 2 possible reasons. First, adaptations made to our mixed-sex body image program to incorporate male body image concerns may be insufficient in addressing muscular-ideal internalization in a targeted manner. For example, the terminology being changed to "ideal appearances" and insufficient examples for male participants may have led to an inadequate understanding of concerns related to

muscular-ideal internalization, thus watering down the intervention effects for male participants. Second, male participants may be less engaged in the body image program than female participants, because of the lack of masculine points of reference [85]. Although app engagement ratings did not differ between sexes, there may be socially desirable or careless responses on the self-report questionnaires. This is also supported by research which highlighted that male participants are less likely to engage in body image interventions and digital mental health apps than female participants [86,87]. Moreover, as participants' responses on the app program were not accessible by researchers to protect users' confidentiality, the quality and length of the counterattitudinal written responses could not be objectively ascertained. Thus, there is a possibility that the men's lower app engagement may have weakened the intervention effects.

Finally, the lack of group differences on media pressure for male participants was unexpected, as media literacy was previously found to be effective in reducing pressures from media influences [88]. A possible explanation may be that our media literacy content was inclined toward female appearance ideals and risk factors and thus the lack of specificity and relevance to male appearance ideals and risk factors may have reduced its effectiveness for male participants.

Strengths and Limitations

First, some causal conclusions can be drawn [89]. The use of an active waitlist control group as an attention waitlist control allowed us to disentangle the effects of attention and other nonspecific factors from the intervention effects, thus strengthening the RCT's effects [90]. Another strength was the low attrition rate. Although some participants withdrew or could not continue because of technical glitches, the overall attrition rate was <10%, with no attrition-related biases. This conferred greater strength to the overall validity of our study. Separate analyses conducted for female and male participants in light of sex differences in body image allowed us to identify that our mixed-sex program was less effective for male participants than for female participants and thus identify ways to enhance intervention effects for male participants. Finally, the 4-week follow-up period gives some confidence that effects for female participants can be maintained over a short-term period.

This study has some limitations. First, student participants may limit the generalizability of findings, as university students and the public may differ in factors such as level of education [91]. Hence, the university sample may not be representative of the general young adult population. Secondly, self-report measures are prone to social desirability bias, expectancies, and demand characteristics, which all may have contributed to the observed effects. Third, incentivizing participants with course credits or money may have motivated their participation and retention.

The sample size for male participants in our study was small despite additional recruitment efforts and thus was likely underpowered. Moreover, in view of sex differences in body image, more research is required to better understand ways to increase the effectiveness of mobile-based body image programs for male participants in a mixed-sex format and address muscularity concerns. To capture male participants' body image concerns more accurately, male-specific measures such as Male Body Attitudes Scale [92] can be used in future studies.

Finally, in light of increasing studies which found self-compassion to mediate the effects of body image interventions, future studies can examine self-compassion as a mechanism of change. It would also be beneficial to obtain qualitative feedback from participants on elements of the body image program, such as their perception of the tone or number of intervention messages, to evaluate the effectiveness of the program.

Conclusions

Overall, this RCT provides preliminary but encouraging support for the effectiveness of a self-guided mHealth body image app using cognitive dissonance and self-compassion approaches for university students. Mobile-based well-being programs are cost-effective and accessible and can thus be widely disseminated to benefit the masses. Future research should seek to further enhance the program's effectiveness with the wider young adult population.

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Authors' Contributions

The main author (WYO) and coauthor (OS) were responsible for the study conceptualization and methodology, designing of the body image mobile phone app program, data curation and formal analysis, and the writing and editing of the protocol and manuscript. The coauthor (OS) also provided supervision of the overall study and procured funding for the study.

Conflicts of Interest

The study was partly funded by Intellect Pte Ltd. The study design, data management, interpretation, analysis, and reporting and the decision to publish the study are entirely independent of Intellect Pte Ltd. OS had a research collaboration with Intellect Pte Ltd at the time of the data collection and has since joined Intellect Pte Ltd as their clinical director.

Multimedia Appendix 1
CONSORT-eHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 3036 KB - mhealth_v10i11e41800_app1.pdf]

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Abbreviations

AES: App Engagement Scale
ANCOVA: analysis of covariance
BIQ: Body Image Ideals Questionnaire
CONSORT: Consolidated Standards of Reporting Trials
mHealth: mobile health
RCT: randomized controlled trial

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Original Paper

Outcomes of a Comprehensive Mobile Smoking Cessation Program With Nicotine Replacement Therapy in Adult Smokers: Pilot Randomized Controlled Trial

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Abstract

Background: Cigarette smoking remains the leading cause of preventable illness and death, underscoring ongoing need for evidence-based solutions. Pivot, a US Clinical Practice Guideline–based mobile smoking cessation program, comprises a personal carbon monoxide breath sensor; a smartphone app; in-app, text-based human-provided coaching; nicotine replacement therapy; and a moderated web-based community. Promising Pivot cohort studies have established the foundation for comparative assessment.

Objective: This study aimed to compare engagement, retention, attitudes toward quitting smoking, smoking behavior, and participant feedback between Pivot and QuitGuide, a US Clinical Practice Guideline–based smoking cessation smartphone app from the National Cancer Institute.

Methods: In this remote pilot randomized controlled trial, cigarette smokers in the United States were recruited on the web and randomized to Pivot or QuitGuide. Participants were offered 12 weeks of free nicotine replacement therapy. Data were self-reported via weekly web-based questionnaires for 12 weeks and at 26 weeks. Outcomes included engagement and retention, attitudes toward quitting smoking, smoking behavior, and participant feedback. The primary outcome was self-reported app openings at 12 weeks. Cessation outcomes included self-reported 7- and 30-day point prevalence abstinence (PPA), abstinence from all tobacco products, and continuous abstinence at 12 and 26 weeks. PPA and continuous abstinence were biovalidated via breath carbon monoxide samples.

Results: Participants comprised 188 smokers (94 Pivot and 94 QuitGuide): mean age 46.4 (SD 9.2) years, 104 (55.3%) women, 128 (68.1%) White individuals, and mean cigarettes per day 17.6 (SD 9.0). Engagement via mean "total app openings through 12 weeks" (primary outcome) was Pivot, 157.9 (SD 210.6) versus QuitGuide, 86.5 (SD 66.3; P<.001). Self-reported 7-day PPA at 12 and 26 weeks was Pivot, 35% (33/94) versus QuitGuide, 28% (26/94; intention to treat [ITT]: P=.28) and Pivot, 36% (34/94) versus QuitGuide, 27% (25/94; ITT: P=.12), respectively. Self-reported 30-day PPA at 12 and 26 weeks was Pivot, 29% (27/94) versus QuitGuide, 22% (21/94; ITT: P=.32) and Pivot, 32% (30/94) versus QuitGuide, 22% (21/94; ITT: P=.12), respectively. The biovalidated abstinence rate at 12 weeks was Pivot, 29% (27/94) versus QuitGuide, 13% (12/94; ITT: P=.008). Biovalidated continuous abstinence at 26 weeks was Pivot, 21% (20/94) versus QuitGuide, 10% (9/94; ITT: P=.03). Participant feedback, including ease of setup, impact on smoking, and likelihood of program recommendation were favorable for Pivot.

Conclusions: In this randomized controlled trial comparing the app-based smoking cessation programs Pivot and QuitGuide, Pivot participants had higher engagement and biovalidated cessation rates and more favorable user feedback at 12 and 26 weeks. These findings support Pivot as an effective, durable mobile smoking cessation program.

Trial Registration: ClinicalTrials.gov NCT04955639; https://clinicaltrials.gov/ct2/show/NCT04955639

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KEYWORDS

smoking cessation; digital health; smartphone; digital sensor; carbon monoxide; breath sensor; biofeedback; mobile apps; health promotion; app; mobile phone

Introduction

Background

Tobacco use is responsible for more than 8 million deaths around the world per year. On its own, smoking is a leading cause of preventable illness and death worldwide [1]. Despite this, most quit attempts are undertaken without assistance and are unsuccessful [2].

In recent years, mobile app–based programs for smoking cessation have become prevalent and show promise with greater accessibility than traditional face-to-face programs. A variety of these programs currently exist, but many lack evidence of their efficacy. A 2019 meta-analysis by Whittaker et al [3] analyzed 5 studies and found no evidence that smartphone app cessation programs improved smoking cessation outcomes when compared with lower-intensity cessation apps or minimal nonapp support (relative risk ratio [RR] 1.00, 95% CI 0.66-1.52; I^2=59%). This finding was of low certainty, however, owing to inconsistencies and imprecision, highlighting the need for more randomized controlled trials (RCTs) of app-based cessation programs.

Bricker et al [4] compared 2 app-based cessation programs in a 2020 RCT. At 12 months, participants randomized to iCanQuit, an acceptance and commitment therapy (ACT)–based smoking cessation app, had 1.49 times higher odds of quitting smoking than participants randomized to QuitGuide, a US Clinical Practice Guideline (USCPG)–based smoking cessation app. Previously, in 2014, Bricker et al [5] ran a similar RCT comparing SmartQuit, another ACT-based smoking cessation app, with QuitGuide. At 2 months, 13% of SmartQuit and 8% of QuitGuide participants quit smoking (odds ratio [OR] 2.7, 95% CI 0.8-10.3). Another RCT, by BinDhim et al [6] in 2018, compared a smoking cessation decision-aid app with an information-only control app. At 6 months, 10.2% using the decision-aid app and 4.8% using the control self-reported continuous abstinence from smoking (RR 2.02, 95% CI 1.08-3.81).

More comprehensive programs with nicotine replacement therapy (NRT) and additional support have also been studied. In a 2020 RCT, Webb et al [7] compared a cognitive behavioral therapy (CBT)–based smoking cessation app with one-on-one coaching (Quit Genius) to Very Brief Advice. All participants had access to 3 months of NRT and a random half of each arm received a carbon monoxide (CO) breath sensor device. At 52 weeks, 34.7% (92/265) of the participants in the treatment arm achieved 7-day point prevalence abstinence (PPA) versus 29.4% (78/265) in the control (RR 1.20, 95% CI 0.94-1.54). The assignment of the CO breath sensor device, or lack thereof, did not significantly predict whether a participant achieved 7-day PPA [7]. Tweet2Quit, a program including an app, SMS text messages, and a Twitter group, was compared with a nonapp control in a 2016 RCT by Pechmann et al [8]. Both groups received 56 days of NRT patches, instruction to set a quit date, and referral to the National Cancer Institute's smoking cessation website [9]. At 60 days, the Tweet2Quit arm had 40% smoking abstinence compared with 20% among controls.

Technology-enabled features of smoking cessation programs, including CO breath sensors, web-based communities, and SMS text messages–based coaching have been explored previously. In *The Tobacco Dependence Treatment Handbook: A Guide to Best Practices* [10] the authors reported that "providing individualized feedback about changes in personal levels of carbon monoxide before and after smoking is a powerful message that encourages individuals to make a quit attempt," demonstrating the utility of CO monitors for smoking cessation. Beard and West [11] provided smokers not seeking out a quit smoking program with personal CO breath sensors for 6 weeks, with a goal to maintain their CO level <10 parts per million (ppm). Participants were not instructed to quit. The 10 participants used the CO monitors an average of 3 times a day, decreased their average daily cigarette consumption from 14.1 (SD 6.03) at baseline to 9.8 (SD 4.95; *P*=.04) during the 2 weeks of daily CO monitoring and to 9.5 (SD 5.50; *P*=.13) at the 6-week follow-up. At follow-up, 50% (5/10) of the participants had attempted to quit smoking and one successfully quit. Most (111/140, 79.3% of the responses) participants reported the CO monitor was helpful and that they felt as though the monitor (7/10, 70% of the participants) had reduced their cigarette consumption. Beard and West [11] concluded that the use of the CO monitors increased motivation to consider a quit attempt. A 2020 cohort study also assessed the use of a personal CO breath sensor, specifically the Pivot Breath Sensor, by 234 adult smokers. The sensor's impact on attitudes toward quitting smoking and smoking behavior was investigated over 12 weeks. Participants in this study had a significant (*P*<.001) increase in motivation to quit smoking, 28.2% (66/234) made at least 1 quit attempt, and 38.5% (90/234) reduced the number of cigarettes smoked per day at 12 weeks [12].

Smoking cessation programs with web-based communities have also been studied. Graham et al [13] conducted a propensity score weighting of the iQUITT study, an RCT of telephone and internet treatment for smoking cessation, where the internet arm of the study included a large and well-established web-based community. Of the 492 participants assigned to the iQUITT study's internet arm, 198 (40.2%) did not engage with the web-based community, 184 (37.4%) engaged both actively and passively, and 110 (22.4%) engaged only passively. At 3 months, Average Treatment Effects weighted abstinence rates were 4.2% for those who did not use the web-based community, 15.1% for those who used the web-based community passively, and 20.4% for those who used the web-based community both passively and actively. Users of the web-based community were also more likely to quit smoking than nonusers. Sadasivam et

al [14] conducted a study testing the functions of Decide2Quit.org, a web-based tobacco intervention that contains a web-based community, SMS text messaging with tobacco treatment specialists, and other major functions to support tobacco cessation. In bivariate comparison among 204 smokers, the web-based community had a positive association with quit outcomes at 6 months and the highest differential in quit outcomes for those that used the function compared with other functions of the web-based quit program. SMS text messaging with tobacco treatment specialists was negatively associated with quit outcomes at 6 months; however, the authors suggest that these results could be confounded by those using the specialists as having the most difficulty in quitting smoking.

Studies focused on the impact of one-on-one text coaching or SMS text messaging with tobacco treatment specialists are limited. Sadasivam et al [15] conducted a secondary analysis of a web-based smoking cessation intervention that includes asynchronous messaging with trained tobacco treatment specialists. The goal of the study was to evaluate the association of this communication with smoking cessation during a period of 6 months. Of the 725 smokers in the study, 245 (33.8%) messaged a tobacco treatment specialist at least once. The amount of SMS text messaging with a tobacco treatment specialist had no association with cessation outcomes at 6 months, although the authors suggest low engagement or lack of power to be explanations for the lack of association found.

A cohort study of the Pivot program was published in 2021 (N=319). During the study, Pivot included a mobile app, a personal CO breath sensor, and text-based human-provided coaching. At 3 months after program completion (mean 7.2, SD 1.2 months after enrollment), 32% (intention to treat [ITT]) and 37.5% (completer) of the participants achieved 7-day PPA; 27.6% (ITT) and 32.4% (completer) reported 30-day PPA [16]. The Pivot program has since undergone updates and now includes access to NRT and a moderated web-based community. These changes, the need for long-term results for app-based cessation programs, and the ongoing need to assess the performance of Pivot within the context of current smoking cessation programs, warrant new investigation of the Pivot program.

Objectives

The primary aim of the study was to compare user engagement and retention in the Pivot smoking cessation program to the current mobile standard of care. The secondary aims were to compare changes in attitudes toward quitting smoking, changes in smoking behavior, and feedback on the user experience.

Methods

Design

In this 2-arm, parallel-group, noncrossover, single-center RCT, participants were randomized to 1 of 2 app-based smoking cessation programs: QuitGuide (control) or Pivot (intervention). All participants had access to 12 weeks of free NRT. A total of 6 reminders to prompt use of the program were emailed to all participants every other week over the first 12 weeks of the study. User engagement and retention, attitudes toward quitting, smoking behavior, and participant feedback were compared between the 2 groups. Here, we report outcomes through 26 weeks, as data collection for the 1- and 2-year time points is ongoing. The study was performed remotely on an ambulatory basis.

Ethics Approval

All participants provided electronic informed consent before participation. The study was reviewed and approved by Solutions IRB, LLC (protocol number 2021/04/38) and registered with ClinicalTrials.gov (NCT04955639).

Participants

Eligibility criteria are presented in Textbox 1.

Textbox 1. Eligibility criteria.

Inclusion criteria

- Aged ≥21 years of age
- Current daily cigarette smoker (≥5 cigarettes per day) for the past 12 months
- Plans to quit smoking in the next 30 days
- Resident of the United States
- Able to read and comprehend English
- Owns and uses a smartphone compatible with the study app (iPhone 5 and above, with operating system iOS 12 and above or Android 7.0 and above, with operating system Android 7.0 and above)
- Has daily internet access on smartphone
- Self-reported comfort with downloading and using smartphone apps

Exclusion criteria

- Pregnancy (self-reported)
- Health contraindications to nicotine replacement therapy use (irregular heartbeat, high blood pressure not controlled with medication, heart attack or stroke within the last 2 months, breastfeeding, skin allergies to adhesive tape or serious skin problems, stomach ulcers, or history of seizures)
- Using other smoking cessation support, including apps, or actively taking medication to quit smoking
- Daily marijuana use
- Residence with another study participant
- Immediate family member is a study participant
- Failure to provide contact information or verify email address
- Participation in a previous study sponsored by Pivot Health Technologies Inc. (formerly Carrot Inc)

Recruitment

Participants were recruited in the United States through web media (Facebook and Google Ads). Potential participants were asked to provide contact information and answer questions on demographics (gender, age, employment status, location via city and state, and race and ethnicity), smartphone ownership, and smoking attitudes and behavior (Stage of Change and cigarettes per day [CPD]) using a web-based screening form. Study staff reviewed each web-based screening form.

Using nonproportional quota sampling, potential participants were called on a first-come-first-served basis, with the aim to enroll 40% to 60% men, no more than 50% of the participants from any decade-spanning age group (eg, 30-39 years of age), no more than 70% of the participants in the non-Hispanic White race category, and up to 20% not employed. The goals of these nonproportional quota sampling ranges were to ensure representation among men, racial and ethnic minorities, age groups, and individuals with varying socioeconomic status. Regarding the nonproportional quota sampling for employment, at the time of protocol design (March 2021 and April 2021), the unemployment rate in the United States was 6% [17]. Acknowledging a higher unemployment rate among people who smoke [18-21] and the desire to include individuals who either do not receive payment for their work or are not pursuing employment (stay-at-home parents, caretakers, students, or retired individuals), we sought to enroll up to 20% of participants who did not have compensated employment.

During the screening phone call, potential participants were asked questions to confirm study eligibility. During this call, study personnel informed the potential participant of the study details and answered any questions.

Potential eligible participants who wanted to proceed with the study were emailed an electronic Health Insurance Portability and Accountability Act authorization form and an electronic informed consent form, which they signed before participating in this study.

Randomization and Blinding

Participants were randomly assigned in a computer-generated 1:1 ratio to either QuitGuide or Pivot using randomly permuted blocks of sizes 2 and 4. The allocation sequence was provided by the Study Randomizer (Phase Locked Software, 2017) application [22]. Participants were stratified by daily smoking frequency (≤14 vs ≥15 CPD), employment status (full-time or part-time employment vs not employed), race and ethnicity (minority race and ethnicity vs non-Hispanic White) and expected difficulty staying quit (scale 1-10; self-reported score of ≤5 vs ≥6). These 4 factors were chosen, as they have been associated with cessation outcomes in prior studies [16,23-28]. Researchers were blinded to treatment allocation until after randomization was performed.

Intervention: Pivot

Pivot is a 12-month digital smoking cessation program based on the USCPG for tobacco use cessation. Pivot includes the Pivot Breath Sensor and Pivot app (Pivot Health Technologies Inc).

The Pivot Breath Sensor is a portable, personal mobile breath sensor that measures the level of CO in exhaled breath. The user submits a breath sample by exhaling into the sensor mouthpiece. The sensor displays the exhaled breath CO value in ppm to the user directly on the device. When paired to the user's smartphone, the user's CO values also populate the Pivot app, where they can be accessed by the user. Displayed CO values are color coded and categorized as most consistent with not smoking (green, 0-6 ppm), possibly smoking (orange, 7-9 ppm), or smoking (red, ≥10 ppm). There was no required use of the sensor; however, the participants were informed that suggested use of the sensor is 4 times per day, spread out over the course of the day, acknowledging they should use the sensor as it best fits with their lives. Users may use the sensor to link their smoking behavior and CO values and track their progress in reducing or quitting smoking.

The self-guided Pivot app leverages evidence-based principles and clinical best practices. This includes the USCPG-recommended 5 A's (Ask, Advise, Assess, Assist, and Arrange), tailoring on readiness to quit [29], the provision of Food and Drug Administration (FDA)–approved NRT with accompanying education on use and adherence [29-31], the incorporation of effective methods for smoking cessation based on CBT and self-determination theory [32-34], and CBT-based counseling through a live, dedicated coach [29,33,35]. Pivot app functions include interactive educational activities, the ability to log cigarettes, set a quit date, create a quit plan, complete practice quits (1-24 hours in duration), play educational games, watch educational videos, interact with one's dedicated human coach via in-app text messaging, view CO breath sample values and trends, learn about and then order NRT, access the moderated web-based Pivot community discussion forum, share goals and progress with the web-based Pivot community discussion forum or one's social network via SMS text messaging or email, and complete daily check-ins after quit date.

The educational journey in the Pivot app comprises 4 tracts, Learn, Reduce, Prepare to Quit, and Maintain My Quit, and is designed to accommodate smokers along the spectrum of readiness to quit. Participants may choose to focus on building self-awareness and learn more about their smoking behavior, create and practice their plan to quit or reduce smoking, make a quit attempt, focus on staying quit, or any combination thereof. Accordingly, participants may navigate between tracts as desired to access content most relevant to their goals and needs.

Pivot users are assigned a human coach with whom they work one-on-one over the duration of their use of Pivot (up to 1 year). Communication between coach and Pivot user is via asynchronous in-app text messaging. Pivot coaches are tobacco treatment specialists. The coach reaches out periodically, approximately once per week, during the participant's active use of Pivot. Participants may reach out to their coach whenever and however often they like.

Pivot users may access the moderated web-based discussion community through the Pivot app. The forum is moderated by a tobacco treatment specialist. The web-based community forum is a place to give and receive support and advice from others going through the Pivot program.

Control: QuitGuide

QuitGuide is a product [9] of a smoking cessation resource created by the Tobacco Control Research Branch at the National Cancer Institute in collaboration with tobacco control professionals and smoking cessation experts and with input from ex-smokers [36]. A well-established smoking cessation app, QuitGuide, has been used in previous RCTs in which digital smoking cessation programs were compared [4,5]. The app focuses on helping users understand their smoking patterns and build the skills needed to become and stay smoke free [36]. Specifically, QuitGuide helps users to focus on motivations to quit; prepare to quit through developing a quit plan, identifying and planning how to address triggers and moods, teaching about FDA-approved smoking cessation medications, and identifying and providing access to social support; quit smoking by acknowledging user progress and teaching skills to address cravings; and stay quit by presenting tips and motivations to stay smoke free and address slips if they occur. QuitGuide app functions include educational reading activities, including focus on FDA-approved cessation medications and associated adherence. Additional QuitGuide app functions comprise tracking and reviewing cigarettes, moods, triggers, and cravings; setting tip message notifications for locations and times when one is prone to smoke; setting a quit date; creating a quit plan; completing journal entries; sharing goals and progress with one's social network via SMS text messaging or email; accessing additional chat and phone support; and providing updates on quit status after quit date.

QuitGuide was used as the control for the following reasons: the content follows the USCPG for tobacco cessation; it is an app-based smoking cessation program, thereby enabling intrastudy comparison of same-modality interventions; the app is nonproprietary and is free to the public; and its use in previous well-designed RCTs [4,5] provides context and enables interstudy comparison to earlier data.

Nicotine Replacement Therapy

Participants had access to free FDA-cleared over-the-counter NRT. Participants were provided with on-label information about the NRT and were able to order it on the web (QuitGuide) or in their study app (Pivot). The types of NRT offered included nicotine patches (7, 14, or 21 mg), nicotine gum (2 or 4 mg), and nicotine lozenges (2 or 4 mg). Participants could order patches, gum, or lozenges alone as monotherapy or patches with either gum or lozenges as combination therapy. Participants were able to order NRT every 2 weeks for up to a 12-week course over the first 12 months of the study. Engagement emails were sent to participants at weeks 1 and 3, reminding them of the availability of NRT and how to order it.

Biovalidation

Biovalidation was sought at 12 and 26 weeks in individuals who reported 7-day or greater PPA on the associated questionnaire. A video call with study staff and the participant was scheduled within 7 days following the participant's response to the associated questionnaire. At the beginning of each

biovalidation visit, participants were asked their CPD, 7-day PPA status, and if they had smoked any other noncigarette (eg, pipes, cigars, or hookah) or combustible materials (eg, cloves or marijuana) over the previous 24 hours.

Participants who indicated they were not at least 7 days abstinent or that they smoke ≥1 CPD were not eligible to undergo further biovalidation testing during the visit. Participants who indicated they were at least 7 days abstinent and did not smoke cigarettes were eligible to proceed with the testing. Participants who indicated they had smoked any other combustible materials over the previous 24 hours were eligible to undergo biovalidation test at that same visit, with the possibility of scheduling a follow-up biovalidation test for the following day with instruction to not smoke the previously reported other combustible substance(s) over the intervening 24-hour period. If a participant was eligible for biovalidation and biovalidation was not achieved, the reason was noted (did not schedule or attend a biovalidation study visit, reported change in smoking status at outset of visit, participant's breath CO sample was ≥10 ppm, etc).

Biovalidation was obtained through CO breath sampling. Participants in the intervention arm used their Pivot Breath Sensor for this test. Shortly before the visit, participants in the control arm were mailed a Pivot Breath Sensor limited to 10 breath samples. On the video call, participants held the breath sensor up to the screen immediately after completing the breath sample so that study staff could see and record the CO ppm measurement on the sensor screen. A CO value of <10 ppm was considered consistent with abstinence [37,38].

After their first biovalidation visit, participants in the control arm were instructed to not use the breath sensor beyond the visit and to place the sensor in a safe place to access for use at a future biovalidation visit should there be one. For subsequent biovalidation visits, participants used their existing breath sensor or were mailed a new one as needed.

Outcomes and Measures

Baseline

The following variables were collected at baseline: demographic information (age, gender, race and ethnicity, household income, education, employment status, and smartphone type); smoking status; smoking history; Heaviness of Smoking Index [39]; success to quit (STQ; scale 1-10) and difficulty to stay quit (DTQ; scale 1-10) [40,41]; and Smoking Abstinence Self-efficacy Questionnaire (SASEQ)—a 6-item survey describing emotional or social situations for which smokers indicate on a 5-point Likert scale (0-4) whether they will be able to refrain from smoking, with total higher scores representing higher self-efficacy [42].

Study outcomes focused on 4 areas: user engagement and retention, attitudes toward quitting, smoking behavior, and participant feedback.

User Engagement and Retention

The preregistered primary outcome of the study was total app openings in Pivot versus QuitGuide at 12 weeks. Additional outcomes included the number of days and number of weeks with ≥1 app opening. App openings were self-reported weekly for the first 12 weeks of the study. Self-report of app use has been reported previously [5] and was necessary because automatic recording of this information was not enabled for QuitGuide.

Attitudes Toward Quitting Smoking

Measures reflecting attitudes toward quitting included the desire to quit (yes or no), STQ (scale 1-10) and DTQ (scale 1-10) [40,41], and SASEQ [42].

Smoking Behavior

Smoking behavior assessment comprised quit attempts, CPD (mean percentage change and the proportion of participants who reduced their CPD by ≥50% compared with baseline), smoking cessation via self-reported 7- and 30-day PPA and biochemically confirmed abstinence, continuous abstinence (self-report and biochemically confirmed), abstinence from all tobacco products (self-report), and the use of NRT.

Participants were considered to have made a quit attempt during the study if they answered ≥1 to the following question: "Since you began the study, how many times have you tried to quit smoking where you've gone at least 1 day without smoking a cigarette, even a single puff?" From this question, mean (SD) quit attempts per participant were quantified as well. Participants were considered to have achieved self-reported 7-day (30-day) PPA if they answered "no" to the following question: "In the last 7 (30) days, have you smoked any cigarettes, even a single puff?" Biochemically confirmed abstinence was defined as self-reporting 7-day abstinence and a breath CO sample <10 ppm at the associated biovalidation visit. Self-reported continuous abstinence was assessed at 26 weeks and was defined as self-report of 7-day (or greater) PPA at 12 weeks, self-report of 30-day PPA at 26 weeks, and no more than 5 cigarettes during the intervening period. Biochemically confirmed continuous abstinence was assessed at 26 weeks and was defined as self-reported continuous abstinence with a breath CO sample <10 ppm at both the associated 12- and 26-week biovalidation visits. Abstinence from all tobacco products was self-reported. NRT use included whether a participant ordered NRT (yes or no), and if so, what type of NRT they ordered, using participant-placed orders.

Participant Feedback

Participant feedback was sought on the setup, user experience, design, and impact of their assigned smoking cessation program. This included user satisfaction with the smoking cessation program (getting started with the program, program design, program was useful for quitting, program helped me quit, and program helped me stay quit). User satisfaction was also assessed through net promoter score (NPS), which queries the likelihood of recommending one's program to a friend or colleague (scale 1-10) [43]. NPS is an industry indicator of participant loyalty to a product or service. NPS was calculated by subtracting the percentage of respondents who answered ≤6 (detractors) from the percentage of respondents who answered 9 or 10 (promotors).

Sample Size

As this is a pilot RCT and the first assessment of Pivot compared with usual care, the sample size is powered to show differences in engagement—specifically, the number of times participants opened their assigned app over the first 12 weeks of the study. In previous clinical studies, Pivot mean app openings were 24.2 to 38.7 (SD 20.8-25.9) by 90 days (data on file). In addition, Bricker et al [5] reported app openings comparing ACT-based smoking cessation apps (SmartQuit and iCanQuit) with QuitGuide. In a study by Bricker et al. [5], at 2-month follow-up, the authors reported that the mean app openings were 37.2 (SD 46.1) for SmartQuit and 15.2 (SD 13.6) for QuitGuide. In a subsequent study, at 12-month follow-up, the mean app openings were 37.5 (SD 88.4) for iCanQuit and 9.9 (SD 50.0) for QuitGuide [4].

On the basis of these data, we estimated a mean of 25 (SD 25) app openings in the Pivot intervention arm versus 15 (SD 19) app openings in the QuitGuide control arm at 12 weeks. Detecting a difference of 10 app openings between Pivot and QuitGuide with a power of 0.8 and an α of.05 would require 156.7 participants, which we round up to 158. In a previous study, 85.3% (272/319) of participants completed the end-of-Pivot questionnaire at a mean of 4.1 (SD 1.4) months after enrollment [44]. In assessing the primary end point at 3 months (12 weeks), we included an expected 15% attrition rate, with the aim to enroll up to 180 participants (up to 90 in each arm).

Statistical Analyses

In this pilot RCT, differences between the Pivot intervention arm and the QuitGuide control arm were evaluated. Baseline comparisons and changes from baseline used unadjusted statistical tests. For numerical data, we calculated the mean (SD) and used a 2-tailed *t* test. For categorical data, we calculated the proportions and used the chi-square test or Fisher exact test. For results where a change from baseline can be measured, each participant's baseline data served as their control to calculate a difference with a later time point (eg, CPD, SASEQ, STQ, and DTQ), which then served as the measurement, and a paired 2-tailed *t* test was used to test for a difference from 0.

For outcomes, regression analyses were adjusted for the randomization stratification covariates to detect differences between the treatment and control arms. Linear regression was used for numerical data to obtain a point estimate of the mean difference. For count outcomes, the incidence rate ratio (IRR) was estimated using Poisson regression when the variance to mean ratio was close to 1 or using negative binomial regressions when the variance to mean ratio was >1. For binary outcomes, the OR was estimated using logistic regression, and the relative risk was estimated using either log-link binomial regression or log-link Poisson regression with robust estimators [45]. For binary outcomes where there was a very high frequency response (eg, ≥95%), only the relative risk was presented. For multicategory outcomes of ≥3, multinomial logistic regression was used to test for proportion differences between the arms. If the multinomial logistic regression model did not converge, categories were collapsed. Statistical significance was set at $P<.05$. Analyses were conducted using SAS (version 9.4; SAS Institute).

In the assessment of quit rates (self-reported and biovalidated PPA and continuous abstinence and self-reported abstinence from all tobacco products), 2 sets of analyses were performed. In the ITT analysis, individuals who did not respond to PPA questions were assumed to be smoking. A study responder analysis was also performed, which only included individuals who completed the questionnaire from the associated time point. For the outcomes of quit attempts and the proportion who reduced CPD by at least 50%, a study completer analysis was performed.

Data Collection

Data collection was performed via web-based questionnaires at baseline, weekly for the first 12 weeks, and at the 26-week follow-up. Collection of participant feedback on one's assigned smoking cessation program was primarily over the first 12 weeks of the study to obtain input temporally closest to program use. Study data were imported directly into a secure database (PostgreSQL; PostgreSQL Global Development Group).

Participants were compensated for completing the web-based questionnaires, earning between US $10 and US $50 per questionnaire for up to US $265 in total for 14 questionnaires over the 26-week study period. Participants were compensated US $50 for each biovalidation visit they completed (up to 2 visits) for up to US $100. In total, participants could earn up to US $365 over the course of the 26-week study. Compensation was in the form of Visa or Mastercard gift cards that were mailed or emailed to their provided address approximately 2 to 3 weeks after completing the associated questionnaire(s) or biovalidation visits. Payments were bundled with participants receiving up to 4 payments over the 26-week course of the study. Remuneration was not tied to quitting smoking.

Handling of Missing Data

Survey completion was high at 12 weeks, 97% (91/94) in QuitGuide and 98% (92/94) in Pivot, and at 6 months, 96% (90/94) in both QuitGuide and 96% (90/94) in Pivot. Therefore, completer and ITT analyses were considered appropriate at the 12- and 26-week time points.

The primary end point of the total number of app openings through 12 weeks was calculated by summing the number of weekly app openings, which were reported by the participants weekly and represented total app openings over the preceding 7 days. There were 170 participants who completed all 12 surveys. There were 4 participants (2 in Pivot and 2 in QuitGuide) who withdrew consent by week 3, accounting for 41 incomplete surveys. App openings for these participants were set to 0, as they did not participate in the study. This left 14 participants (8 Pivot and 6 QuitGuide) with one or more surveys not completed for 44 incomplete surveys. Although this only represented 7.4% of total participants and 2% of total surveys, imputation was necessary to calculate the total app openings, total days with app openings, and total weeks with app openings.

There was no pattern of missingness upon visual inspection, and multiple imputation method was performed using SAS multiple imputation procedure full conditional specification predicted mean matching with 25 imputations [46]. The primary end point of total app openings by the intervention and control arms was then compared in a negative binomial regression model adjusted for the 4 randomization covariates in each of the imputations with SAS MIANALYZE. Similarly, total days with app openings and total weeks with app openings were analyzed using negative binomial regression and Poisson regression, respectively. The mean of the imputed data was used for reporting descriptive statistics.

Results

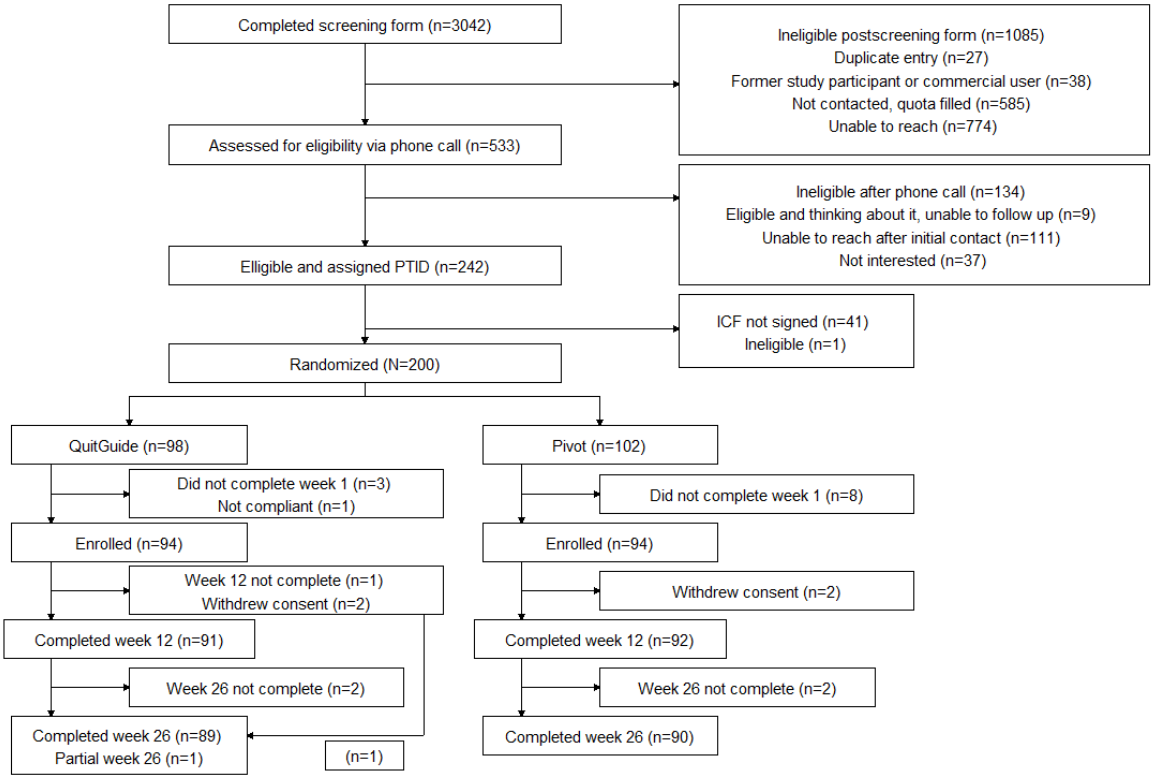
Enrollment and Questionnaire Completion

From June 2021 to October 2021, a total of 3042 web-based screening forms were received; 533 (17.5%) met the screening eligibility criteria and responded to an initial outbound phone call from study staff. Of the 3042 individuals, 292 (9.6%) did not proceed further, most commonly (134/3042, 4.4%) owing to ineligibility after the phone call or lack of response to subsequent outreach (111/3042, 3.6%) after initial contact. Of 3042 individuals, 188 (6.2%) were randomized and completed enrollment (94 in each arm), comprising the ITT sample. All nonproportional quota sampling targets were achieved.

Because of the multistep enrollment process, the study slightly overenrolled by 4.4% (8/180 participants; 4 in each arm). Considering the minimal risk profile of the app-based smoking cessation programs and the ambulatory nature of the study in which participants completed the web-based questionnaires at their discretion, this overenrollment was not felt to be significant.

Study questionnaire completion rate was high; 97.3% (183/188) and 95.2% (179/188) of the participants completed the 12- and 26-week questionnaires, respectively, and comprised the study responder samples at those time points. A participant partially completed the 26-week questionnaire; in the associated study responder analyses, the denominator was 180. In each arm, 2 participants withdrew consent. Questionnaire completion rates did not differ between the 2 study arms. Study enrollment and attrition are depicted in the CONSORT (Consolidated Standards of Reporting Trials) flow diagram (Figure 1).

Figure 1. Study participant CONSORT (Consolidated Standards of Reporting Trials) flow diagram. ICF: informed consent form; PTID: participant identification number.



Baseline Characteristics

The study sample had a mean age of 46.4 (SD 9.2) years, comprised 55.3% (104/188) women, was predominantly White (128/188, 68.1%), smoked a mean of 17.6 (SD 9.0) CPD at baseline, and had been smoking for a mean of 26.8 (SD 10.3) years. The mean Heaviness of Smoking Index was 3.2 (SD 1.2). Participants represented 42 of the 50 states in the United States along with the District of Columbia. The following states were not represented: Alaska, Delaware, Maine, Montana, North Dakota, New Hampshire, Vermont, and Wyoming. On average, participants had made 2.0 (SD 3.6) quit attempts over the past 12 months. Baseline demographic characteristics and smoking behavior were balanced between treatment groups at baseline. Participant baseline data are detailed in Table 1.

Table 1. Participant baseline data.

Characteristics	All (N=188)	Pivot (n=94)	QuitGuide (n=94)	*P* value
Demographics				
Age (years), mean (SD)	46.4 (9.2)	46.6 (10.1)	46.1 (8.2)	.70
Gender (women), n (%)	104 (55.3)	50 (53.2)	54 (57.5)	.56
Ethnicity and race, n (%)				.58
White	128 (68.1)	66 (70.2)	62 (66)	
Black	36 (19.2)	15 (16)	21 (22.3)	
American Indian	1 (0.5)	1 (1.1)	0 (0)	
Hispanic, Latino, or Spanish origin	13 (6.9)	8 (8.5)	5 (5.3)	
Asian	1 (0.5)	0 (0)	1 (1.1)	
Native Hawaiian	2 (1.1)	0 (0)	2 (2.1)	
Some other race	3 (1.6)	2 (2.1)	1 (1.1)	
Prefer not to answer	4 (2.1)	2 (2.1)	2 (2.1)	
Education, n (%)				.63
Less than 8th grade	1 (0.5)	0 (0)	1 (1.1)	
Some high school	2 (1.1)	1 (1.1)	1 (1.1)	
High school or General Educational Development	27 (14.4)	15 (16)	12 (12.8)	
Some college	80 (42.6)	35 (37.2)	45 (47.9)	
Associate’s (2 years) degree	28 (14.9)	13 (13.8)	15 (16)	
Bachelor’s (4 years) degree	31 (16.5)	18 (19.2)	13 (13.8)	
Master’s degree	15 (8)	10 (10.6)	5 (5.3)	
Professional or doctorate degree	4 (2.1)	2 (2.1)	2 (2.1)	
Income (US $), n (%)				.36
<25,000	32 (17)	14 (14.9)	18 (19.2)	
25,000-34,999	26 (13.8)	14 (14.9)	12 (12.8)	
35,000-49,999	42 (22.3)	19 (20.2)	23 (24.5)	
50,000-74,999	32 (17)	13 (13.8)	19 (20.2)	
75,000-99,999	23 (12.2)	12 (12.8)	11 (11.7)	
100,000-149,999	15 (8)	8 (8.5)	7 (7.5)	
≥150,000	10 (5.3)	8 (8.5)	2 (2.1)	
Prefer not to answer	8 (4.3)	6 (6.4)	2 (2.1)	
Employment, n (%)				.83
Yes, ≥20 hours per week	117 (62.2)	59 (62.8)	58 (61.7)	
Yes, <20 hours per week	37 (19.7)	17 (18.1)	20 (21.3)	
No	34 (18.1)	18 (19.2)	16 (17)	
Self-reported health, n (%)				.34
Excellent	5 (2.7)	4 (4.3)	1 (1.1)	
Very good	57 (30.3)	24 (25.5)	33 (35.1)	
Good	99 (52.7)	51 (54.3)	48 (51.1)	
Fair	26 (13.8)	14 (14.9)	12 (12.8)	
Poor	1 (0.5)	1 (1.1)	0 (0)	
Smartphone, n (%)				.30
iPhone	113 (60.1)	60 (63.8)	53 (56.4)	

Characteristics	All (N=188)	Pivot (n=94)	QuitGuide (n=94)	*P* value
Android	75 (39.9)	34 (36.2)	41 (43.6)	
Smoking and quitting behavior				
Cigarettes smoked per day, mean (SD)	17.6 (9)	18.0 (9.6)	17.2 (8.5)	.55
Years smoking, mean (SD)	26.8 (10.3)	27.7 (10.4)	25.8 (10.1)	.21
First cigarette smoked after waking, n (%)				.54
Within 5 minutes	67 (35.6)	30 (31.9)	37 (39.4)	
6-30 minutes	92 (48.9)	47 (50)	45 (47.9)	
31-60 minutes	22 (11.7)	12 (12.8)	10 (10.6)	
After 60 minutes	7 (3.7)	5 (5.3)	2 (2.1)	
Tobacco products used, n (%)				.42
Cigarettes only	162 (86.2)	79 (84)	83 (88.3)	
Cigarettes+e-cigarettes or vaping	15 (8)	10 (10.6)	5 (5.3)	
Cigarettes+cigars	3 (1.6)	1 (1.1)	2 (2.1)	
Cigarettes+e-cigarettes or vaping+cigars	2 (1.1)	1 (1.1)	1 (1.1)	
Cigarettes+chew or snuff	2 (1.1)	2 (2.1)	0 (0)	
Cigarettes+e-cigarettes, vaping+chew, or snuff	1 (0.5)	0 (0)	1 (1.1)	
Cigarettes+e-cigarettes or vaping+pipe	1 (0.5)	0 (0)	1 (1.1)	
Cigarettes+hookah+cigars	1 (0.5)	0 (0)	1 (1.1)	
Cigarettes+hookah	1 (0.5)	1 (1.1)	0 (0)	
HSI[a], mean (SD)	3.2 (1.2)	3.2 (1.3)	3.2 (1.2)	.72
Quit attempts in the past 12 months, mean (SD)	2.0 (3.6)	1.9 (3.4)	2.2 (3.8)	.63
Methods used in past quit attempts[b], n (%)				
Cold turkey	140 (74.5)	67 (71.3)	73 (77.7)	.72
NRT[c]	92 (48.9)	53 (56.4)	39 (41.5)	.06
e-Cigarettes or vaping	65 (34.6)	33 (35.1)	32 (34.0)	>.99
Varenicline or Chantix; Bupropion or Zyban or Wellbutrin	71 (37.8)	39 (41.5)	32 (34)	.37
None	16 (8.5)	5 (5.3)	11 (11.7)	.19
Hypnotherapy	11 (5.9)	7 (7.5)	4 (4.3)	.53
Quit Smoking classes	10 (5.3)	7 (7.5)	3 (3.2)	.33
Acupuncture	10 (5.3)	7 (7.5)	3 (3.2)	.33
Smartphone app	9 (4.8)	6 (6.4)	3 (3.2)	.49
Counseling	4 (2.1)	2 (2.1)	2 (2.1)	>.99
Other	4 (2.1)	1 (1.1)	3 (3.2)	.62
Attitudes toward quitting smoking				
DTQ[d], mean (SD)	3.5 (2.5)	3.5 (2.3)	3.6 (2.6)	.72
STQ[e], mean (SD)	4.5 (2.4)	4.6 (2.4)	4.3 (2.3)	.33

Characteristics	All (N=188)	Pivot (n=94)	QuitGuide (n=94)	*P* value
SASEQ[f], mean (SD)	11.7 (4.8)	11.8 (4.7)	11.5 (4.9)	.69

[a]HSI: Heaviness of Smoking Index—low (0-1), medium (2-4), and high (5,6).

[b]Participants were asked to select all that apply.

[c]NRT: nicotine replacement therapy.

[d]DTQ: difficulty to stay quit—If you were to quit smoking right now, how difficult do you think it would be to stay smoke free? (1=really hard to stay quit; 10=really easy to stay quit).

[e]STQ: success to quit—If you were to quit smoking right now, how successful would you be? (1=not at all successful; 10=completely successful).

[f]SASEQ: Smoking Abstinence Self-efficacy Questionnaire (score 1-24).

User Engagement and Retention

For the primary study outcome, Pivot participants self-reported a mean of 157.9 (SD 210.6) total app openings versus 86.5 (SD 66.3) in QuitGuide (IRR 1.8, 95% CI 1.4-2.3; *P*<.001) over the first 12 weeks of the study. The number of days with ≥1 app opening through 12 weeks was not different between the 2 groups: 49.6 (SD 24.1) in Pivot versus 50.4 (SD 25.2) in QuitGuide (IRR 1.0, 95% CI 0.8-1.1; *P*=.73). Also, the number of weeks with ≥1 app opening was not different between the 2 groups: 11.0 (SD 2.2) in Pivot versus 11.0 (SD 2.3) in QuitGuide (IRR 1.0, 95% CI 0.9-1.1; *P*=.91).

Self-report of logging into their app at least once a week was reported in ≥85% of the participants in each arm for each week through 12 weeks; in QuitGuide, it ranged from 85% to 97%, and in Pivot, it was 86% to 98%.

Attitudes Toward Quitting Smoking

At 4 weeks, all responding participants indicated an ongoing desire to quit smoking (91/91, 100% in Pivot and 88/88, 100% in QuitGuide). Self-efficacy via SASEQ, STQ, and DTQ significantly increased in both groups from baseline to 12 weeks. The difference in these measures between the 2 groups at 12 weeks was not significant (Table 2).

Table 2. Changes in attitudes toward quitting smoking from baseline to 12 weeks (n=188).

Measure	All		QuitGuide		Pivot		*P* value[a]	Point estimate[b] (95% CI)	*P* value
	Value, n (%)	Value, mean (SD)	Value, n (%)	Value, mean (SD)	Value, n (%)	Value, mean (SD)			
SASEQ[c]									
Baseline	188 (100)	11.7 (4.8)	94 (100)	11.5 (4.9)	94 (100)	11.8 (4.7)	.69	—[d]	—
12 weeks	183 (97.3)	14.3 (6.5)	91 (97)	14.1 (6.2)	92 (98)	14.5 (6.9)	—	0.32 (−1.5 to 2.2)	.73
Change	—	2.7 (7.3)	—	2.7 (7.9)[e]	—	2.6 (6.7)[f]	—	0.08 (−2.0 to 2.2)	.94
STQ[g]									
Baseline	188 (100)	4.5 (2.4)	94 (100)	4.3 (2.3)	94 (100)	4.6 (2.4)	.33	—	—
12 weeks	183 (97.3)	6.2 (3.1)	91 (97)	5.8 (3.1)	92 (98)	6.6 (3.0)	—	0.79 (−0.08 to 1.6)	.07
Change	—	1.8 (3.6)	—	1.6 (3.6)[e]	—	2.0 (3.6)[e]	—	0.41 (−0.57 to 1.4)	.41
DTQ[h]									
Baseline	188 (100)	3.5 (2.5)	94 (100)	3.6 (2.6)	94 (100)	3.5 (2.3)	.72	—	—
12 weeks	183 (97.3)	5.4 (3.1)	91 (97)	5.2 (3.0)	92 (98)	5.7 (3.1)	—	0.47 (−0.40 to 1.3)	.29
Change	—	1.9 (3.5)	—	1.7 (3.4)[e]	—	2.2 (3.7)[e]	—	0.59 (−0.29 to 1.5)	.18

[a]2-tailed *t* test.

[b]Point estimate obtained from linear regression adjusted with randomization covariates: daily smoking frequency (≤14 vs ≥15 cigarettes per day), employment status (full-time or part-time employment vs not employed), race and ethnicity (minority race and ethnicity vs non-Hispanic White) and expected difficulty staying quit (scale 1-10; self-reported score of ≤5 vs ≥6).

[c]SASEQ: Smoking Abstinence and Self-efficacy Questionnaire (score 1-24).

[d]Not available.

[e]Paired *t* test difference from baseline to 12 weeks; *P*<.001.

[f]Paired *t* test difference from baseline to 12 weeks; *P*=.001.

[g]STQ: success to quit—If you were smoking right now, how successful would you be? (1=not at all successful; 10=completely successful).

[h]DTQ: difficulty to stay quit—If you were to quit smoking right now, how difficult do you think it would be to stay smoke free? (1=really hard to stay quit; 10=really easy to stay quit).

Smoking Behavior

Quit Attempts

Overall, 96.6% (173/179) of the responders reported making at least 1 quit attempt through 26 weeks, with comparable proportions in each study group: Pivot, 96% (86/90) and QuitGuide, 98% (87/89; RR Poisson 1.0, 95% CI 0.9-1.0; *P*=.41). On average, QuitGuide participants reported more quit attempts: Pivot, 4.2 (SD 4.4) versus QuitGuide, 6.3 (SD 6.1; IRR negative binomial 0.7, 95% CI 0.5-0.9; *P*=.003).

Change in CPD

Among participants who responded at 26 weeks (N=180), CPD were reduced by 62.6% (SD 38.1%) from baseline. Within each group, the reduction in CPD from baseline to 26 weeks was significant (*P*<.001 for both). The CPD reduction was similar between the 2 groups: Pivot, −62.1% (SD 40.3%) versus QuitGuide, −63.1% (SD 35.9%; point estimate 1.1, 95% CI −9.9 to 12.0; *P*=.85).

Among participants who did not report 7-day (or greater) PPA at 26 weeks (N=121), CPD were reduced by 44.4% (SD 33.7%) from baseline. Within each group, the reduction in CPD from baseline to 26 weeks was significant (*P*<.001 for both). The reduction in CPD was similar between the 2 groups: Pivot, −39.1% (SD 34.7%) versus QuitGuide, −48.9% (SD 32.5%; point estimate 11.6, 95% CI −0.4 to 23.6; *P*=.06).

Among participants who responded at 26 weeks (N=180), the proportion who reduced CPD by ≥50% was similar between the 2 groups: Pivot, 62% (56/90) versus QuitGuide, 66% (59/90; OR 0.9, 95% CI 0.5-1.7; *P*=.65; RR 1.0, 95% CI 0.8-1.2; *P*=.77).

Focusing on participants who did not report 7-day (or greater) PPA at 26 weeks (N=121), the proportion who reduced CPD by ≥50% was similar between the 2 groups: Pivot, 39% (22/56) versus QuitGuide, 52% (34/65; OR 0.5, 95% CI 0.2-1.1; *P*=.10; RR 0.7, 95% CI 0.5-1.1; *P*=.09).

Cessation Rates

Cessation rates included self-reported 7- and 30-day PPA, continuous abstinence and abstinence from all tobacco products, and biochemically confirmed abstinence and biochemically confirmed continuous abstinence, as detailed in Table 3. At 12 and 26 weeks, differences between the 2 study groups in self-reported 7- and 30-day PPA rates and abstinence from all tobacco products were not statistically significant. By contrast, differences in biochemically confirmed abstinence and biochemically confirmed continuous abstinence rates were significant at 12 and 26 weeks. At 12 weeks, biochemically confirmed abstinence (ITT) was achieved in 29% (27/94) of the Pivot participants versus 13% (12/94) of the QuitGuide participants (OR 2.8, 95% CI 1.3-6.1; *P*=.008; RR 2.3, 95% CI 1.2-4.2; *P*=.008). At 26 weeks, biochemically confirmed continuous abstinence (ITT) was achieved in 21% (20/94) of the Pivot participants versus 10% (9/94) of the QuitGuide participants (OR 2.7, 95% CI 1.1-6.4; *P*=.03; RR 2.2, 95% CI 1.1-4.6; *P*=.03). Notably, at 12 and 26 weeks, the participation rate in biovalidation visits was high (84.7% overall; >80% for each group at 12 and 26 weeks) and was comparable between the 2 groups.

Table 3. Smoking cessation rates at 12 and 26 weeks (n=188).

Outcome	Overall, n (%)	Pivot, n (%)	QuitGuide, n (%)	Odds ratio (95% CI)	*P* value	Relative risk (95% CI)[a]	*P* value
12 weeks							
7-day PPA[b]; ITT[c]	59 (31.4)	33 (35.1)	26 (27.7)	1.4 (0.8-2.7)	.28	1.2 (0.8-1.8)	.50
7-day PPA; responder[d]	59 (32.2)	33 (35.9)	26 (28.6)	1.4 (0.8-2.7)	.30	1.2 (0.8-1.8)	.53
30-day PPA; ITT	48 (25.5)	27 (28.7)	21 (22.3)	1.4 (0.7-2.8)	.32	1.2 (0.7-1.9)	.56
30-day PPA; responder[d]	48 (26.2)	27 (29.3)	21 (23.1)	1.4 (0.7-2.7)	.35	1.2 (0.7-1.9)	.59
Biochemically confirmed abstinence; ITT[e]	39 (20.7)	27 (28.7)	12 (12.8)	2.8 (1.3-6.1)	.008	2.3 (1.2-4.2)	.008
Biochemically confirmed abstinence; responder[d,e]	39 (21.3)	27 (29.3)	12 (13.2)	2.8 (1.3-6.1)	.009	2.3 (1.2-4.1)	.009
Self-reported abstinence from all tobacco products; ITT	56 (29.8)	31 (33)	25 (26.6)	1.2 (0.6-2.3)	.56	1.1 (0.7-1.6)	.82
Self-reported abstinence from all tobacco products; responder[d]	56 (30.6)	31 (33.7)	25 (27.5)	1.2 (0.6-2.2)	.60	1.0 (0.7-1.6)	.87
26 weeks							
7-day PPA; ITT[c]	59 (31.4)	34 (36.2)	25 (26.6)	1.7 (0.9-3.2)	.12	1.3 (0.8-1.9)[f]	.27
7-day PPA; responder[g]	59 (32.8)	34 (37.8)	25 (27.8)	1.7 (0.9-3.2)	.13	1.5 (1.0-2.3)	.06
30-day PPA; ITT	51 (27.1)	30 (31.9)	21 (22.3)	1.7 (0.9-3.4)	.12	1.4 (0.9-2.2)	.18
30-day PPA; responder[g]	51 (28.3)	30 (33.3)	21 (23.3)	1.7 (0.9-3.4)	.13	1.4 (0.9-2.22)	.19
Biochemically confirmed abstinence; ITT[h]	40 (21.3)	26 (27.7)	14 (14.9)	2.3 (1.1-4.8)	.03	1.9 (1.1-3.5)	.02
Biochemically confirmed abstinence; responder[g,h]	40 (22.2)	26 (28.9)	14 (15.6)	2.3 (1.1-4.8)	.03	1.9 (1.1-3.4)	.02
Self-reported continuous abstinence; ITT	39 (20.7)	24 (25.5)	15 (16.0)	1.9 (0.9-3.8)	.10	1.6 (0.9-2.8)	.11
Self-reported continuous abstinence; responder[i]	39 (21.8)	24 (26.7)	15 (16.9)	1.8 (0.9-3.9)	.11	1.6 (0.9-2.8)	.12
Biochemically confirmed continuous abstinence; ITT	29 (15.4)	20 (21.3)	9 (9.6)	2.7 (1.1-6.4)	.03	2.2 (1.1-4.6)[f]	.03
Biochemically confirmed continuous abstinence; responder[i]	29 (16.2)	20 (22.2)	9 (10.1)	2.7 (1.1-6.3)	.03	2.3 (1.1-4.7)	.02
Self-reported abstinence from all tobacco products; ITT	55 (29.3)	32 (34)	23 (24.5)	1.6 (0.9-3.1)	.13	1.5 (1.0-2.3)	.06
Self-reported abstinence from all tobacco products; responder[g]	55 (30.6)	32 (35.6)	23 (25.6)	1.6 (0.8-3.1)	.16	1.5 (1.0-2.2)	.08

[a]Negative binomial regression.

[b]PPA: point prevalence abstinence.

[c]ITT: intention to treat; total N=188: 94 in Pivot and 94 in QuitGuide.

[d]Responders to 12-week questionnaire; N=183 total: 92 in Pivot and 91 in QuitGuide.

[e]Completers of 12-week biovalidation visit; n=50 total: 29 in Pivot and 21 in QuitGuide.

[f]Log-link Poisson regression.

[g]Responders to 26-week questionnaire; N=180 total: 90 in Pivot and 90 in QuitGuide (includes responses from 1 partial responder).

[h]Completers of 26-week biovalidation visit; n=50 total: 29 in Pivot and 21 in QuitGuide.

[i]Responders to 26-week questionnaire; N=179 total: 90 in Pivot and 89 in QuitGuide.

Use of NRT

At 26 weeks, 99% (93/94) of the Pivot participants had ordered NRT compared with 82% (77/94) of the QuitGuide participants (RR 1.2, 95% CI 1.1-1.3; *P*<.001). The average number of NRT orders placed per participant was 3.1 (SD 1.9) in Pivot and 1.6 (SD 1.5) in QuitGuide (IRR 1.9, 95% CI 1.5-2.3; *P*<.001). Combination therapy (patch+gum or patch+lozenge) was the most common regimen among participants (Table 4).

Table 4. Nicotine replacement therapy (NRT) orders placed by participants through 26 weeks (P<.001)[a].

	All (n=188), n (%)	Pivot (n=94), n (%)	QuitGuide (n=94), n (%)
≥1 NRT single therapy[b] order	31 (16.5)	23 (24.5)	8 (8.5)
≥1 NRT combination therapy[c] order	101 (53.7)	44 (46.8)	57 (60.6)
≥1 NRT single therapy order+≥1 NRT combination therapy order	38 (20.2)	26 (27.7)	12 (12.8)
None	18 (9.6)	1 (1.1)	17 (18.1)
Total	188 (100)	94 (100)	94 (100)

[b]Single therapy: nicotine patch alone, nicotine gum alone, or nicotine lozenge alone.

[c]Combination therapy: nicotine patch+nicotine gum or nicotine patch+nicotine lozenge.

[a]Multinomial logistic regression adjusted for randomization covariates.

Participant Feedback

In general, participant feedback was more favorable for the Pivot program (Multimedia Appendix 1). The Pivot program was ranked as easier to set up and start using (scale 1-10, higher value equates to easier): Pivot, 8.2 (SD 2.3) versus QuitGuide, 7.1 (SD 3.0; point estimate 1.0, 95% CI 0.2-1.8; P=.01). In both groups, high proportions of participants indicated their study program helped them with their goals related to smoking (true or false): Pivot, 86% (79/92) versus QuitGuide, 76% (69/91; OR 2.0, 95% CI 0.9-4.2; P=.08; RR 1.1, 95% CI 1.0-1.3; P=.17). Among participants who reported 7-day PPA at 6 months (n=59), most reported their study program helped them quit smoking (true or false): Pivot, 100% (34/34) versus QuitGuide, 88% (22/25; RR 1.1, 95% CI 1.0-1.3; P=.08).

NPS was sought at 4, 12, and 26 weeks and was significantly higher for Pivot at each time point (Multimedia Appendix 2). Specifically, at 4, 12, and 26 weeks, the NPS for Pivot versus QuitGuide was 50.6 versus 1.1, 44.6 versus 11.0, and 57.8 versus 23.6, respectively.

Discussion

Principal Findings

This pilot RCT compared user engagement and retention, change in attitudes toward quitting smoking, change in smoking behavior, and participant feedback in adult smokers randomized to either the Pivot or QuitGuide app-based smoking cessation programs. Program engagement as assessed by total app openings through 12 weeks, the preregistered primary outcome of the study, was significantly higher in Pivot than in QuitGuide (P<.001). Measures assessing attitudes toward quitting smoking, including SASEQ, STQ, and DTQ, improved significantly in each group through 12 weeks but were not different among groups. Most (173/188, 92%) participants made at least 1 quit attempt, with QuitGuide participants reporting more quit attempts through 26 weeks (P=.003). The study was not powered for differences in quit rates; although self-reported 7- and 30-day quit rates were approximately 10 percentage points higher in Pivot at 26 weeks (eg, 7-day PPA at 26 weeks was 36.2% in Pivot and 26.6% in QuitGuide; ITT), these differences were not statistically significant. However, differences in biovalidated quit rates were significant at 12 weeks (28.7% Pivot vs 12.8% QuitGuide, ITT; P=.008) and 26 weeks (27.7% Pivot vs 14.9% QuitGuide, ITT; P=.03), as was the difference in the biovalidated continuous quit rate at 26 weeks (21.3% Pivot vs 9.6% QuitGuide, ITT; P=.03). In general, participants rated the Pivot program more favorably, including the setup and impact of the program and the likelihood of recommending their program to a friend or colleague.

Comparison With Prior Work

Engagement

For self-reported app openings, the primary outcome of user engagement, both study arms had greater engagement than expected. At 12 weeks, Pivot had an average of 157.9 total app openings and QuitGuide had 86.5, greater than the self-reported 37.2 average app openings for the SmartQuit arm and 15.2 for the QuitGuide arm reported at 8 weeks in the study by Bricker et al [5]. Although both studies used weekly or biweekly email engagement reminders, this study collected use data through weekly web-based questionnaires for 12 weeks, whereas Bricker et al [5] collected use data at 2 months after randomization. In addition, these data represent 1 more month of app use (12 weeks) than those reported by Bricker et al [5] (8 weeks). These study design differences could have contributed to the increase in self-reported app use between the 2 studies. For additional context, the following number of app openings for digital smoking cessation programs were reported through in-app data or Google Analytics (not self-report) in other studies: mean 100.6 app openings at 8 weeks with Clickotine [47], mean 37.5 app openings at 12 months with iCanQuit [4], and mean 37 app openings at 4 weeks after quit date with Quit Genius [38].

Smoking Cessation

Digital smoking cessation interventions have a wide range in their offerings. In a broad assessment of digital smoking cessation interventions with outcomes at 6 months, 7-day PPA rates range from 9.8% to 33.9% [4,48-51]. In this study, 36% (34/94) of the Pivot participants reported 7-day PPA, which was slightly above this range. This higher quit rate may reflect the multifaceted nature of Pivot—smartphone app, coaching, medication, and personal CO breath sensor—yielding a variety of smoking cessation tools to support its users.

Narrowing the scope to studies with smoking cessation programs similar to Pivot, 7-day PPA outcomes at 6 months range from 33.9% to 35.9% [4,7,16]; Pivot's 7-day PPA rate of 36.2% is comparable. Similarly, 32% (30/94) of the Pivot participants

achieved 30-day PPA at 6 months, rates that are similar to the 25% to 31.3% previously reported [4,16]. Published continuous abstinence rates at 6 months from smoking cessation programs similar to Pivot range from 23.8% to 27.2% [7,16]; the rate of 25.5% from this study again aligns with these results.

Comparison of cessation outcomes with QuitGuide is limited; however, Bricker et al [4] reported that 24% and 14.7% of participants achieved 7- and 30-day PPA at 6 months [4], respectively, compared with 26.6% and 22.3% in this study.

Making direct comparisons between Pivot and similar programs is somewhat limited owing to differences in study design, data collection time points, and study populations but does provide context to consider these results. For differences that are relevant for the aforementioned comparisons, examples include lack of NRT provision, CO breath sensor, coaching, and biovalidation in the studies by Bricker et al [4,5] and biovalidation of a minority of participants in the study by Webb et al [7,38]. Nonetheless, the growing body of outcome data for digital, app-based smoking cessation interventions, with similar quit rates from different investigator groups, increases confidence and credibility in this approach to cessation.

Self-reported Versus Biovalidated Abstinence Rates

Biovalidated abstinence rates and continuous abstinence rates were lower than the associated self-reported rates in both groups, although this was more pronounced in the QuitGuide arm. The first contributing factor was participants who did not schedule or did not attend their scheduled videoconference biovalidation visit. This accounted for 12% to 19% of potential eligible participants and was not different between the 2 study arms; similar and higher attrition rates have been reported elsewhere [7,38,52]. Notably, the discrepancy was primarily due to a change in smoking status (ie, relapse in the last 7 days since completing the associated study questionnaire) as reported at the outset of the biovalidation visits; this occurred in 15% (15/100) of all completed visits, specifically in 26% (11/42) of the 12- and 26-week visits completed by QuitGuide participants and in 10% (4/58) of these visits completed by Pivot participants. Obtaining a CO breath sample value that was discordant with self-reported abstinence was less common and occurred in 6% (6/100) of all completed visits, specifically in 12% (5/42) of the 12- and 26-week visits completed by QuitGuide participants and in 2% (1/58) of these visits completed by Pivot participants.

These results suggest a role of quit status instability in the discrepancy between self-reported and biovalidated quit rates in this study, particularly among QuitGuide participants. Although we believe it is less likely, we also cannot exclude the possibility of inaccurate self-reporting of quit status on the study questionnaires, leading to the scheduling of biovalidation visits; the expected effect would be inflated self-reported quit rates. Inaccurate self-reporting could be the result of motivation to seek additional compensation through the biovalidation visits or the result of differential experience between the 2 study arms with the breath sensor. Regarding compensation as a motivation, in the background of comparable socioeconomic characteristics in the 2 study arms, we have no reason to expect this to show up disproportionately in one arm over the other. Moreover, if compensation were a significant motivator, we might expect "repeat offenders": participants who self-reported abstinence on their questionnaires, then declared relapse at the outset of the subsequent biovalidation visit at both 12 and 26 weeks. However, none of the participants demonstrated this behavior. The impact of previous experience with a CO breath sensor was explored in the RCT conducted by Webb et al [7,38], in 530 adult smokers in which CO breath sensors were provided to 50% of all participants in both arms. The investigators reported, "Whether or not a participant was provided with a CO device did not significantly predict quit rate (P=.29 in logistic regression with CO device and intervention main effects)."

Comparison to previous studies is challenging owing to differences in methodology. However, our results relating to the decrease from self-reported to CO-biovalidated quit rates seem to fall in the range of those previously reported. Webb et al [7,38] conducted an RCT of 530 adult smokers in the United Kingdom, randomized to an app-based clinician-assisted smoking cessation program (Quit Genius) or Very Brief Advice. They reported that breath sample results corresponded with self-reported abstinence in 93.6% of the participants at 26 weeks. Notably, biovalidation was performed in a minority (approximately 40%) of self-reported abstainers. Piper et al [52] conducted an RCT in 623 adult smokers in the United States randomized to recommended usual care (10 minutes of in-person counseling, 8 weeks of nicotine patch, and referral to quitline services) or abstinence-optimized treatment (3 weeks of prequit mini lozenges, 26 weeks of nicotine patch+mini lozenges, 3 in-person and 8 phone counseling sessions, and 7-11 automated calls to prompt medication use). In contrast to the study by Webb et al [7,38], Piper et al [52] reported biovalidation rates that were less than half of self-reported abstinence rates (eg, 39.3% self-reported 7-day PPA decreased to 15.9% biochemically confirmed abstinence in the abstinence-optimized treatment group at 26 weeks). Finally, Garrison et al [48] assessed CO-confirmed abstinence rates in an RCT assessing app-based mindfulness training with experience sampling versus experience sampling alone in 325 adult smokers. They reported an overall 18.2% self-reported 7-day PPA rate compared with 11.1% overall CO-verified abstinence rate at 6 months. Characteristics of study design and population have been shown to influence biovalidation rates. Some such relevant factors are present in this and aforementioned studies, including varying degrees of contact from minimal to face to face and varying cessation program intensity [52]. As the body of evidence on biovalidation continues to grow, so too will more informed narratives of optimal use and appropriate expectations for differences in self-reported versus biovalidated quit rates.

Notable Similarities and Differences Among Study Group Outcomes

Both groups had significant increases in measures of self-efficacy and confidence in quitting at 12 weeks, but these differences were not significant between the study groups. Both groups also reported significant decreases in CPD over time, with approximately 40% to 50% of those who did not achieve 7-day PPA in each group reducing their CPD by ≥50% at 26 weeks; again, these differences were not significant among the groups. In the setting of biovalidated quit rates that were

significantly different among the study groups, it is interesting to note these milestones did not track in a similar fashion, considering they have historically been associated with an increased likelihood of quitting smoking [16,51,53-57].

The study groups did have significant differences in program engagement, with more program use, via total app openings, in the Pivot group. This finding aligns with the higher biovalidated abstinence and biovalidated continuous abstinence rates in the Pivot group. Study participants in both groups reported comparable number of days and duration (in weeks) of program use. Accordingly, the higher total app openings reported in Pivot suggests greater use per day. Higher program engagement has been associated with better outcomes in app-based smoking cessation programs [4,51,58]. Although the primary outcome sought to compare engagement of the holistic Pivot and QuitGuide smoking cessation programs via app openings, it is worth noting the possible influence on app use patterns of specific features in Pivot that are not present in QuitGuide, such as the breath sensor and in-app coach messaging. The intent and design of this study was not conducive to the assessment of individual app functions in facilitating engagement, which is a topic requiring finer discriminatory evaluation (such as A/B testing) that is of interest for future studies.

Another difference between the 2 study groups includes more quit attempts per person in QuitGuide. Coupled with the lower biovalidated abstinence and continuous abstinence rates in this group largely due to short-term relapse, this suggests less stability of quit among the QuitGuide users. Similar findings of higher quit attempts with lower quit rates have been reported in control arms elsewhere [7]. Finally, NRT use was higher in the Pivot study arm, which one would expect in this group with higher biovalidated abstinence and continuous abstinence rates. Although both study groups had access to free NRT with standardized repeated reminders of this access, it is likely that a more comprehensive incorporation of NRT in the Pivot program, through both education and support by tobacco cessation coaches contributed to the increased NRT use in this group.

Strengths and Limitations

This study had several strengths. First, the study population was diverse and balanced, with nonproportional quota sampling goals achieved. Also, the comparison of same-modality interventions, with the control being a well-established and well-studied app-based cessation program helps minimize potential modality-related confounding and provides context for our results. Another strength is the inclusion of biovalidation for all those who reported 7-day or greater abstinence at 12 and 26 weeks. In addition, all the following metrics were robust: participant retention (approximately 98% in each arm), survey completion rates (≥92% for each survey), and biovalidation visit completion rates (approximately 85% overall).

This study also had several limitations. First, the inclusion criterion of intention to quit in the next 30 days resulted in a study population that may not reflect the general population of smokers. Aggregating across studies and populations, Prochaska et al [55] estimated that at any given time, approximately 20% of smokers were thinking of quitting smoking in the next 30 days, 35% to 40% were thinking of quitting in the next 6 months, and 40% to 45% were not seriously thinking of quitting. In a previous cohort study of Pivot in which the study population more closely aligned with the general population of smokers (66% were not seriously thinking of quitting in the next 30 days at study entry), this factor was not predictive of cessation outcomes. Furthermore, there is some benefit to this inclusion criterion in that this aspect of our study population matches similar previous studies, more readily facilitating comparison.

Second, the self-reporting of engagement, including app openings is not as accurate as the report of such data through in-app or Google Analytics use data. However, we did not have this capability with QuitGuide. Although we expect this might result in overestimation of app openings, we have no reason to believe participants in either arm would be more likely to do so. The fact that the study arms reported a similar number of days and weeks of app use lends further credibility to the reported differential in app openings.

Third, as a pilot RCT and the first comparison of Pivot to comparable usual care, this study was not powered for cessation outcomes. Differences in self-reported abstinence were not significant, whereas differences in biovalidated abstinence rates were. It is unclear whether a larger study would have yielded significant differences in self-reported cessation outcomes or biovalidated abstinence rates; that question remains to be answered in a study powered accordingly.

Fourth, the Pivot program included additional cessation tools that the QuitGuide program did not, including a CO breath sensor, access to SMS text messaging–based coaching with a tobacco cessation coach, and a moderated web-based community support forum. The study compares the holistic programs but is limited in that it cannot determine if, and to what extent, any of these features in Pivot were more effective than the QuitGuide app plus NRT.

Fifth, the possible impact of compensation must also be considered. We took steps to minimize the impact of compensation, including conservative payment amounts that were commensurate with participant effort, delaying payment by 2 to 3 weeks from completion of compensated events, and not tying compensation to outcomes. Nonetheless, we cannot exclude some influence of study payment on participant behavior.

Sixth, after randomization, all researchers were unblinded to participant group allocation. This can have implications for study conduct such as possible unbalanced participant communication and data collection efforts. Accordingly, we designed the study with mitigating factors such as scheduled, standardized, and scripted written and verbal participant communications that were reviewed by the institutional review board. We believe that the high and comparable questionnaire and biovalidation visit completion rates (>92% for questionnaires and >80% for biovalidation visits at 12 and 26 weeks in both study arms) reflect favorably on our attempt to minimize the possible effect of unblinded researchers.

Seventh, exhaled CO as a biovalidation test for smoking cessation is imperfect. The half-life of CO is, on average, 4

hours and is influenced by activity level (ie, shorter half-life when exercising and longer when sleeping). Accordingly, smokers may be able to abstain from smoking for several hours before providing a breath sample and obtain a CO value consistent with "not smoking"; we cannot exclude this occurrence in the biovalidation visits. Moreover, secondhand smoke, use of other combustible substances such as marijuana, and environmental or occupational CO exposure can increase CO levels. That said, the limitations of other biovalidation methods made exhaled CO, which is noninvasive, less expensive, and easy for a lay user to perform the preferred option. Specifically, although cotinine, a nicotine metabolite, has a longer half-life (≥8-30 hours) than CO and therefore requires longer abstinence periods (2-7 days) to reach "nonsmoking" levels, its collection from body fluids is more onerous and will yield positive results in individuals using NRT, which was problematic with our study design. Anabasine and anatabine are minor tobacco alkaloids that are specific for tobacco-derived products (eg, cigarettes, cigars, and smokeless tobacco). They are well suited for testing individuals for tobacco use who are using NRT. However, these biomarkers require urine collection and chromatography–mass spectrometry measurement [59]. Altogether, when considering the remote nature of this study and the provision of NRT, we felt exhaled CO, despite its imperfections, was our best option for biovalidation.

Finally, it should be noted that recruitment, enrollment, and study conduct were performed during the COVID-19 pandemic and during a time characterized by heightened social, political, and economic stressors. Although it is beyond the scope of the study to quantify these factors, it is worth noting as this is a difference between this study and the aforementioned comparator studies. The impact is unknown at this time.

Conclusions

Previous cohort studies assessing Pivot established the foundation for further comparative assessment, leading to this study. This RCT compared Pivot with a well-established app-based smoking cessation program and found that Pivot produced higher engagement, higher biovalidated cessation rates, and more favorable user feedback. This study, with 6-month outcomes, supports the efficacy and durability of Pivot and adds to the growing body of evidence identifying an emerging role for digital, app-based interventions for smoking cessation. As the data narrative for rising digital smoking cessation programs unfolds, areas ripe for future assessment include longer-term durability data, evaluation of the contributions to program engagement and abstinence rates of individual app functions such as coaching and breath sensor result tracking, and assessment of the cost-effectiveness of digital app-based interventions.

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Data Availability

Deidentified data will be shared on reasonable request, stating the purpose, to the corresponding author, which is subject to approval by the sponsor.

Authors' Contributions

JDM, CAF, DJB, and DSU designed the study. JDM, CAF, and MTU recruited the participants. JDM and DJB oversaw the study. CAF managed the database. CAF and JAG determined the most appropriate analyses and performed them. MTU performed many of the functions of study conduct, including managing participant interactions, data collection, participant compliance with questionnaires and visits, scheduling and running biovalidation visits, and study payments. CAF and JDM assisted with the aforementioned study conduct tasks as needed. JDM and MTU prepared the original draft of the manuscript. JDM, CAF, MTU, DJB, DSU, and JAG reviewed and edited the manuscript before submission.

Conflicts of Interest

JDM, CAF, MTU, DJB, and DSU are current employees of Pivot Health Technologies Inc (Pivot), the developer of the Pivot smoking cessation program. They receive salary and stock options from Pivot. DSU is the president and chief executive officer of Pivot and an investor in the company. JAG is a paid statistical consultant.

Multimedia Appendix 1
Participant feedback.
[DOCX File , 22 KB - mhealth_v10i11e41658_app1.docx]

Multimedia Appendix 2
Net promoter score.
[DOCX File , 14 KB - mhealth_v10i11e41658_app2.docx]

Multimedia Appendix 3
CONSORT-eHEALTH checklist (V 1.6.1) [60].
[PDF File (Adobe PDF File), 1377 KB - mhealth_v10i11e41658_app3.pdf]

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Abbreviations

ACT: acceptance and commitment therapy

CBT: cognitive behavioral therapy
CO: carbon monoxide
CONSORT: Consolidated Standards of Reporting Trials
CPD: cigarettes per day
DTQ: difficulty to stay quit
FDA: Food and Drug Administration
IRR: incidence rate ratio
ITT: intention to treat
NPS: net promoter score
NRT: nicotine replacement therapy
OR: odds ratio
PPA: point prevalence abstinence
ppm: parts per million
RCT: randomized controlled trial
RR: relative risk ratio
SASEQ: Smoking Abstinence Self-efficacy Questionnaire
STQ: success to quit
USCPG: US Clinical Practice Guideline

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Original Paper

Text Message Reminders to Improve Immunization Appointment Attendance in Alberta, Canada: The Childhood Immunization Reminder Project Pilot Study

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Abstract

Background: Vaccine coverage for 18-month-old children in Canada is often below the recommended level, which may be partially because of parental forgetfulness. SMS text message reminders have been shown to potentially improve childhood immunization uptake but have not been widely used in Alberta, Canada. In addition, it has been noted that language barriers may impede immunization service delivery but continue to remain unaddressed in many existing reminder and recall systems.

Objective: This study aimed to assess the effectiveness and acceptability of using SMS text messages containing a link to web-based immunization information in different languages to remind parents of their child's 18-month immunization appointment.

Methods: The Childhood Immunization Reminder Project was a pilot intervention at 2 public health centers, one each in Lethbridge and Edmonton, Alberta, Canada. Two SMS text message reminders were sent to parents: a booking reminder 3 months before their child turned 18 months old and an appointment reminder 3 days before their scheduled appointment. Booking reminders included a link to the study website hosting immunization information in 9 languages. To evaluate intervention effectiveness, we compared the absolute attendance no-show rates before the intervention and after the intervention. The acceptability of the intervention was evaluated through web-based surveys completed by parents and public health center staff. Google Analytics was used to determine how often web-based immunization information was accessed, from where, and in which languages.

Results: Following the intervention, the health center in Edmonton had a reduction of 6.4% (95% CI 3%-9.8%) in appointment no-shows, with no change at the Lethbridge Health Center (0.8%, 95% CI −1.4% to 3%). The acceptability surveys were completed by 222 parents (response rate: 23.9%) and 22 staff members. Almost all (>95%) respondents indicated that the reminders were helpful and provided useful suggestions for improvement. All surveyed parents (222/222, 100%) found it helpful to read web-based immunization information in their language of choice. Google Analytics data showed that immunization information was most often read in English (118/207, 57%), Punjabi (52/207, 25.1%), Arabic (13/207, 6.3%), Spanish (12/207, 5.8%), Italian (4/207, 1.9%), Chinese (4/207, 1.9%), French (2/207, 0.9%), Tagalog (1/207, 0.5%), and Vietnamese (1/207, 0.5%).

Conclusions: The study's findings support the use of SMS text message reminders as a convenient and acceptable method to minimize parental forgetfulness and potentially reduce appointment no-shows. The diverse languages accessed in web-based immunization information suggest the need to provide appropriate translated immunization information. Further research is needed to evaluate the impact of SMS text message reminders on childhood immunization coverage in different settings.

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KEYWORDS

text message; SMS; immunization reminder; reminder-recall; routine immunization; childhood; immunization; reminder; children; language barrier; Canada; vaccine; vaccination; coverage

Introduction

Background

Immunization is a safe and cost-effective intervention that substantially reduces childhood morbidity and mortality [1]. Routine childhood immunization is publicly funded across Canada. However, childhood vaccine coverage remains suboptimal [2]. Evidence from Canada and globally has shown a link between suboptimal vaccine coverage and vaccine-preventable disease outbreaks [3,4].

It is a well-recognized phenomenon that the uptake of infant vaccines exhibits a precipitous drop at the 18-month vaccine doses [5-7]. The vaccines administered at 18 months of age in Canada include diphtheria-tetanus-acellular pertussis-polio-*Haemophilus influenzae* type b (DTaP-IPV-Hib) in all provinces or territories, measles-mumps-rubella-varicella (MMRV) in 7 provinces or territories, and pneumococcal conjugate 13-valent (Pneu C13) and hepatitis B in one province or territory each [8]. The drop in coverage at 18 months is exemplified in Alberta, where 2021 coverage levels for the third dose of DTaP-IPV-Hib, typically given at 6 months, was 89%, but only 75% for the fourth dose, given at 18 months [9].

The literature has shown that parental forgetfulness of immunization appointments is a key barrier to 18-month vaccine uptake [10,11]. Factors contributing to this forgetfulness in Canadian parents include the following: (1) the perception that infant vaccines are completed by 12 months of age, (2) the end of paid parental leave and return to work, (3) a 6-month gap between appointments, and (4) the inability of some booking systems to schedule an appointment 6 months in advance [12,13]. People with low socioeconomic status are more likely to have low vaccine coverage because of challenges in caring for multiple children, multiple household moves, inadequate income, and language barriers [14]. Suboptimal immunization coverage among certain populations is problematic and creates work for health care providers in catching up with missed doses. Hence, there is a need for a robust immunization appointment reminder system to help alleviate some of these challenges.

Previous research has shown that SMS text message reminders improve childhood immunization uptake [3,15], particularly when educational information is included [16,17]. Furthermore, providing educational information in different languages can promote engagement with immunization information and help parents of different ethnic backgrounds understand immunization benefits [18]. SMS text messaging has also been shown to be relatively low cost, technologically easy, widely available, and applicable to various health problems [19,20].

Objectives

Given that the effectiveness of public health interventions is context specific [21], assessing whether a new SMS text message intervention would have the intended impact (ie, fewer missed appointments) and would be acceptable to stakeholders is crucial. There was interest among public health stakeholders in Alberta in testing an SMS text messaging reminder system for preschool immunization. Thus, this study aimed to assess the effectiveness and acceptability of using SMS text messages containing a link to web-based immunization information in different languages to remind parents of their child's 18-month immunization appointment.

Methods

Setting

Alberta is a western Canadian province with approximately 4.4 million residents. The province is divided into 5 zones for the administration of health services by Alberta Health Services (AHS). Routine preschool immunization is delivered exclusively by nurses at public health centers (PHCs).

Intervention

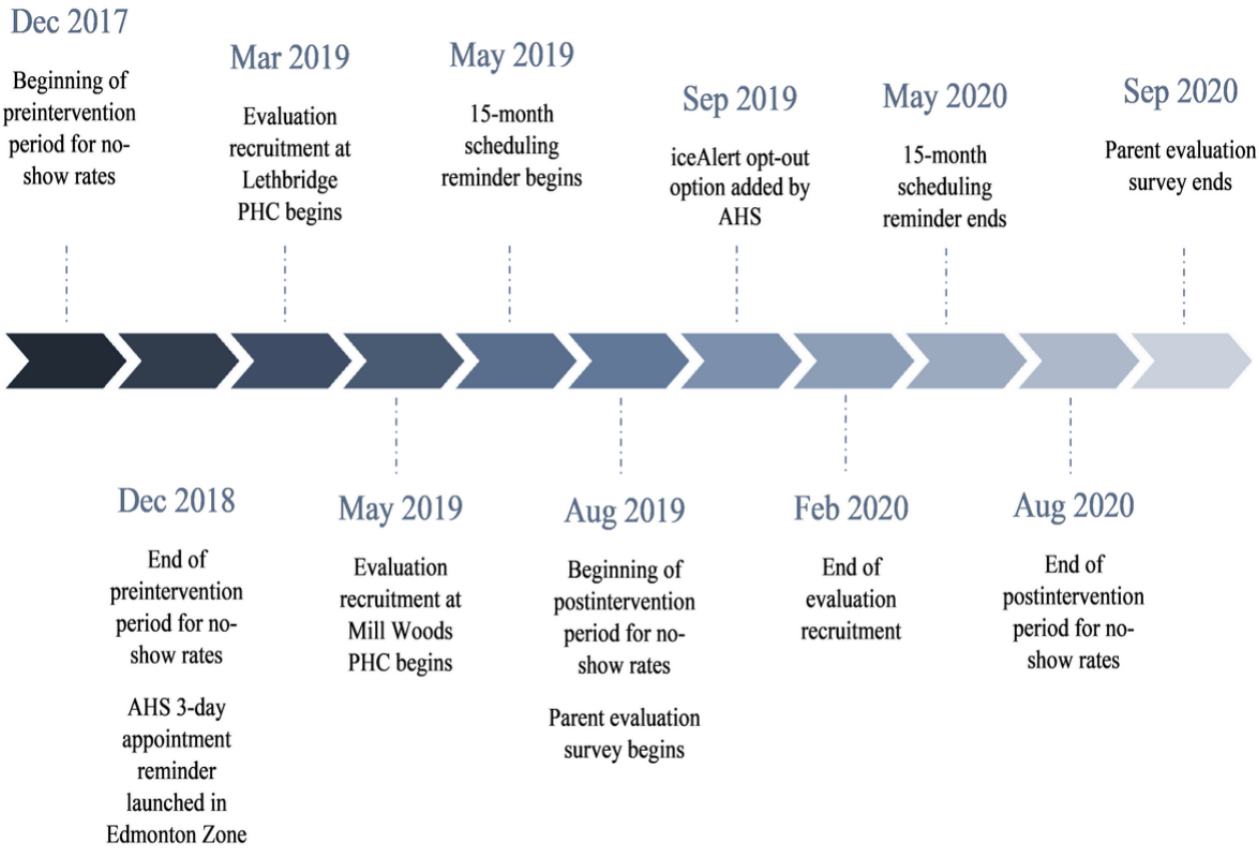
The Childhood Immunization Reminder Project (ChIRP) was a pilot intervention aimed at improving attendance at 18-month immunization appointments by sending SMS text message reminders to parents. ChIRP was implemented at two PHCs: (1) Mill Woods PHC in the Edmonton health zone, which serves an ethnically diverse population in a high-density urban city with a total population of 1.1 million [22], and (2) Lethbridge PHC in the South Health Zone, which serves a more ethnically

homogenous population in a small city within a rural area with a population of 102,000 [22].

Using an automated system (iceAlert), 2 SMS text message reminders were sent to each parent participating in the study. Messages were sent to the primary phone number on file provided by the parents during registration. Most were cell phone numbers, but voice message reminders were sent instead of SMS text messages if the phone number provided was a landline number. The first message was sent 3 months before the child turned 18 months (ie, when the child was 15 months old) to remind parents to book the 18-month appointment or to reschedule an existing appointment if needed. The reminders were sent monthly between May 2019 and May 2020 to all parents of children who turned 15 months old in that month and had a postal code within the service area of Mill Woods or Lethbridge PHCs. This reminder included a link to the study website hosting immunization information in 9 languages (English, French, Arabic, traditional Chinese, Italian, Punjabi, Spanish, Tagalog, and Vietnamese).

The second message was a reminder of the date and time of the booked 18-month appointment, which was sent 3 days before the scheduled visit. This reminder was initiated by AHS in December 2018, shortly before the start of ChIRP, and was, therefore, incorporated into the evaluation. This was an opt-out system (ie, parents received the message unless they asked not to). Figure 1 shows the timeline of the intervention and evaluation periods.

Figure 1. Timeline of study intervention and evaluation periods. AHS: Alberta Health Services; PHC: public health center.



Evaluation

Effectiveness

To evaluate the effectiveness of the intervention, we compared absolute no-show rates before (December 2017 to December 2018) and after (August 2019 to August 2020) the intervention in both PHCs using routinely collected administrative data from AHS. No-shows were defined as children who had missed their scheduled appointments, including those who rescheduled missed appointments. We identified all children with 18-month immunization appointments at the PHCs by using provincial patient identification numbers. Children were excluded from the analysis if their appointment was canceled or outside the preintervention or postintervention periods, they had not yet had their appointment, or were aged >24 months. No-show rates were determined by dividing the total number of no-shows by the total number of 18-month immunization appointments at each PHC. The no-show rates at the intervention sites were compared with PHCs with similar client demographics in the same health zone (ie, Northeast Edmonton PHC for Mill Woods and Medicine Hat PHC for Lethbridge) using a 2-sample proportion test. The analysis was performed using R (version 3.6.3; R Foundation for Statistical Computing) [23] and Stata (version 15.1; StataCorp).

Acceptability

Parents and PHC staff evaluated the acceptability of the reminder intervention. The PHC staff recruited parents for the web-based survey evaluation during their child's 12-month immunization appointment, starting in March (Lethbridge) or May 2019 (Edmonton) and continuing until February 2020.

Interested parents received an information sheet and consent form (available in 9 languages) that collected their name, child's name and date of birth, and mobile phone number. There were no eligibility restrictions in terms of age, gender, or other sociodemographic characteristics other than needing a mobile phone to receive the evaluation survey link. In consultation with PHC managers, a parallel survey was sent to all staff who worked at either participating PHC during the intervention period, including nurses and clerical staff. Informed consent was obtained from all the participants.

Participating parents were sent a text message containing a link to a web-based survey when their child was 19 months old, after the intended 18-month immunization appointment. Parent surveys were completed between September 2019 and October 2020. The PHC staff were sent the staff survey link via email at the end of the intervention period in December 2020 or January 2021. Survey data were collected and managed using REDCap (Research Electronic Data Capture; Vanderbilt University) tools hosted and supported by the Women and Children's Health Research Institute at the University of Alberta [24].

Sociodemographic information collected from parents included residential location, whether they were born in Canada, language or languages read, education level, and annual household income. The PHC staff provided the PHC's location and their job position. Parents were asked about the helpfulness of the reminders, when the reminders should be sent, what actions they took because of the reminders, and whether their child had attended the 18-month immunization appointment. The PHC staff evaluated the helpfulness and impact of the reminders, when and how many reminders should be sent, and which other routine vaccine programs (2-month, 4-month, 6-month, 12-month, preschool, and school-based) should be considered for reminders.

Both parents and PHC staff evaluated the helpfulness and impact of the web-based immunization information included in the reminder. Google Analytics [25] was used to determine how often the information was accessed, from where, and in which languages. The survey data were analyzed using SPSS (version 26; IBM Corp) [26]. Descriptive statistics (ie, frequencies or percentages) were calculated for the survey responses.

Ethics Approval

This study was approved by the Health Research Ethics Board of the University of Alberta (study ID: Pro00085642).

Results

Overview

Throughout the intervention period (May 2019 to May 2020), a total of 3307 booking reminders were successfully sent, including 2885 SMS text messages and 422 voice notifications. A small number of reminders (n=133) were not delivered. Data on the number of 3-day appointment reminders sent were not available because these reminders were sent zone-wide by AHS.

Effectiveness

After removing those who had not yet had an appointment or had incomplete data, the Mill Woods PHC had 638 appointments for 18-month immunizations during the preintervention period. Of the 638 appointments, 116 (18.2%) were either no-show or initially no-show and then rebooked. During the postintervention period, there were 1508 appointments for 18-month immunizations, with 178 (11.8%) no-shows. Data from the Northeast Edmonton PHC are shown for comparison (Table 1). Between the preintervention and postintervention periods, Mill Woods experienced a 6.4% (95% CI 3.0%-9.8%) decline in absolute no-show rates, significantly more than the control site in the Northeast Edmonton PHC (Table 1).

At Lethbridge PHC, there were 1657 appointments for 18-month immunization during the preintervention period, 186 (11.22%) of which were no-shows. During the postintervention period, there were 1653 appointments and 198 (11.97%) no-shows. Data from the Medicine Hat PHC are shown for comparison. There were no significant differences between preintervention and postintervention no-show rates in the other intervention (Lethbridge) and control site (Medicine Hat).

Table 1. Absolute no-show[a] rates and change in rates before the intervention (December 2017 to December 2018) and after the intervention (August 2019 to August 2020).

Health zone	Preintervention rates		Postintervention rates		Change	
	Rate, n (%)	95% CI	Rate, n (%)	95% CI	Rate, %[b]	95% CI
Edmonton zone						
Mill Woods (intervention site)						
Attended	522 (81.8)	78.8 to 84.8	1330 (88.2)	86.6 to 89.8	6.4	3.0 to 9.8
No-show	116 (18.2)	15.2 to 21.2	178 (11.8)	10.2 to 13.4	−6.4	−9.8 to −3.0
Northeast Edmonton (control site)						
Attended	388 (85.7)	82.5 to 88.9	1105 (81.9)	79.8 to 84.0	−3.8	−7.6 to 0.0
No-show	65 (14.3)	11.1 to 17.5	244 (18.1)	16.0 to 20.2	3.8	0.0 to 7.6
South zone						
Lethbridge (intervention site)						
Attended	1471 (88.8)	87.3 to 90.3	1455 (88)	86.4 to 89.6	−0.8	−3.0 to 1.4
No-show	186 (11.2)	9.7 to 12.7	198 (12)	6.0 to 13.6	0.8	−1.4 to 3.0
Medicine Hat (control site)						
Attended	904 (89)	87.1 to 90.9	824 (88.1)	86.0 to 90.2	−0.9	−3.7 to 1.9
No-show	112 (11)	9.1 to 12.9	111 (11.9)	5.4 to 14.0	0.9	−1.9 to 3.7

[a]No-show was defined as when a client failed to turn up for their scheduled appointment, including those who initially did not turn up for their scheduled appointment and later rebooked it.

[b]Change in rates calculated as the difference between postintervention and preintervention rates.

Acceptability

A total of 929 parents consented to participate in the evaluation survey (Mill Woods, n=484; Lethbridge, n=445), whereas 107 declined to participate (Mill Woods, n=24; Lethbridge, n=83). Of those who consented, 222 completed the parent survey (Mill Woods, n=105; Lethbridge, n=117) and 10 declined the survey after receiving it (Mill Woods, n=7; Lethbridge, n=3), with a response rate of 23.9% (222/929). Of those who responded, 93.7% (208/222) reported attending the 18-month visit, whereas 6.3% (14/222) reported missing it. A total of 22 PHC staff members completed the staff survey (Mill Woods, n=12; Lethbridge, n=10). The number who received the invitation was not available, as the PHC managers were responsible for forwarding the invitation to all staff who worked during the intervention period.

Sociodemographic Characteristics

As seen in Table 2, a total of 51.8% (115/222) of the parent sample was located in or near Lethbridge and 46.8% (104/222) was located in or near Mill Woods. Most were born in Canada (203/222, 91.4%), were most comfortable reading English (207/222, 93.2%), had a university degree (104/222, 46.8%) or a college certificate or diploma (87/222, 39.2%), and had an annual household income of greater than CAD $90,000 (US $65,894.85; 77/222, 34.7%). Slightly over half of the PHC staff sample was employed at Mill Woods (12/22, 55%), with the remainder employed at Lethbridge (10/22, 46%). Most of the surveyed staff members were nurses (19/22, 86%).

Table 2. Sociodemographic characteristics of parents (n=222) and public health center staff (n=22).

Variable	Respondents, n (%)
Parents	
Location	
In or near Lethbridge	115 (51.8)
In or near Mill Woods (Edmonton)	104 (46.8)
Not specified	3 (1.4)
Arrived in Canada in the last 5 years	
Yes	16 (7.2)
No	197 (88.7)
No response	9 (4.1)
Language most comfortable reading	
English	207 (93.2)
Spanish	4 (1.8)
Punjabi	2 (0.9)
Chinese	1 (0.5)
Others[a]	7 (3.1)
No response	1 (0.5)
Highest level of education completed	
University degree	104 (46.8)
College or other post–high-school academic certificate or diploma	87 (39.2)
High school	21 (9.5)
Lower than high school	1 (0.5)
Prefer not to answer or no response	9 (4)
Annual household income (CAD $)[b]	
<30,000	22 (9.9)
30,000-59,999	36 (16.2)
60,000-89,999	42 (18.9)
>90,000	77 (34.7)
Prefer not to answer	33 (14.9)
Do not know	6 (2.7)
No response	6 (2.7)
Public health center staff	
Health center location	
Mill Woods (Edmonton zone)	12 (55)
Lethbridge (south zone)	10 (46)
Job position	
Nurse	19 (86)
Manager	2 (9)
Administrative support	1 (5)

[a]Other languages included Arabic, Dinka, Somali, Swedish, Ukrainian, Urdu, Yoruba, and not specified (all n=1).

[b]At the time of study, CAD $1 was approximately equal to US $0.73.

Fifteen-Month Booking Reminder

In total, 51.4% (114/222) of the parents surveyed reported receiving the 15-month booking reminder (Table 3). Of these 114 parents, 96.5% (n=110) reported that it was helpful. Of the 110 parents who found the reminder helpful, 30.9% (n=34) booked or rescheduled their child's 18-month immunization appointment after receiving the reminder. Of all surveyed parents (N=222), most reported that a reminder to book the 18-month immunization appointment should be sent when children were 17 months old (n=114, 51.4%) rather than when they were 15 months old (when it was delivered for the study).

As shown in Table 3, most PHC staff members reported that the 15-month reminder was helpful (21/22, 96%). A total of 81% (18/22) of the staff reported that more clients came to their scheduled appointments than usual during the 1-year intervention period. Staff from the 2 PHCs had different preferences for when to send the booking reminder; the Mill Woods staff preferred the reminder be sent at 15 months (41.7%) while Lethbridge staff preferred 16 months (6/10, 60%). Most staff members at both PHCs reported that 2 immunization booking reminders should be sent to clients (12/22, 55%).

As shown in Figure 2, a total of 19 PHC staff members (Mill Woods, n=11; Lethbridge, n=8) ranked childhood vaccine programs for booking reminders according to their priority. One participant from Mill Woods and 2 participants from Lethbridge did not provide a ranking. Of the 19 participants who provided rankings, some provided <6 rankings, so the total for each ranking may not add up to 19. The 2-month (8/19, 42%) and 12-month (7/19, 37%) vaccine programs were most commonly ranked first for scheduling or booking reminders, followed by the preschool program (4/19, 21%). Almost half of the PHC staff ranked the school-based vaccine program as the lowest priority (9/19, 47%).

Table 3. Evaluation of the 15-month booking reminder by parents who reported receiving the 15-month reminder (n=114) and public health center staff who completed the survey (n=22).

Variable	Response, n (%)		
	Mill Woods	Lethbridge	Total
Parents			
15-month reminder was helpful (n=114)			
Yes	57 (96.6)	53 (96.4)	110 (96.5)
No	1 (1.7)	1 (1.8)	2 (1.8)
I do not know	1 (1.7)	1 (1.8)	2 (1.7)
Impact of the 15-month reminder (n=110)[a]			
Booked appointment	14 (24.6)	14 (26.4)	28 (25.5)
Changed appointment	4 (7)	2 (3.8)	6 (5.5)
Did nothing	37 (64.9)	34 (64.2)	71 (64.5)
Forgot to book or reschedule	1 (1.8)	2 (3.8)	3 (2.7)
Other	1 (1.8)	1 (1.9)	2 (1.8)
Why the 5-month reminder was helpful (n=110)[a,b]			
Reminded of the appointment	55 (96.5)	53 (100)	108 (98.2)
Specified the name of the child	15 (26.3)	16 (30.2)	31 (28.2)
Included phone number to call for booking	18 (31.6)	24 (45.3)	42 (38.2)
Included vaccine information link	5 (8.8)	14 (26.4)	19 (17.3)
Best time to send the reminder (n=222)[c]			
When child is 15 months	32 (30.5)	31 (26.5)	63 (28.4)
When child is 16 months	25 (23.8)	29 (24.8)	54 (24.4)
When child is 17 months	48 (45.7)	66 (56.4)	114 (51.4)
Other	10 (9.5)	5 (4.3)	15 (6.8)
Public health center staff			
15-month reminder was helpful (n=22)			
Yes	12 (100)	9 (90)	21 (95.5)
No	0 (0)	1 (10)	1 (4.5)
Not sure or do not know	0 (0)	0 (0)	0 (0)
Impact of the 15-month reminder (n=21)[b,d]			
More clients came to their scheduled immunization than usual	10 (83.3)	8 (88.9)	18 (85.7)
More clients canceled or rescheduled than usual	1 (8.3)	2 (22.2)	3 (14.3)
Other	2 (16.7)	1 (11.1)	3 (14.3)
No change	0 (0)	0 (0)	0 (0)
Best time to send the reminder (n=22)			
When child is 15 months	5 (41.7)	2 (20)	7 (31.8)
When child is 16 months	4 (33.3)	6 (60)	10 (45.5)
When child is 17 months	3 (25)	0 (0)	3 (13.7)
No need to send a booking or rescheduling reminder	0 (0)	1 (10)	1 (4.5)
Other	0 (0)	1 (10)	1 (4.5)
How many reminders should be sent (n=22)			
1	4 (33.3)	3 (30)	7 (31.8)

Variable	Response, n (%)		
	Mill Woods	Lethbridge	Total
2	6 (50)	6 (60)	12 (54.5)
3	2 (16.7)	1 (10)	3 (13.7)

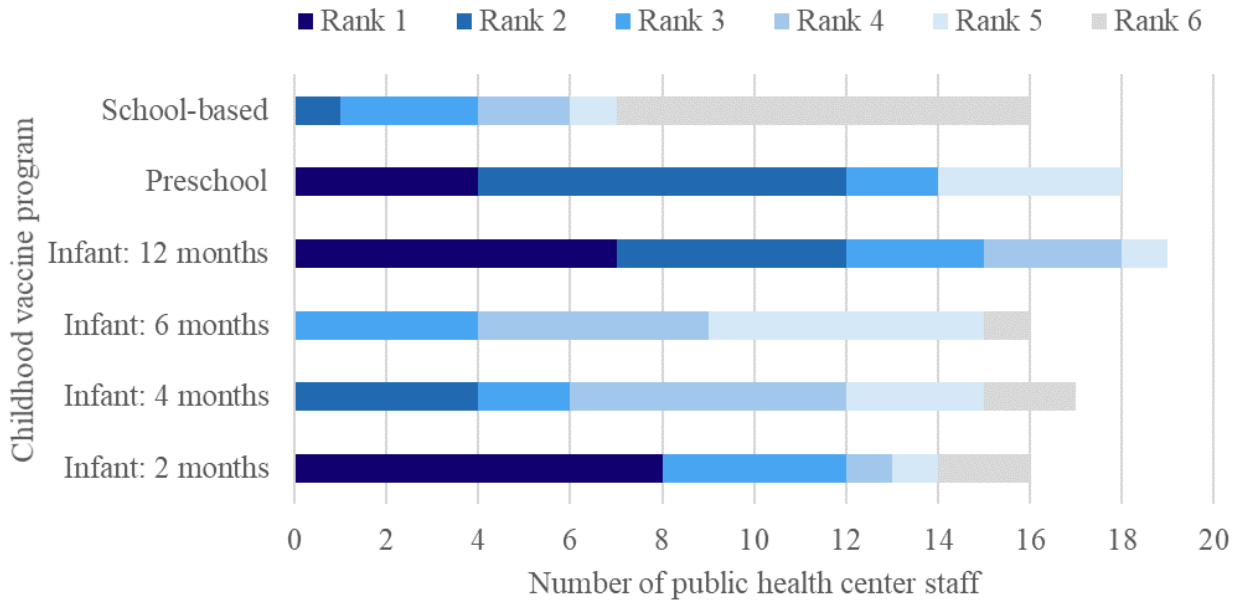
[a]For parents who responded that the 15-month reminder was helpful (Mill Woods: n=57; Lethbridge: n=53).

[b]Respondents could select more than one option.

[c]Answered by all parents, not just those who received the 15-month reminder.

[d]For staff who responded that the 15-month reminder was helpful.

Figure 2. Public health center staff (n=19) rankings of childhood vaccine programs for priority of scheduling or booking reminders (of those who answered yes to whether reminders will be helpful for other routine vaccine programs).



Three-Day Appointment Reminder

In total, 79.3% (176/222) of the surveyed parents reported receiving the 3-day appointment reminder (Table 4), and 6.8% (12/176) of the parents reported changing their appointments. Slightly over half (113/222, 50.9%) of the surveyed parents indicated that the best time to send reminders was 3 days before the appointment. The second preferred time to send reminders was a week before the appointment (85/222, 38.3%). Most parents (208/222, 93.6%) reported attending the 18-month immunization appointment.

Among the PHC staff, most (21/22, 96%) reported that the 3-day reminder was helpful (Table 4). Over half of the staff (12/22, 55%) indicated that the best time to send this reminder was 3 days before the visit, and 59% (13/22) of the staff indicated that only 1 reminder should be sent.

Table 4. Evaluation of the 3-day appointment reminder, among parents who reported receiving the 3-day reminder (n=176) and public health center staff who completed the survey (n=22).

Variable	Response, n (%)		
	Mill Woods	Lethbridge	Total
Parents			
3-day reminder was helpful to remember the appointment date and time (n=176)			
Yes	89 (98.9)	86 (100)	175 (99.4)
No	1 (1.1)	0 (0)	1 (0.6)
Impact of the 3-day reminder (n=176)			
Changed appointment	7 (7.8)	5 (5.8)	12 (6.8)
Did nothing	82 (91.1)	79 (91.9)	161 (91.4)
Other	1 (1.1)	2 (2.3)	3 (1.7)
Best time to send the reminder (n=222)[a]			
On the same day as the appointment	9 (8.6)	9 (7.7)	18 (8.1)
1 day before the appointment	23 (21.9)	30 (25.6)	53 (23.9)
2 days before the appointment	16 (15.2)	23 (19.7)	39 (17.6)
3 days before the appointment	53 (50.5)	60 (51.3)	113 (50.9)
1 week before the appointment	36 (34.3)	49 (41.9)	85 (38.3)
2 weeks before the appointment	8 (7.6)	3 (2.6)	11 (5.0)
1 month before the appointment	10 (9.5)	7 (6.0)	17 (7.7)
Other	0 (0)	2 (1.7)	2 (0.9)
Attendance at the 18-month immunization appointment (n=222)[b]			
Yes	99 (94.3)	109 (93.2)	208 (93.6)
No	6 (5.7)	8 (6.8)	14 (6.3)
Public health center staff (n=22)			
3-day reminder was helpful			
Yes	11 (91.7)	10 (100)	21 (95.5)
No	0 (0)	0 (0)	0 (0)
Not sure or I do not know	1 (8.3)	0 (0)	1 (4.5)
Best time to send reminder			
1 week before the visit	0 (0)	2 (20)	2 (9.1)
3 days before the visit	7 (58.3)	5 (50)	12 (54.6)
2 days before the visit	2 (16.7)	1 (10)	3 (13.6)
1 day before the visit	3 (25)	0 (0)	3 (13.6)
Other	0 (0)	1 (10)	1 (4.6)
How many date and time appointments should be sent			
1	6 (50)	7 (70)	13 (59.1)
2	4 (33.3)	2 (20)	6 (27.3)
3	2 (16.7)	1 (10)	3 (13.6)

[a]Answered by all parents, not just those who received the 3-day reminder.

[b]One respondent did not specify their other response, and the other respondent specified that no reminders should be sent.

Web-Based Immunization Information

Survey Data

Approximately half (51/114, 44.7%) of the parents who received the 15-month reminder reported reading the web-based immunization information (Table 5). Most participants read this information in English (47/51, 92%), found it helpful to read in their language of choice (51/51, 100%), and felt more prepared for their child's appointment (50/51, 98%). The most common reason for not reading the information was already knowing the information (28/63, 44%). For parents who did not receive the 15-month reminder (108/222, 48.6%; data not shown), most reported that reading immunization information in their language of choice would be helpful (97/108, 89.8%) and that they would be more prepared for their child's appointment (81/108, 75%).

As shown in Table 5, some PHC staff reported that more clients read the immunization information sheets than usual (6/19, 32%), more clients engaged in conversation about vaccines (4/19, 21%), and more clients asked questions about vaccines (6/19, 31%). Others reported that they noticed no changes in clients reading the immunization information sheets (7/19, 37%), conversations about vaccines during the visit (8/19, 42%), or the efficiency of exchanging knowledge with clients during the visit (6/19, 31%).

Table 5. Evaluation of immunization information sheet use, among parents who reported receiving the 15-month reminder (n=114) and public health center staff (n=19).

Variable	Response, n (%)		
	Mill Woods	Lethbridge	Total
Parents			
Read web-based information about vaccines (n=114)			
Yes	31 (52.5)	20 (36.4)	51 (44.7)
No	28 (47.5)	35 (63.6)	63 (55.3)
Language or languages read (n=51)[a,b,c]			
English	29 (93.5)	18 (90)	47 (92.2)
Punjabi	6 (19.4)	1 (5)	7 (13.7)
Tagalog	2 (6.5)	0 (0)	2 (3.9)
Spanish	0 (0)	2 (10)	2 (3.9)
French	1 (3.2)	0 (0)	1 (2)
Helpful to read immunization information in language of choice (n=51)[a]			
Yes	31 (100)	20 (100)	51 (100)
No	0 (0)	0 (0)	0 (0)
After reading the immunization information, felt more prepared for child's appointment (n=51)[a]			
Yes	30 (96.8)	20 (100)	50 (98)
No	1 (3.2)	0 (0)	1 (2)
Reasons for not reading the web-based immunization information (n=63)[b,d]			
Already knew the information	11 (39.3)	17 (48.6)	28 (44.4)
Did not see a link to information in reminder	5 (17.9)	1 (2.9)	6 (9.5)
Too long	2 (7.1)	2 (5.7)	4 (6.3)
Forgot	2 (7.1)	1 (2.9)	3 (4.8)
Not enough time	0 (0)	3 (8.6)	3 (4.8)
Language of choice not available	1 (3.6)	1 (2.9)	2 (3.2)
Felt information was unnecessary, as had already decided to get child immunized	2 (7.1)	0 (0)	2 (3.2)
Felt doctors or nurses would provide the information	2 (7.1)	0 (0)	2 (3.2)
Had no concerns with immunization	0 (0)	2 (5.7)	2 (3.2)
Difficult to understand	0 (0)	1 (2.9)	1 (1.6)
Font too small on device screen	0 (0)	1 (2.9)	1 (1.6)
Did not specify	3 (10.7)	8 (22.9)	11 (17.5)
PHC[e] staff: nurses			
Impact of offering immunization information sheets in other languages (n=19)			
I did not notice any change	6 (50)	1 (10)	7 (36.8)
More clients read the information sheets than usual	4 (33.3)	2 (20)	6 (31.6)
Not sure or I do not know	2 (16.7)	2 (20)	4 (21.1)
Other	0 (0)	2 (20)	2 (10.5)
Impact of offering immunization information sheets in other languages on the conversation about vaccines during the visit (n=19)			
I did not notice any change	6 (50)	2 (20)	8 (42.1)
I noticed more clients engaging in the conversation than usual	4 (33.3)	0 (0)	4 (21.1)
Not sure or I do not know	2 (16.7)	5 (50)	7 (36.8)

Variable	Response, n (%)		
	Mill Woods	Lethbridge	Total
Impact of offering immunization information sheets in other languages on the efficiency of exchanging knowledge with clients during the visit (n=19)			
I do not think it changed anything	5 (41.7)	1 (10)	6 (31.2)
I noticed more clients asking questions about vaccines than usual	5 (41.7)	1 (10)	6 (31.2)
Not sure or I do not know	2 (16.7)	5 (50)	7 (36.8)
How to increase use of the immunization information sheets (n=22)[b,f]			
Provide the link to the website in the appointment reminder text (ie, the 3-day reminder)	9 (75)	8 (80)	17 (77.3)
Promote the website using posters or handouts in the health center	9 (75)	7 (70)	16 (72.7)
Have printed copies of the information sheets (in various languages) available at the health center	6 (50)	6 (60)	12 (54.5)
Other	0 (0)	1 (10)	1 (4.5)

[a]For parents who reported reading web-based immunization information (Mill Woods: n=31, Lethbridge: n=20).

[b]Respondents could select more than one option.

[c]Other potential language options included Arabic, Chinese, Italian, and Vietnamese; however, these options were not selected by any parent.

[d]For parents who reported that they did not read web-based immunization information (Mill Woods: n=28, Lethbridge: n=35).

[e]PHC: public health center.

[f]Question asked to all public health center staff (n=22).

Web-Based Access Data

According to Google Analytics, ChIRP web-based immunization information pages received 207 unique visits during the intervention period. Immunization information was most often read in English (118/207, 57%), followed by Punjabi (52/207, 25.1%), Arabic (13/207, 6.3%), Spanish (12/207, 5.8%), Italian (4/207, 1.9%), Chinese (4/207, 1.9%), French (2/207, 1%), Tagalog (1/207, 0.5%), and Vietnamese (1/207, 0.5%).

Discussion

This pilot intervention aimed to assess the effectiveness and acceptability of SMS text message reminders for preschool immunization appointments. Consistent with previous literature [19,27], our study suggests that SMS text message reminders can reduce appointment no-shows and are acceptable to parents and health service providers.

No-show Rates

There was a decline in absolute no-show rates at Mill Woods PHC, which corresponds with other studies [28,29] reporting that SMS text message reminders improved immunization appointment attendance. Lethbridge PHC did not exhibit a decline in no-shows; however, they had higher attendance before the intervention, likely because of preexisting strategies at that site (eg, manual reminders) as indicated by K Jong (personal communication, June 15, 2020), so perhaps the intervention had less impact.

SMS Text Message Reminders

Overall, parents reported high acceptability of the 15-month and 3-day message reminders, with almost all stating that they were helpful. Literature has shown that parents often prefer SMS text message reminders over mail or email because of the convenience and timeliness [27,30,31]. Jacobson Vann et al [3] found that SMS text message reminders increased the booking of immunization visits as they acted as a call to action for parents. In our study, a third of the surveyed parents reported booking or rescheduling their child's 18-month immunization appointment after receiving the 15-month reminder. It is possible that these parents may have missed the appointments had they not received a reminder [32]. However, most surveyed parents reported no action upon receiving the 15-month or 3-day reminders, which corresponds with the small changes in no-shows observed in this study. Overall, most parents reported that their child received their 18-month immunization as scheduled. Improvement in the timely receipt of childhood vaccines minimizes risks for vaccine-preventable diseases [30] and may reduce extra work to recall parents [33].

Most of the surveyed PHC staff stated that SMS text message reminders were helpful, indicating provider support for the intervention. This reflects the readiness to engage parents in positive discussions about childhood immunizations and encourage them to subscribe to reminder services [34]. In addition, most PHC staff reported that more clients came to their scheduled immunizations than usual during the intervention. Our no-show analysis revealed a significant improvement in appointment attendance at Mill Woods PHC following the intervention. PHC staff from both sites supported the expansion of this intervention to the 2-month and 12-month immunization programs.

Parents and PHC staff agreed that the best time to send appointment reminders was 3 days before the appointment but had different preferences for the booking (15-month) reminder, with staff preferring the reminder to be sent earlier. This difference in preferences is likely because of staff needing to

schedule in advance to accommodate many immunization appointments, whereas parents may not be thinking about the 18-month appointment until their child is 17 months old or may forget the appointment if the reminder is sent too early. Interestingly, the staff at Mill Woods PHC preferred the reminder to be sent earlier than the Lethbridge staff. This may reflect differences in the size of the 2 PHCs; Mill Woods serves a larger urban area and thus requires parents to book in advance, whereas Lethbridge serves a smaller urban population within a rural zone and may accommodate appointments on shorter notice.

Web-Based Immunization Information

The web-based immunization information in different languages was also positively received by parents. According to the Google Analytics data, many participants accessed the information in other languages. There is increasing awareness that language barriers impede immunization service delivery, but they continue to remain unaddressed in many existing reminder and recall systems [33]. Our study and previous work [35] have shown that parents favor language-specific immunization information.

Notably, the Google Analytics data showed a different picture of website activity than the parent survey. Specifically, Google Analytics showed more visits to the website (n=207) compared with the number of survey participants who reported accessing the information (n=51). As the link to the website was sent to all parents receiving the intervention, it is possible that nonsurvey participants accessed the information. In addition, Google Analytics showed more diversity in the languages accessed on the website (ie, more non-English users) compared with the parent survey. This may reflect the fact that English-speaking participants may have been more likely to complete the survey than participants whose first language was not English. The diverse languages accessed by parents suggest the need to provide appropriately translated immunization information.

Implications

Using SMS text message reminders for immunization appointments may be a convenient and cost-effective way of reducing appointment no-shows. The acceptability of the intervention by parents and PHC staff means that there is potential for SMS text message reminders to be implemented for other immunization programs, particularly 2-month and 12-month immunizations, as well as in other provinces. Future research should consider the use of experimental studies to evaluate the impact of SMS text message reminders on immunization coverage following widespread implementation.

To maximize the effectiveness of an SMS text message reminder system, it is important to make it appealing to both parents and PHC staff. For example, parents preferred later booking reminders than staff; therefore, perhaps sending both early and later reminders might be a useful compromise.

Strengths and Limitations

A strength of this study is the diverse perspectives obtained from both parents and PHC staff at 2 different sites in Alberta: one large urban site and one small urban site in a rural area. We were also able to assess the change in no-show rates at both clinics, using data over an extended time (ie, 1 year for both baseline and intervention), and in comparison with a control site for each. The limitations of this study include a low parent survey response rate (222/929, 23.9%), which may be because of the 7-month gap between recruitment and when links to the evaluation survey were sent out. It is possible that parents who responded to the survey differed from nonrespondents. For example, as the survey was conducted in English, non-English speakers were likely to be underrepresented. In addition, a lower proportion of survey respondents did not attend their child's 18-month immunization appointment compared with the calculated no-show rates at the 2 clinics, which means that our survey likely underrepresented no-shows. However, it is encouraging that the survey respondents had diverse sociodemographic characteristics, such as income. The number of surveyed PHC staff was also low, which may be explained by the increased strain on health care providers during the COVID-19 pandemic [36]. In addition, at the onset of the pandemic, reminders were paused for 1 month, while PHCs adapted to new ways of service delivery. In addition, we cannot definitively attribute the decline in no-show rates to the intervention. However, our comparison over time and between PHCs gives us some confidence. As more parents reported receiving the 3-day reminder compared with the 15-month reminder, it is possible that parents may have forgotten about the 15-month reminder, which was sent 4 months before the evaluation, compared with the 3-day reminder, sent 1 month prior. Finally, as the intervention and evaluation were only carried out at 2 PHCs in Alberta, the generalizability may be limited. However, this was a pilot study to determine acceptability, with the potential to carry out large-scale interventions and evaluations in the future.

Conclusions

This study found that parents and staff at the 2 PHCs were highly accepting of the SMS text message reminder system implemented to address the drop in coverage for 18-month immunizations. The intervention reduced the number of missed appointments at the urban intervention site. Findings support the use of SMS text message reminders as a convenient and acceptable method to minimize parental forgetfulness and potentially reduce appointment no-shows.

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Authors' Contributions

All authors attest that they met the International Committee of Medical Journal Editors criteria for authorship. SEM was involved in conceptualization, funding acquisition, investigation, formal analysis, writing (review and editing), and supervision. EM was involved in formal analysis and writing (original draft, review, and editing). HS was involved in formal analysis and writing (original draft, review, and editing). AA was involved in conceptualization, investigation, project administration, formal analysis, and writing (review and editing). AFW was involved in analytical design, statistical analysis, and writing (review and editing). All other authors assisted with conceptualization, methodology, and writing (review and editing).

Conflicts of Interest

KA is a cofounder and the chief operating officer of CANImmunize Inc. All other authors declare no conflicts of interest.

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Abbreviations

AHS: Alberta Health Services
ChIRP: Childhood Immunization Reminder Project
DTaP-IPV-Hib: diphtheria-tetanus-acellular pertussis-polio-Haemophilus influenzae type b
MMRV: measles-mumps-rubella-varicella
PHC: public health center
REDCap: Research Electronic Data Capture

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Review

Effectiveness of Mobile Medical Apps in Ensuring Medication Safety Among Patients With Chronic Diseases: Systematic Review and Meta-analysis

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Abstract

Background: Along with the rapid growth of the global aging society, the mobile and health digital market has expanded greatly. Countless mobile medical apps (mmApps) have sprung up in the internet market, aiming to help patients with chronic diseases achieve medication safety.

Objective: Based on the medication safety action plans proposed by the World Health Organization, we aimed to explore the effectiveness of mmApps in ensuring the medication safety of patients with chronic diseases, including whether mmApps can improve the willingness to report adverse drug events (ADEs), improve patients' medication adherence, and reduce medication errors. We hoped to verify our hypothesis through a systematic review and meta-analysis.

Methods: The meta-analysis was performed in strict accordance with the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines and included literature searched from 7 databases—PubMed, Web Of Science, Embase, CINAHL, China National Knowledge Infrastructure, Wanfang, and SinoMed. The publication time was limited to the time of database establishment to April 30, 2022. Studies were screened based on inclusion and exclusion criteria. The data extracted included authors, years of publication, countries or regions, participants' characteristics, intervention groups, and control groups, among others. Our quality assessment followed the guidelines of the *Cochrane Handbook for Systematic Reviews of Interventions, Version 6.3*. RevMan 5.2 software (Cochrane Collaboration) was used to analyze the statistical data, and a sensitivity analysis was performed to assess data stability. The degree of stability was calculated by using a different statistical method and excluding large-sample studies from the analysis.

Results: We included 8 studies from 5 countries (China, the United States, France, Canada, and Spain) that were published from January 1, 2014, to December 31, 2021. The total number of participants was 1355, and we analyzed the characteristics of included studies, each app's features, the risk of bias, and quality. The results showed that mmApps could increase ADE reporting willingness (relative risk [RR] 2.59, 95% CI 1.26-5.30; *P*=.009) and significantly improve medication adherence (RR 1.17, 95% CI 1.04-1.31; *P*=.007), but they had little effect on reducing medication errors (RR 1.54, 95% CI 0.33-7.29; *P*=.58).

Conclusions: We analyzed the following three merits of mmApps, with regard to facilitating the willingness to report ADEs: mmApps facilitate more communication between patients and physicians, patients attach more importance to ADE reporting, and the processing of results is transparent. The use of mmApps improved medication adherence among patients with chronic diseases by conveying medical solutions, providing educational support, tracking medications, and allowing for remote consultations. Finally, we found 3 potential reasons for why our medication error results differed from those of other studies.

Trial Registration: PROSPERO International Prospective Register of Systematic Reviews CRD42022322072; https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=322072

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KEYWORDS

mobile application; medication safety; systematic review; meta-analysis; mobile health; mHealth; health app; adherence; pharmaceutical; drug safety; medication error; drug error; review methodology; search strategy; eHealth; digital health; adverse event; adverse effect

Introduction

Medication safety has been a major concern of international organizations and government agencies. The World Health Organization (WHO) [1] selected medication safety as the theme for World Patient Safety Day 2022. *Medication safety* refers to ensuring that the right medications are used by the right patients in the right way. This topic was mentioned again after the WHO launched the "Third Global Patient Safety Challenge: Medication Without Harm" in 2017 [2], reflecting the extremely important role of medication safety in ensuring patient safety. According to the WHO [3], more than 60% of patients with chronic diseases in the world have long-term disease states and take multiple drugs. As such, medication safety has become a significant issue. If adverse drug events (ADEs) continue to occur, they will result in more than US $420 million in economic losses; increase disease burden and rehospitalization rates; and result in a series of adverse consequences, such as disability, fainting, and even death [4,5]. Studies have shown that approximately 80% of medication errors are preventable [3]. In order to ensure medication safety, the WHO proposed the following specific action plans [6]: (1) engaging patients and families in reporting ADEs, (2) improving patients' medication adherence, and (3) reducing medication errors. Therefore, this study was guided by the WHO's medication safety action plans and explored how to ensure patient safety in terms of the above three action plans.

In recent years, along with the rapid growth of the global aging society, the mobile and health digital market has greatly expanded. Countless mobile medical apps (mmApps) have sprung up in the internet market, aiming to help patients with chronic diseases achieve medication safety. By the end of 2020, around 3.25 million mmApps were downloaded from common app stores (ie, the Android and Apple app stores)—a full 50% increase from 10 years ago [7]. These mmApps were invented and created with the help of big data and 5G technology, and they have functions such as medication reminders, self-diagnosis functions, ADE reporting functions, information acquisition and consultation functions, and wellness management functions [8]. However, most scholars mainly focus on the role of mmApps in improving medication adherence [9-11], thus ignoring their equally important role in ADE reporting and medication error reduction.

We hypothesized that mmApps could effectively guarantee medication safety by facilitating the reporting of ADEs, improving medication adherence, and reducing medication errors, and we validated our hypothesis through a systematic review and meta-analysis.

Methods

Study Protocol and Registration

The systematic review and meta-analysis were conducted by following the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines [12], and our study was registered in PROSPERO (an international database of prospectively registered systematic reviews; registration number: CRD42022322072) on April 2022.

Search Strategy

We conducted a systematic search of PubMed, Web Of Science, Embase, CINAHL, China National Knowledge Infrastructure, Wanfang (a traditional Chinese literature database), and SinoMed (a Chinese biomedical database). The publication time was limited to the time of database establishment to April 30, 2022. The publication language was restricted to Chinese and English. We conducted the search by using a combination of keywords and MeSH (Medical Subject Headings) terms. For example, our search strategy for PubMed involved using the following search string: "(((medication errors OR look-alike sound-alike medication errors OR high-alert drug error OR drug use error*) OR (medication adherence OR drug adherence OR medication persistence OR medication compliance OR drug compliance)) OR (adverse drug event* OR ADE OR drug related side effects AND adverse reaction* OR drug side effects OR adverse drug reaction* OR side effects of drugs OR drug toxicity)) AND (mobile application* OR mobile App* OR portable software App*OR smartphone Apps OR portable electronic Apps OR portable electronic application)." More research details are provided in Multimedia Appendix 1.

Inclusion and Exclusion Criteria

The inclusion criteria were as follows: (1) age≥18 years, (2) at least one chronic disease, (3) an intervention group that used mmApps and a control group that underwent usual care (ie, without using mmApps), and (4) clinical trials.

The exclusion criteria were as follows: (1) the presence of confounding factors in randomized controlled trials, such as mixed methods (a combination of qualitative and quantitative methods); (2) the experimental procedures are not clear and transparent (eg, the intervention procedures or results are not clearly expressed); and (3) duplicate publications and publications for which we were unable to contact the authors.

Data Extraction

We created a Microsoft Excel spreadsheet to extract key information from the included studies, including authors, years of publication, countries or regions, participants' characteristics, intervention groups, control groups, names of apps, functions

of apps, intervention durations, outcomes, and measurement tools.

Participants

The studies involved participants (aged ≥18 years) with a chronic disease, including hypertension, diabetes, coronary heart disease, arthritis, and other single chronic diseases. However, studies that involved patients with multiple coexisting chronic diseases were also included.

Intervention

Owing to different intervention measures, participants were divided into control groups and intervention groups. Control groups underwent usual care, such as keeping a medication diary, attending regular follow-up visits, and attending medication safety lectures. Intervention groups used mmApps in addition to undergoing the usual care provided to control groups. These mmApps included, but were not limited to, smartphone mmApps, iPad (Apple Inc) mmApps, and WeChat (Tencent Holdings Limited) mini-programs.

Outcome Measures

In terms of medication safety outcomes, we focused on medication adherence, which was calculated by examining medication doses and frequencies in patients with chronic diseases to verify whether they matched physicians' prescriptions. Another important outcome was the rate of ADE reporting, which depended on whether patients reported the occurrence of ADEs. The third outcome was medication errors. Despite using mmApps, there was still the possibility of medication errors; taking the wrong pill or the wrong dose, giving medications to the wrong patient, and taking medications in the wrong manner or at the wrong time were considered medication errors.

Quality Assessment

The literature quality assessment was based on 7 criteria from the *Cochrane Handbook for Systematic Reviews of Interventions, Version 6.3*, which was updated by the Cochrane Collaboration in 2022 [13]. The reviewers made a separate judgment for each item (ie, low risk of bias, high risk of bias, or unclear risk of bias). If a study fully met these criteria, the likelihood of various biases was low, and the quality grade was "A." If these criteria were partially met, the probability of bias was moderate, and the quality grade was "B." If these criteria were not met at all, the probability of bias was high, and the quality grade was "C." Two investigators with evidence-based training were invited to simultaneously evaluate the quality of the included literature, and a third investigator was consulted when disagreements occurred. Articles with an overall quality level of A or B were included, and articles with an overall quality level of C were excluded.

Statistical Analysis

RevMan 5.2 software (Cochrane Collaboration) was used to analyze the data. Weighted mean differences were used to analyze the effect sizes of continuous variables, and relative risk (RR) was used to analyze the effect sizes of dichotomous variables. Further, 95% CIs were used to represent the sizes of combined effects. Additionally, heterogeneity was tested. If I^2 was <50%, the homogeneity was considered to be good, and a fixed effect model was used for the analysis. If I^2 was >50%, the heterogeneity was considered to be large, and a random effect model was used for the analysis. Heterogeneity was explained in terms of clinical and methodological heterogeneity, and a subgroup analysis was performed, if necessary.

Sensitivity Analysis

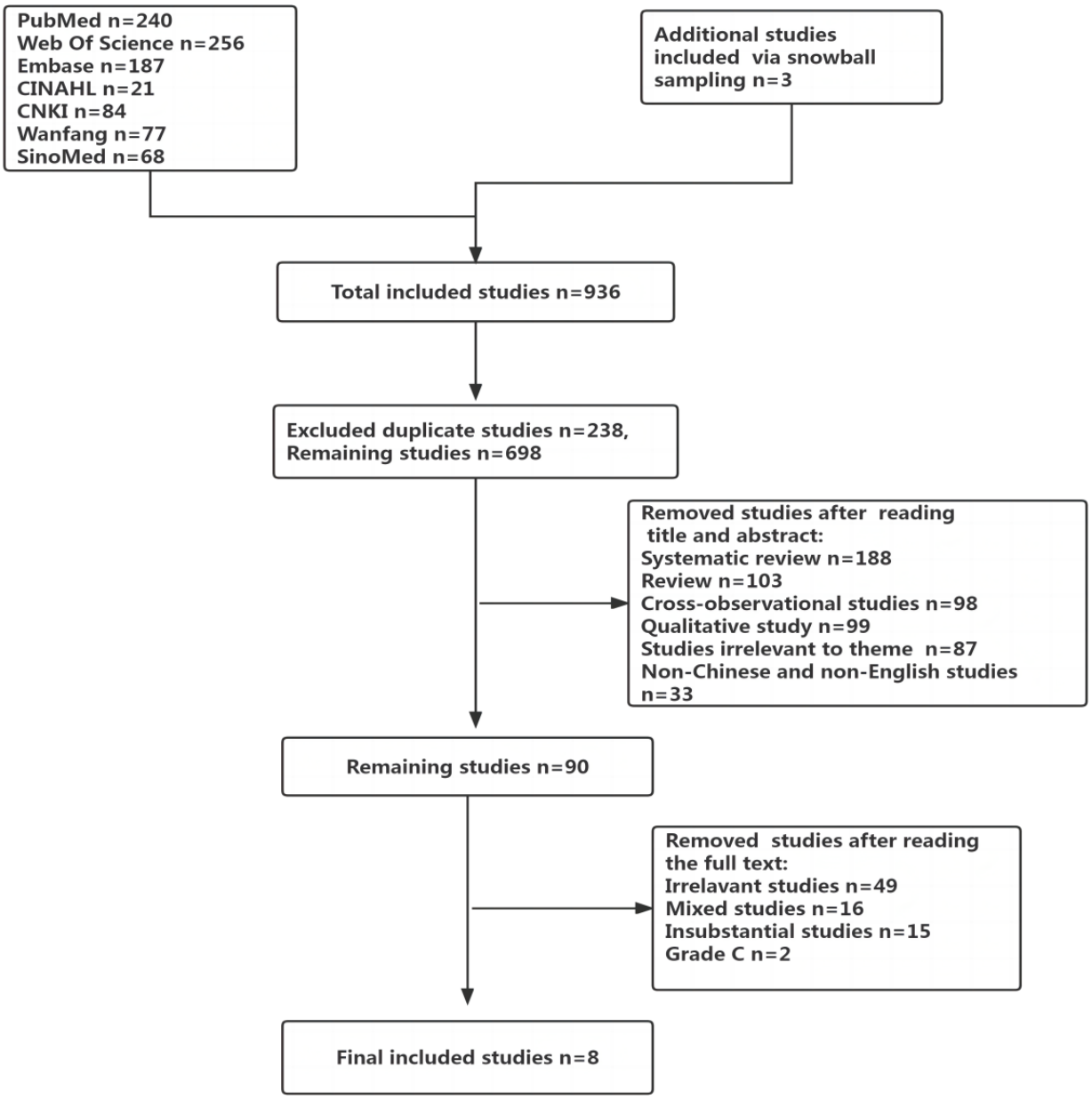
A sensitivity analysis was performed to assess data stability. The degree of stability was calculated by using a different statistical method and excluding large-sample studies from the analysis, so as to verify whether our results were robust and reliable.

Results

Identified and Included Studies

We searched 7 databases and obtained 936 articles. The first step was to exclude duplicate articles via NoteExpress software (AegeanSoftware Corp), which left us with 698 articles. In the second step, studies were excluded by screening titles and abstracts, which left us with 90 articles. In the third step, studies were excluded by carefully screening the full text of articles. Finally, we included 8 articles. The retrieval and selection process is shown in Figure 1.

Figure 1. Flow diagram of the study retrieval and selection process.



Characteristics of Included Studies

There were 1355 participants in the 8 studies, which were from 5 countries (China, the United States, France, Canada, and Spain). The publication times ranged from January 1, 2014, to December 31, 2021. The median sample size was 169 (range 61-268), and the following chronic diseases were included in the studies: pulmonary tuberculosis [14], renal cancer or prostate cancer [15], influenza [16], multiple sclerosis [17], oral cancer [18], and multiple chronic diseases [19-21]. The median intervention duration was 6 (range 1-25) months. The intervention groups used mmApps, and the control groups underwent usual care (ie, they did not use mmApps). As for the outcomes, 3 studies reported ADEs [16,17,19], 4 studies measured medication adherence [14,15,18,20], and 4 studies calculated the frequency of medication errors [15,17,20,21]. Further details are shown in Table 1.

Table 1. Detailed information of included studies.

Authors and year	Country	Participants	Sample size	Names of apps	App functions	Intervention vs control	Duration	Outcomes
Mira et al [20], 2014	Spain	Older patients taking multiple medications	N=99 (CG[a]: n=48; IG[b]: n=51)	ALICE	Providing prescriptions and medical advice, showing medication images, and sending multiple reminders	mmApp[c] vs UC[d]	3 months	Medication errors (CG: n=5, 10.4%; IG: n=8, 15.7%) and medication adherence (MMAS-4[e])
Mira et al [21], 2015	Spain	Older patients with multiple chronic diseases	N=61 (CG: n=30; IG: n=31)	TUMEDICIN	Providing information on the purpose of a given medicine, daily doses, possible adverse effects, and main cautions	mmApp vs UC	3 months	Medication errors (CG: n=13, 43.3%; IG: n=6, 19.4%)
Wei et al [14], 2019	China	Patients with pulmonary tuberculosis	N=300 (CG: n=l40; IG: n=160)	E-monitor Box and WeChat (Tencent Holdings Limited)	Monitoring patients' adherence history and outpatient visits, reporting ADEs[f], and reminding patients to take their medications	mmApp vs UC	6 months	High medication adherence (CG: n=101, 72.1%; IG: n=96, 60%)
Agboola et al [15], 2014	United States	Patients with renal cancer or prostate cancer	N=150 (CG: n=76; IG: n=74)	CORA[g]	Providing coaching for self-efficacy in self-care and reporting and managing symptoms	mmApp vs UC	3 months	Medication errors (CG: n=23, 30.3%; IG: n=14, 18.9%) and medication adherence (MMAS-8[h])
Wilson et al [16], 2016	Canada	Patients reporting adverse events after influenza vaccination	N=152 (CG: n=76; IG: n=76)	CANVAS	Reporting ADEs spontaneously and evaluating user experience	mmApp vs UC	1 month	ADE reporting cases (CG: n=15, 19.7%; IG: n=35, 46.1%)
Montastruc et al [19], 2018	France	Patients with chronic diseases	N=268 (CG: n=133; IG: n=135)	VigiBIP	Providing spontaneous reports of pharmacy vigilance and drug safety information	mmApp vs UC	25 months	ADE reporting cases (CG: n=59, 44.4%; IG: n=94, 69.6%)
Defer et al [17], 2021	France	Patients with multiple sclerosis	N=159 (CG: n=68; IG: n=91)	My eReport	Not mentioned	mmApp vs UC	6 months	ADE reporting cases (CG: n=5, 7.4%; IG: n=43, 47.3%) and medication error cases (CG: n=3, 0.4%; IG: n=64, 70.3%)
Greer et al [18], 2020	United States	Patients undergoing oral cancer therapy	N=166 (CG: n=86; IG: n=80)	Smartphone mobile app	Medication plans with reminders, a symptom reporting module, and patient education	mmApp vs UC	3 months	High medication adherence cases (CG: n=66, 76.7%; IG: n=69, 86.3%)

[a]CG: control group.

[b]IG: intervention group.

[c]mmApp: mobile medical app.

[d]UC: usual care (ie, did not use a mobile medical app).

[e]MMAS-4: Morisky Medication Adherence Scale-4 item.

[f]ADE: adverse drug event.

[g]CORA: Chemotherapy Assistant.

[h]MMAS-8: Morisky Medication Adherence Scale-8 item.

Features of Apps in Included Studies

In all 8 studies, the intervention groups used mmApps, and each app had its own characteristics. Mira et al [20,21] focused on the impact of mmApps on medication self-management among patients with chronic diseases. They invented an app called "ALICE" in 2014, which could provide prescriptions and medical advice, display medication images, and send multiple reminders. In 2015, the mmApp was improved and optimized by adding QR code scanning functions and renamed as "TUMEDICIN." The app could scan QR codes on medical products and provide information, including information on the purpose of a medication, daily doses, possible adverse effects, and main precautions.

Wei et al [14] implemented an electronic monitoring intervention based on WeChat (a local social software that has achieved large-scale population coverage) that could be used to monitor patient adherence and outpatient clinic visits, report adverse drug reactions, and remind people to take their medicine. US scholars mainly concentrated on medication safety for patients undergoing cancer treatment. Agboola et al [15] developed Chemotherapy Assistant (CORA) to help patients with renal cancer or prostate cancer report and manage their symptoms by improving their self-efficacy. Greer et al [18] used a smartphone mobile app to execute medication plans, and the app included reminders, a symptom reporting function, and patient education.

Wilson et al [16] and Montastruc et al [19] showed great interest in the reporting of ADEs and independently developed CANVAS (an app for automatically reporting ADEs and evaluating user experience) and VigiBIP (an app for spontaneously reporting pharmacy vigilance and drug safety information), respectively. All of the mmApps reported in this study were developed based on real-time communication technology and intelligent automatic identification technology, which simplifies complex clinical practices and provides convenience for medical staff.

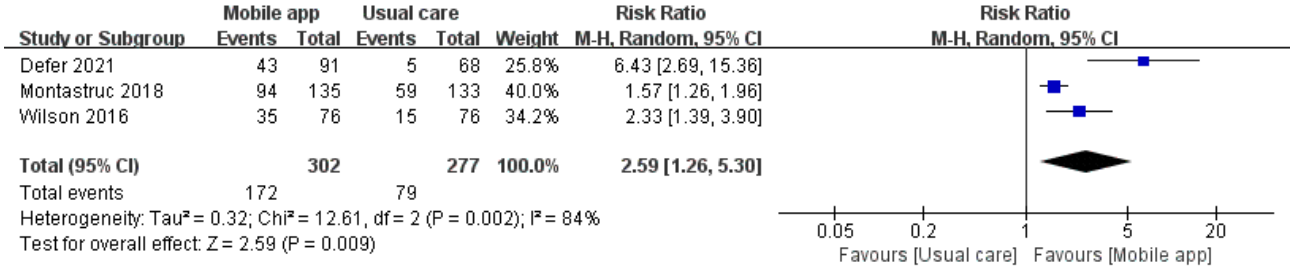
Meta-analysis of Intervention Efficacy

mmApps Facilitated ADE Reporting

In the Defer et al [17] study, participants reported adverse drug reactions with My eReport, through which they submitted their basic information (name, age, weight, gender, and medical history), medication information (drug name, method, dose, and date of taking medication), and adverse reactions (descriptions of the start of the reaction, processes for managing the reaction, outcomes of the reaction, and information on how users felt after the reaction). Montastruc et al [19] studied spontaneous adverse drug reaction reports that were received through VigiBIP, a free smartphone app for reporting adverse drug reactions and requesting drug safety information. Wilson et al [16] provided a mechanism for automatically reporting ADEs. All of their findings were recorded on a private cloud server. Paying more attention to pharmacovigilance can help prevent ADEs from happening again.

In total, 3 studies compared the effects of mmApps and usual care on the reporting of ADEs. A total of 579 patients were included. These studies had large heterogeneity, and we used a random effect model to analyze their results. Our results showed that mmApps had a statistically significant effect on ADE reporting (RR 2.59, 95% CI 1.26-5.30; *P*=.009; Figure 2).

Figure 2. Forest plot of the effects of mobile apps and usual care on adverse drug event reporting [16,17,19]. M-H: Mantel-Haenszel.

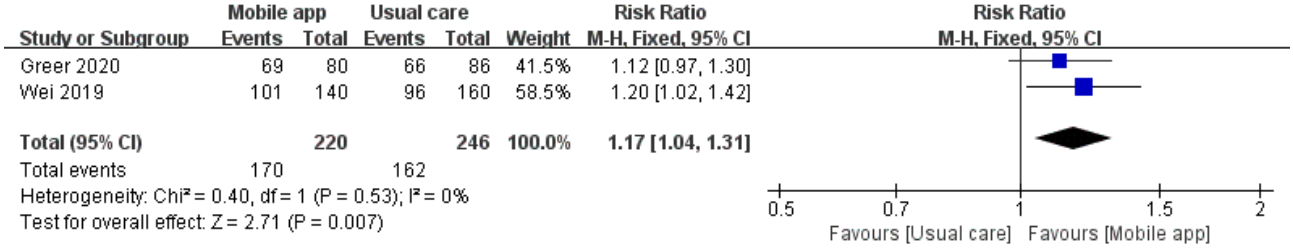


mmApps Improved Medication Adherence

There were 4 studies in which the outcome was medication adherence, but only 2 of these studies were included in the meta-analysis. The other two studies were excluded due to the large heterogeneity in the measurement tools used for assessing medication adherence (one study tool was the Morisky Medication Adherence Scale [MMAS]-4 item [20], and the other was the MMAS-8 item [15]). So far, the most popular measurement tool for assessing medication adherence is the MMAS [22], which is a self-reported medication adherence scale that was first proposed by Morisky et al [22] in 1986. After more than 20 years of development, it has been revised from the original 4-item scale to the 8-item scale that most people use now. However, the MMAS is susceptible to the influence of patients' memory bias; with the increase of age, memory declines, and the reliability of the MMAS decreases. Further, different measurement tools may have different impacts on the results of medication adherence. As such, we decided to include the Greer et al [18] and Wei et al [14] studies, as they assessed the same outcome and used the same measurement tools.

A total of 2 studies compared the effects of mmApps and usual care on medication adherence. A total of 466 patients were included. The heterogeneity was small, and we used a fixed effect model to analyze their results. Our results showed that mmApps had a statistically significant effect on medication adherence (RR 1.17, 95% CI 1.04-1.31; *P*=.007; Figure 3).

Figure 3. Forest plot of the effects of mobile apps and usual care on medication adherence [14,18]. M-H: Mantel-Haenszel.

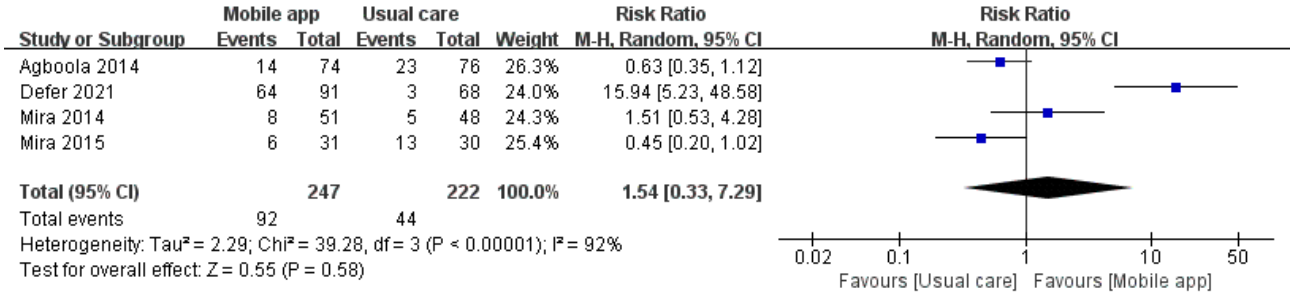


mmApps Scarcely Prevented Medication Errors

Agboola et al [15] and Defer et al [17] developed CORA and My eReport, respectively, which were personalized, mobile phone–based self-management apps for helping patients with renal cancer or prostate cancer on oral anticancer medications. These apps could reduce medication errors though health education (ie, they increased patients' understanding of medications, drug side effects, safe storage, best practices, and home security for antitumor drugs), psychological support, the early reporting of symptoms, and disease management. Mira et al [20,21] ensured and promoted safer medications for older patients via the use of QR and European Article Number-13 codes. Their results showed that 13 of the 30 (43%) patients in the control group experienced at least one medication error within 1 year, while 6 of the 31 (19%) patients in the intervention group experienced medication errors. Of the 6 medication error cases, 2 were the result of confusion related to incorrect medications, 1 was related to side effects resulting from drug mixing, 2 were related to taking medications at incorrect times, and 1 was related to taking a higher than prescribed medication dose.

In total, 4 studies compared the effects of mmApps and usual care on medication errors. A total of 469 patients were included. These studies had large heterogeneity, and we used a random effect model to analyze their results. Our results showed that mmApps did not have a statistically significant effect on medication errors (RR 1.54, 95% CI 0.33-7.29; *P*=.58; Figure 4).

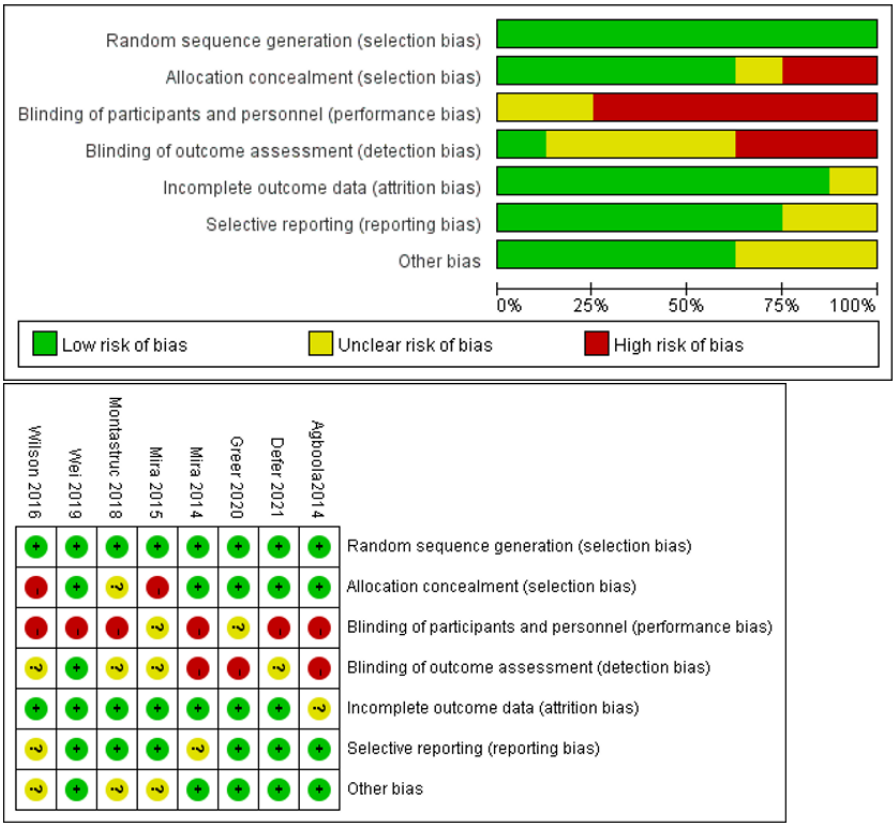
Figure 4. Forest plot of the effects of mobile apps and usual care on medication errors [15,17,20,21]. M-H: Mantel-Haenszel.



Risk of Bias and Quality Assessment

All 8 articles reported adequate random sequence generation and thus had a low risk of bias in this regard. Further, 5 studies reported allocation concealment, so the risk of bias was low in this regard, and 2 studies did not mention concealment and were rated as having a high risk of bias in this regard. As for performance bias, 6 studies were not blinded, so they were rated as having a high risk of bias, and the presence of blinding in the other two studies was unclear. Most of the studies (7/8, 88%) reported results and follow-ups, so the risk of attrition bias was low. With regard to reporting bias, 2 studies had an unclear risk of bias because they did not clearly express participant characteristics, and the other studies had a low risk of bias. In summary, all 8 studies partially met the quality criteria, and their quality grade was "B." Therefore, they were all included in this study. The specific risk of bias and quality evaluation results are shown in Figure 5.

Figure 5. Risk of bias summary for each included study [14-21].



Sensitivity Analysis

To explore the stability and the degree of stability of our study's results, we used a different statistical method to analyze the results. It was found that after changing the statistical method for analyzing different outcome indicators, there were no differences in ADE reporting and medication adherence results, indicating low sensitivity and robust and reliable results, as shown in Table 2.

As for medication error results, our original results (RR 1.54, 95% CI 0.33-7.29; *P*=.58) changed when we removed large-sample studies (RR 0.69, 95% CI 0.38-1.24; *P*=.21) [17]. The results did not change substantially, indicating low sensitivity and robust and reliable results.

Table 2. Sensitivity analysis of different outcome indicators.

Models	Relative risk (95% CI)	*Z* value	*P* value
Adverse drug event reporting			
Random effect model	2.59 (1.26-5.30)	2.59	.009
Fixed effect model	2.06 (1.67-2.53)	6.83	＜.001
Medication adherence			
Random effect model	1.16 (1.04-1.29)	2.65	.008
Fixed effect model	1.17 (1.04-1.31)	2.71	.007
Medication errors			
Model that retained large-sample studies	1.54 (0.33-7.29)	0.55	.58
Model that did not retain large-sample studies	0.69 (0.38-1.24)	1.25	.21

Discussion

Principal Findings

The results of our study verify our hypothesis—mmApps can effectively improve patients' ADE reporting willingness (RR 2.59, 95% CI 1.26-5.30; *P*=.009). This is a brand new result that has not been reported by others. Reporting ADEs and near-miss events was considered an important measure for ensuring medication safety, and information about these events is valuable and can be used to prevent ADEs. The Organization for Economic Co-operation and Development [23] recommends that patients should report ADEs, as ADE reporting does not require enormous financial costs and human resources. Further, ADE reporting is excellent in terms of its value; if done well, ADE reporting can reduce the incidence of harm by 15% and

decrease economical burdens, thereby saving millions of dollars each year [24]. mmApps have some merits with regard to increasing ADE reporting willingness. First, they facilitate more communication between physicians and patients [25]. Patients ask physicians for help when they encounter professional terms and confusing problems. Second, patients attach more importance to ADE reporting. Medical staff encourage patients to participate in ADE reporting, and as a result, patients generally realize that their medication safety is considered a top priority. Third, the processing of results is transparent [26]. Patients can use mmApps to obtain feedback about submissions regarding conditions, such as whether a submission is successful and how many people submit the same questions. Additionally, it is convenient for patients to be able to browse through an app to see results as they are processed. We hope to explore more functions that help increase the ADE reporting rate among patients, such as measures for improving patients' enthusiasm through spiritual encouragement and material reward.

Our study results showed that mmApps can improve medication adherence (RR 1.17, 95% CI 1.04-1.31; *P*=.007). This may be because mmApps reminded patients to take their medicine regularly, provided educational support, and recorded patient histories To some degree, mmApps also strengthened self-effectiveness among patients with chronic diseases and improved quality of life. Degenerative memory, polypharmacy, and comorbidities are common among patients with chronic diseases. As such, they are at high risk of medication nonadherence, and it is not easy to improve medication adherence in this population. Fortunately, we can convey medical solutions through wireless mobile networks, track medications, and even conduct remote consultations with the help of mmApps. Intelligent mmApps empower patients and facilitate self-management at home and abroad. As an auxiliary to physician intervention, mmApps encourage more patients to participate in medical decision-making, thereby improving their disease control capabilities [7]. Further, mmApps are affordable and convenient technologies that rely on existing mobile networks to remotely monitor patients who are difficult to contact or require strict monitoring. Such apps also have the potential to improve the control of risk factors and health conditions. They especially work well for patients with chronic diseases, such as arterial hypertension [27], diabetes [28], and heart failure [29].

Our meta-analysis showed that mmApps had no significant effect on reducing medication errors (RR 0.41, 95% CI 0.13-1.33; *P*=.58). This finding is different from those of other studies. For example, Baumann et al [30] validated a mobile app that was an appropriate and feasible tool for reducing simple calculation and handling errors in drug administration. Moreover, Siebert et al [31] studied a mobile app that reduced prehospital medication errors by providing simulated pediatric resuscitation education. As for our different results, we thought of the following reasons. First, it is possible that patients were not able to identify medication error types well, resulting in the capture of only a small sample medication errors. Second, the studied mmApps may have been limited in terms of their functionality (eg, a lack of accurate identification functions). For instance, an app that scans barcodes on medicine bottle labels is only useful if a patient uses it before taking the medication. Additionally, such apps only provide specific patient and medication information, and they cannot be used to determine whether a medicine bottle has been opened. However, such apps can reduce medication errors by 54% to 87% if a medicine bottle barcode is available and if patients use these apps properly [21]. The third reason is that mmApps have not yet formed a comprehensive and timely information dissemination network and do not fully cover all chronic diseases, resulting in unequal medical information transmission and the easy omission of medication error cases [32]. Although our research showed that mmApps cannot reduce the incidence of medication errors directly, they can be used to achieve medication safety by reminding patients to take their medications regularly and providing health information. Therefore, to some extent, mobile apps can reduce medication errors indirectly. So far, there is no consensus on whether mmApps reduce medication errors. As such, more and higher-level studies are needed to verify their effects on medication errors in the future.

Limitations

There may be some limitations to this study. First, with respect to the quality assessment, the quality of the included articles was low, and the overall strength of the evidence was moderate. Second, most studies (5/8, 63%) lacked randomization and double-blinding. As such, stricter inclusion criteria and more rigorous randomized controlled trial studies should be considered in the future. Third, the intervention durations were inconsistent. The shortest study was only conducted for 1 month, which could have had an impact on the results. We hoped that the duration of intervention in the included studies would be at least 6 months. Finally, we did not perform a cost-benefit analysis of mmApps, which is important for helping patients decide whether to use an mmApp. Therefore, we plan to do more research on mmApps' economic and time costs.

Conclusion

A total of 8 articles were included in this study. We focused on the effects of mmApps on medication safety, and our results showed that mmApps could increase ADE reporting willingness (*P*=.009) and significantly improve medication adherence (*P*=.007) but had little effect on reducing medication errors (*P*=.58). We analyzed several merits of mmApps, with regard to facilitating the willingness to report ADEs; acquired data on how mmApps improved medication adherence among patients with chronic diseases; and found 3 potential reasons for why our medication error results differed from those of other studies.

Acknowledgments

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Data Availability

The data are openly available in a public repository.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Search strategy for the literature databases.
[DOCX File , 22 KB - mhealth_v10i11e39819_app1.docx]

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Abbreviations

ADE: adverse drug event
CORA: Chemotherapy Assistant
MeSH: Medical Subject Headings
mmApp: mobile medical app
MMAS: Morisky Medication Adherence Scale
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RR: relative risk
WHO: World Health Organization

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Original Paper

Wearable Activity Tracker Use and Physical Activity Among Informal Caregivers in the United States: Quantitative Study

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Abstract

Background: With an increase in aging population and chronic medical conditions in the United States, the role of informal caregivers has become paramount as they engage in the care of their loved ones. Mounting evidence suggests that such responsibilities place substantial burden on informal caregivers and can negatively impact their health. New wearable health and activity trackers (wearables) are increasingly being used to facilitate and monitor healthy behaviors and to improve health outcomes. Although prior studies have examined the efficacy of wearables in improving health and well-being in the general population, little is known about their benefits among informal caregivers.

Objective: This study aimed to examine the association between use of wearables and levels of physical activity (PA) among informal caregivers in the United States.

Methods: We used data from the National Cancer Institute's Health Information National Trends Survey 5 (cycle 3, 2019 and cycle 4, 2020) for a nationally representative sample of 1273 community-dwelling informal caregivers—aged ≥18 years, 60% (757/1273) female, 75.7% (990/1273) had some college or more in education, and 67.3% (885/1273) had ≥1 chronic medical condition—in the United States. Using jackknife replicate weights, a multivariable logistic regression was fit to assess an independent association between the use of wearables and a binary outcome: meeting or not meeting the current World Health Organization's recommendation of PA for adults (≥150 minutes of at least moderate-intensity PA per week).

Results: More than one-third (466/1273, 37.8%) of the informal caregivers met the recommendations for adult PA. However, those who reported using wearables (390/1273, 31.7%) had slightly higher odds of meeting PA recommendations (adjusted odds ratios 1.1, 95% CI 1.04-1.77; *P*=.04) compared with those who did not use wearables.

Conclusions: The results demonstrated a positive association between the use of wearables and levels of PA among informal caregivers in the United States. Therefore, efforts to incorporate wearable technology into the development of health-promoting programs or interventions for informal caregivers could potentially improve their health and well-being. However, any such effort should address the disparities in access to innovative digital technologies, including wearables, to promote health equity. Future longitudinal studies are required to further support the current findings of this study.

(JMIR Mhealth Uhealth 2022;10(11):e40391) doi:10.2196/40391

KEYWORDS

informal caregivers; caregiving; health and activity trackers; wearables; physical activity; health-promoting behavior; mobile phone

Introduction

With a rapidly aging global population, the number of people living with chronic medical conditions (CCs) is increasing. The role of caregivers for this population, including informal caregivers, has become critical as they get involved in the delivery of care and provision of support to patients inside or outside formal health care settings [1]. Evidence suggests that informal caregivers may encounter challenges in providing care, which often requires considerable time and effort. This caregiving burden may result in poorer health outcomes among the caregivers [2,3]. Those caring for patients with Alzheimer disease, other dementias, and cancer are more likely to experience additional burden or distress associated with the caregiving, leading to even worse health outcomes, including depressive symptoms, lower rates of physical inactivity, poorer diet, and insufficient sleep [1,4,5].

Physical activity (PA) is one of the essential components of maintaining good health [6]. PA refers to any body movement or activity generated by skeletal muscles that uses energy, comprising both aerobic exercise and muscle-strengthening activities [7]. The benefits of PA are extensive, including disease prevention, symptom reduction, improved mental health and cognition, and improved quality of life [8-11]. Adults who engage in both aerobic and muscle-strengthening activities, as recommended by national and international PA guidelines, have a 21% to 40% lower risk for all-cause mortality and lower cause-specific cardiovascular mortality [12,13]. Muscle-strengthening activities promote physical and social functioning, reduce body pain, and improve mental and general health status while negating some of effects of CCs and other illnesses [10,11,14]. Despite the importance of PA in maintaining good health [15], a relatively small percentage of people in the United States regularly work out or engage in PA. In 2018, for instance, only 23.2% of the population in the United States met both the recommended levels of aerobic and muscle-strengthening activities [16]. These figures are concerning given that a lack of PA can lead to acute or chronic disease and reduced longevity [17,18]. A systematic review by Reiner et al [18] explored the long-term relationship between PA and selected chronic conditions or diseases (including obesity, type 2 diabetes, Alzheimer disease or dementia, and coronary heart disease) and found that PA appears to be associated with reduced risk for, or preventing, most age-related diseases. On the basis of existing literature, Brown et al [17] examined the effects of PA on healthy brain aging and found that PA can contribute to maintaining improved cognition.

Information and communication technologies—including smartphones and electronic health and activity trackers (henceforth, wearables)—are increasingly being used as tools to facilitate the delivery of care and help improve health outcomes among patients and caregivers. The number of wearable users, as well as willingness to wear these technologies, has substantially grown in recent years both in the United States and worldwide. As of 2022, there are approximately 67 million adult wearable users in the United States, a figure that has increased by almost 42 million users since 2014 [19]. About 21% of adults in the United States (aged ≥18 years) report regularly wearing a smart watch or a wearable fitness tracker, and 53% of adults in the United States show willingness to wear technology that tracks their vital signs and their lifestyle or fitness levels [20,21]. These devices can be used to collect data on PA such as the number of steps taken, calories burned, and heart rate [22,23]. Other sophisticated wearable technology can collect information on blood pressure, glucose levels, blood oxygen saturation, and duration or quality of sleep [23]. Wearables that are embedded in the body or worn as accessories in health care are being increasingly used for monitoring and assessing health [22,24,25]. These tools function by wirelessly sending and receiving various physiological and other health information in an efficient way [26,27]. Mounting evidence suggests the benefits of wearable devices for tracking and monitoring health as safe and cost-effective tools to promote health behavior change such as enhancing PA [28]. Furthermore, the data-generating capabilities of wearables provide substantial value to the users in their health management [29]. In medical settings and patient treatment, incorporating and using wearable data in the health care decision-making process has shown great potential in patient monitoring and enhanced planning and intervention by providing timely feedback [25,29].

Despite numerous studies focused on developing and evaluating wearable devices designed to improve care delivery and health outcomes in the general population [30-32], little is known about how wearable devices impact caregivers, particularly informal caregivers. To our knowledge, no study dealing with this issue has been conducted thus far on a national sample of informal caregivers in the United States. This study examined the association between the use of wearables and PA levels among informal caregivers in the United States. We hypothesize that informal caregivers who use wearables are more likely to be engaged in PA and meet the current World Health Organization (WHO) recommendations of weekly PA of at least moderate intensity compared with informal caregivers who do not use these devices.

Methods

Data, Settings, and the Study Sample

For this study, we used data from the Health Information National Trends Survey (HINTS), a nationally representative, cross-sectional, probability-based survey conducted by the United States National Cancer Institute every few years since 2003 [33]. The HINTS, focusing on civilian noninstitutionalized adults aged ≥18 years, compiles information on access to, use of, and needs for health-related information, perceptions, knowledge, and behaviors. However, this survey is not a cancer-specific survey per se [34,35]. More recently, HINTS began collecting information on wearables use as well. We specifically used data from HINTS 5 cycles 3 (2019) and 4 (2020) because these 2 recent cycles of data contain information on wearables use. All 4 cycles of HINTS 5 involved self-administered mailed questionnaires [36] except for cycle 3, which involved a multimode survey that, in addition to the mail-in surveys, incorporated 2 experimental conditions of a web pilot. All mail-in surveys in cycle 3 and all groups in the multimode survey in cycle 4 received a US $2 prepaid monetary

incentive to encourage participation; they received an additional US $10 Amazon e-gift card for participating in the second web pilot experimental (Web Bonus) survey in cycle 4.

HINTS 5 cycle 3 data collection began in January 2019 and concluded in April 2019 with an overall response rate of 30.3%. HINTS 5 cycle 4 was fielded between February 2020 and June 2020 with a response rate of 36.7%. The combined HINTS 5 cycles 3 and 4 resulted in an initial unweighted sample of 9303 adults aged ≥18 years. However, our analytical sample included 1273 self-identified informal caregivers. The informal caregiver status was assigned based on participant response to the following two survey questions: "Are you currently caring for or making health care decisions for someone with a medical, behavioral, disability, or other condition?" and "Do you provide any of this care professionally as part of a job (for example, as a nurse or professional home health aide)?"

PA and Electronic Activity Trackers

The primary outcome of interest in this study was a binary measure indicating whether the informal caregivers were meeting the current WHO recommendations of moderate PA for adults (ie, ≥150 minutes of at least moderate-intensity PA per week) [15]. The measure was derived from a composite of combined participant responses to 2 questions in the HINTS survey. The participants were asked, "In a typical week, how many days do you do any PA or exercise of at least moderate intensity?" They were then asked, "On the days that you do any PA or exercise of at least moderate intensity, how long do you typically do these activities?" On the basis of the participant' responses, the number of days per week of at least moderate-intensity PA was multiplied by the number of reported minutes per day of PA to compute weekly minutes of at least moderate-intensity PA for each respondent. We classified survey respondents into those with ≥150 minutes of at least moderate-intensity PA per week and those with <150 minutes of at least moderate-intensity PA per week, indicating meeting versus not meeting the current WHO recommendations of moderate PA for adults, respectively. The main independent variable was a binary measure assessing whether the informal caregiver has used wearables during the past 12 months (yes vs no). This indicator was derived from the participant's response to the survey question, "In the past 12 months, have you used an electronic wearable device to monitor or track your health or activity? For example, a Fitbit, Apple Watch, or Garmin Vivofit."

Other Explanatory Variables

We followed the constructs of the Social-Ecological Model [37] and Social Cognitive Theory [38] to select study covariates. Drawing from these theoretical frameworks, several sociodemographic characteristics related to informal caregivers were included as control measures in our analyses. Respondents' ages were categorized into "18 to 34," "35 to 49," "50 to 64," and "≥65" years. Sex was a binary variable, "male versus female." Each respondent's race and ethnicity was categorized into "non-Hispanic White," "non-Hispanic Black," "Hispanic," and "non-Hispanic Asian and others." Marital status was represented through a nominal variable, "married or living as married," "divorced, widowed, or separated," and "single or never married." Informal caregivers' education was categorized as "less than high school," "high school graduate," "some college," and "college graduate or more." Other incorporated socioeconomic status characteristics included annual household income, which was categorized as "<US $20,000," "US $20,000 to US $35,000," "US $35,001 to US $50,000," "US $50,001 to US $75,000," and ">US $75,000." Other variables included whether the respondents had a smartphone, "yes versus no"; metropolitan statistical area (MSA) residency, "MSA versus non-MSA"; and having a regular provider, "yes versus no." The incorporated measures of health and health behaviors included number of reported CCs, which was categorized as "none," "1," and "≥2." The number of CCs was constructed based on a history of diagnosed medical conditions including diabetes or high blood sugar; high blood pressure or hypertension; heart conditions such as myocardial infarction, angina, or congestive heart failure; chronic lung disease, asthma, emphysema, or chronic bronchitis; depression or anxiety disorder; and cancer. Smoking status was categorized as "current," "former," and "never"; each respondent's BMI (calculated as weight in kilograms divided by the square of height in meters [kg per m^2]) was categorized into "underweight or normal (BMI ≤24.9 kg/m^2)," "overweight (BMI=25-29.9 kg/m^2)," and "obese (BMI ≥30kg/m^2)." We also incorporated 2 measures of caregiver self-efficacy: self-rated general health status—which was categorized as "excellent or very good," "good," and "fair or poor"—and caregiver's self-reported confidence in taking care of own health—categorized as "completely confident," "very confident," and "somewhat, a little, or not confident at all."

Statistical Approach

We first calculated the unweighted frequencies and weighted proportions for the entire sample of informal caregivers and then by subgroups based on PA levels. Wald chi-square was used to test for equal proportions in 2-way analyses. Univariate and multivariable logistic regressions were fit to assess the association between the use of wearables and the binary PA outcome. The fully adjusted model incorporated the primary independent variable and the entire pool of selected covariates. Multicollinearities were checked, and the significance of interaction terms was assessed by the likelihood ratio test. Assessing for multicollinearities was performed by first exploring the correlation matrix and then the variance inflation factor and tolerance. There were no threats of multicollinearity between the model variables. The final generated outputs included odds ratios (ORs), their 95% CIs, and associated *P* values. In the above analytical steps, final person weights and jackknife replicate weights from the HINTS data set were used to estimate national-level values and more accurate SEs of estimates. The significance threshold was set at $P<.05$. All analyses were performed using the SAS statistical software (version SAS 9.4; SAS Institute Inc).

Ethical Considerations

This study involved analyses of secondary data from the HINTS 5 data set, which is primarily deidentified and publicly available. The institutional review board of Westat, the organization that administers the survey, and the institutional review board of the National Cancer Institute Office of Human Subjects Research

both granted exempted status for the use and analysis of HINTS data. Additional details about the HINTS survey design, methodology, and access to public data can be found on the survey website [39].

Results

The analytical sample of 1273 caregivers represented a national-level estimate of approximately 73.1 million informal caregivers in the United States. Table 1 shows unweighted sample frequencies and weighted national-level proportions for characteristics of the informal caregivers. Approximately 37.8% (466/1273) of caregivers reported ≥150 minutes of at least moderate-intensity PA per week, whereas about one-third (390/1273, 31.7%) of them reported using wearables during the past 12 months. About 56.3% (813/1273) of caregivers were aged ≥50 years, 60% (757/1273) were females, and 63.6% (706/1273) were non-Hispanic White adults. Other characteristics included the following: 70% (815/1273) were married or living as married, 75.7% (990/1273) had some college or more in education, 44.5% (491/1273) had an annual household income of >US $75,000, 89.7% (1058/1273) had a smartphone, 88.1% (1144/1273) were residing in an MSA in the United States, and 72% (935/1273) reported having a regular provider. A large proportion of caregivers (885/1273, 67.3%) had ≥1 CC, 38.3% (461/1273) were current or former smokers, and 38% (477/1273) were obese (BMI of ≥30 kg/m^2). Of the 1273 informal caregivers, 578 (44.2%) rated their general health status as excellent or very good, and 67.9% (904/1273) of the informal caregivers were completely confident or very confident about taking care of their own health (Table 1).

Among those meeting the recommendations of engaging in ≥150 minutes of at least moderate-intensity PA per week, approximately 43.1% (201/466) reported using wearables during the past 12 months (Table 1). For this specific subgroup of caregivers, 54.4% (283/466) were aged ≥50 years, 54.7% (252/466) were females, and 60.9% (278/466) were non-Hispanic White adults. Furthermore, almost 75% (315/466) of the caregivers were married or living as married, 84.1% (583/466) had some college or more in education, 55.3% (224/466) had an annual household income >US $75,000, 92.2% (411/466) had a smartphone, 89.6% (424/466) were residing in an MSA in the United States, and 71.7% (345/466) had a regular health care provider. About 62.4% (293/466) of the caregivers had ≥1 CC, 33.4% (153/466) were current or former smokers, and 37.3% (176/466) were either under or normal weight (BMI ≤24.9 kg/m^2). Approximately 56.6% (278/466) of the caregivers reported their general health status as being excellent or very good, and 77.9% (376/466) of the caregivers reported that they were completely confident or very confident about taking care of their own health.

From our multivariable logistic regression model, informal caregivers who reported wearable use during the past 12 months had higher odds (adjusted OR 1.1, 95% CI 1.04-1.77; *P*=.04) of engaging in ≥150 minutes of at least moderate-intensity PA per week compared with those who did not use wearables (Table 2). Apart from wearables use, caregiver's annual household income and self-rated general health status were associated with the levels of PA. Caregivers with an income of US $20,000 to US $35,000 (adjusted OR 2.67, 95% CI 1.01-7.08; *P*=.048), US $35,001 to US $50,000 (adjusted OR 2.91, 95% CI 1.17-7.24; *P*=.02), US $50,001 to US $75,000 (adjusted OR 3.72, 95% CI 1.28-10.81; *P*=.02), and >US $75,000 (adjusted OR 3.70, 95% CI 1.51-9.60; *P*=.005) had higher odds of engaging in ≥150 minutes of at least moderate-intensity PA per week relative to caregivers with an annual income of <US $20,000. Caregivers who self-rated their health as fair or poor had lower odds (adjusted OR 0.39, 95% CI 0.16-0.94; *P*=.04) of engaging in ≥150 minutes of at least moderate-intensity PA per week compared with caregivers who rated their own health as excellent or very good.

Table 1. Informal caregiver characteristics in the United States (HINTS[a] 5—cycles 3, 2019 and 4, 2020; N=1273).

Characteristics	Sample, frequency (weighted %)[b]	Minutes per week of at least moderate-intensity exercise, frequency (weighted %)[b]		*P* values opted from Wald χ^2 test
		≥150 minutes (n=466)	<150 minutes (n=764)	
Minutes per week of at least moderate-intensity exercise				
≥150 minutes	466 (37.8)	—[c]	—	—
<150 minutes	764 (62.2)	—	—	—
Electronic wearable device use[d]				
Yes	390 (31.7)	201 (42.1)	179 (26.4)	.03
No	873 (68.3)	262 (57.9)	581 (73.6)	—
Age groups (years)				
18-34	103 (11.7)	35 (9.9)	67 (13.1)	.62
35-49	318 (32)	136 (35.7)	180 (30.5)	—
50-64	457 (39.6)	166 (39.1)	284 (40.7)	—
≥65	356 (16.7)	117 (15.3)	218 (15.7)	—
Sex				
Male	426 (40)	184 (45.3)	232 (37.4)	.06
Female	757 (60)	252 (54.7)	488 (62.6)	—
Race and ethnicity				
Hispanic	188 (15.3)	63 (15.8)	119 (14.7)	—
Non-Hispanic Asian and others	104 (12)	38 (14.0)	66 (11.1)	—
Non-Hispanic Black	150 (9.1)	54 (9.3)	93 (9.1)	—
Non-Hispanic White	706 (63.6)	278 (60.9)	410 (65.1)	.86
Marital status				
Married or living as married	815 (70)	315 (74.8)	484 (67.5)	.13
Divorced, widowed, or separated	268 (12.4)	85 (10.2)	172 (13.3)	—
Single or never married	149 (17.6)	55 (15)	91 (19.2)	—
Education				
Less than high school	66 (5.2)	21 (5.4)	40 (4.5)	.002
High school graduate	182 (19.1)	45 (10.5)	128 (23.7)	—
Some college	372 (43.8)	138 (45.4)	226 (43.2)	—
College graduate or more	618 (31.9)	243 (38.7)	357 (28.6)	—
Annual household income (US $)				
<20,000	184 (16.3)	47 (8.3)	124 (19.6)	.004
20,000-35,000	121 (10.9)	37 (9.2)	81 (11.8)	—
35,001-50,000	138 (11.2)	51 (9.6)	84 (12.3)	—
50,001-75,000	210 (17.1)	69 (17.6)	137 (16.9)	—
>75,000	491 (44.5)	224 (55.3)	262 (39.4)	—
Have a smartphone[e]				
Yes	1058 (89.7)	411 (92.2)	624 (88.7)	.17
No	188 (10.3)	45 (7.8)	128 (11.3)	—
MSA[f] residency				
MSA	1144 (88.1)	424 (89.6)	682 (86.9)	.46

Characteristics	Sample, frequency (weighted %)[b]	Minutes per week of at least moderate-intensity exercise, frequency (weighted %)[b]		*P* values opted from Wald χ^2 test
		≥150 minutes (n=466)	<150 minutes (n=764)	
Non-MSA	129 (11.9)	42 (10.4)	82 (13.1)	—
Have a regular provider				
Yes	935 (72)	345 (71.7)	570 (73.0)	.77
No	323 (28)	116 (28.3)	190 (27)	—
Chronic medical conditions				
None	384 (32.7)	173 (37.6)	200 (30.2)	.09
1	393 (31.6)	146 (32.4)	235 (31)	—
≥2	492 (35.7)	147 (30)	328 (38.8)	—
Smoking status				
Current	138 (13.2)	54 (14.4)	82 (12.3)	.04
Former	323 (25.1)	99 (19)	214 (28.1)	—
Never	790 (61.7)	310 (66.6)	461 (59.6)	—
BMI (kg/m^2)				
Underweight or normal (≤24.9)	379 (31.6)	176 (37.3)	187 (27.5)	.02
Overweight (25-29.9)	385 (30.4)	155 (31.7)	222 (29.5)	—
Obese (≥30)	477 (38)	127 (31)	339 (43)	—
Self-rated general health status				
Excellent or very good	578 (44.2)	278 (56.6)	283 (37)	<.001
Good	478 (38.6)	145 (33.5)	320 (41.7)	—
Fair or poor	207 (17.2)	41 (9.9)	156 (21.3)	—
Confidence in taking care of own health				
Completely confident	304 (23.6)	153 (31.2)	138 (19)	<.001
Very confident	600 (44.3)	223 (46.7)	362 (42.9)	—
Somewhat, a little, or not confident at all	367 (32.1)	90 (22.1)	264 (38.1)	—

[a]HINTS: Health Information National Trends Survey.

[b]Frequencies represent sample frequencies; proportions are population-level estimates that were generated by adjusting for complex survey features of the HINTS data (N=73.1 million).

[c]Not available.

[d]Such as Fitbit, AppleWatch, or Garmin Vivofit.

[e]Such as iPhone, Android, Blackberry, or Windows phone.

[f]MSA: metropolitan statistical area.

Table 2. Logistic regressions modeling the association between use of electronic activity trackers (wearables) and meeting recommendations of physical activity (≥150 minutes per week of at least moderate-intensity exercise) among informal caregivers.

Characteristics	Crude OR[a] (95% CI)	Adjusted OR (95% CI)
Electronic wearable device use[b]		
Yes	1.9 (1.12-2.26)[c]	1.1 (1.04-1.77)[c]
No	Reference	Reference
Age groups (years)		
18-34	Reference	Reference
35-49	1.55 (0.77-3.13)	1.06 (0.46-2.45)
50-64	1.27 (0.67-2.44)	0.79 (0.38-1.64)
≥65	1.3 (0.64-2.64)	0.98 (0.38-2.51)
Sex		
Male	Reference	Reference
Female	0.72 (0.51-1.02)	0.72 (0.43-1.22)
Race and ethnicity		
Hispanic	1.15 (0.67-1.96)	1.5 (0.79-2.85)
Non-Hispanic Asian and others	1.35 (0.61-2.99)	1.39 (0.49-3.99)
Non-Hispanic Black	1.09 (0.61-1.94)	1.85 (0.77-4.43)
Non-Hispanic White	Reference	Reference
Marital status		
Married or living as married	1.42 (0.82-2.48)	1.08 (0.53-2.21)
Divorced, widowed, or separated	0.98 (0.52-1.88)	1.19 (0.45-3.13)
Single or never married	Reference	Reference
Education		
Less than high school	Reference	Reference
High school graduate	0.36 (0.14-0.94)[c]	0.32 (0.1-1.26)
Some college	0.86 (0.33-2.25)	0.55 (0.15-1.99)
College graduate or more	1.11 (0.46-2.69)	0.57 (0.15-2.13)
Annual household income (US $)		
<20,000	Reference	Reference
20,000-35,000	1.86 (0.95-3.67)	2.67 (1.01-7.08)[c]
35,001-50,000	1.86 (0.94-3.65)	2.91 (1.17-7.24)[c]
50,001-75,000	2.46 (1.21-4.99)[c]	3.72 (1.28-10.81)[c]
>75,000	3.32 (1.85-5.95)[d]	3.8 (1.51-9.6)[e]
Have a smartphone[f]		
Yes	1.52 (0.81-2.85)	0.82 (0.31-2.13)
No	Reference	Reference
MSA[g] residency		
MSA	Reference	Reference
Non-MSA	0.77 (0.36-1.64)	1.3 (0.54-3.16)
Have a regular provider		
Yes	0.94 (0.6-1.46)	1.13 (0.61-2.08)

Characteristics	Crude OR[a] (95% CI)	Adjusted OR (95% CI)
No	Reference	Reference
Chronic medical conditions		
None	Reference	Reference
1	0.84 (0.53-1.32)	1.08 (0.61-1.92)
≥2	0.62 (0.41-0.95)[c]	1.19 (0.66-2.15)
Smoking status		
Current	Reference	Reference
Former	0.58 (0.28-1.2)	0.47 (0.19-1.13)
Never	0.96 (0.49-1.88)	0.73 (0.31-1.68)
BMI (kg/m^2)		
Underweight or normal (≤24.9)	Reference	Reference
Overweight (25-29.9)	0.79 (0.49-1.29)	0.90 (0.47-1.69)
Obese (≥30)	0.53 (0.33-0.85)[e]	0.62 (0.31-1.23)
Self-rated general health status		
Excellent or very good	Reference	Reference
Good	0.53 (0.38-0.73)[d]	0.66 (0.38-1.13)
Fair or poor	0.30 (0.16-0.57)[d]	0.39 (0.16-0.94)[c]
Confidence in taking care of own health		
Completely confident	Reference	Reference
Very confident	0.66 (0.43-1.02)	0.81 (0.45-1.47)
Somewhat, a little, or not confident at all	0.35 (0.22-0.56)[d]	0.74 (0.37-1.46)

[a]OR: odds ratio.

[b]Such as Fitbit, AppleWatch, or Garmin Vivofit.

[c]*P*<.05.

[d]*P*<.001.

[e]*P*<.01.

[f]Such as iPhone, Android, Blackberry, or Windows phone.

[g]MSA: metropolitan statistical area.

Discussion

Principal Findings and Implications for Policy and Practice

Using a nationally representative sample of 1273 informal caregivers in the United States (73.1 million at the national level), we examined whether informal caregivers who use wearables met the current WHO recommendations of ≥150 minutes of at least moderate-intensity PA for adults. Study findings revealed that informal caregivers who reported using wearables during the past 12 months had higher odds of meeting PA recommendations. Informal caregivers are pillars of current health care systems, as they provide essential care and emotional support to their loved ones. However, they often experience significant burden associated with their caregiving roles, which can negatively impact their health and well-being. Those who care for older patients with CCs (ie, cancer, hypertension, etc), dementia or Alzheimer disease are even more likely to report poorer physical and mental health as well as social and financial challenges attributed to the caregiving burden, including limited time and resources.

Mounting evidence exists about the use of information technologies and their health-related benefits among various groups of populations, including informal caregivers [30-32]. For instance, Matthews et al [32] assessed how family caregivers deal with challenging aspects of dementia to inform formal interventions designed to strengthen their caregiving knowledge and skills. The findings indicated that family caregivers of people with dementia could use a novel, wearable camera system to collect evidence of dementia-related behaviors and interactions that may affect the health and safety of the caregiving dyad. Furthermore, Egan et al [30] co-designed and assessed a mobile app named CareFit to educate and support caregivers to perform regular PA at home during and after COVID-19 restrictions by integrating a transtheoretical model of behavior change based on the United Kingdom's guidelines for PA. They found that integrating PA into the CareFit app

with functions such as a weekly planner and educational material for users is feasible. In addition, an observational study by Martinato et al [31] assessed Vivoactive HR (Garmin) smartwatch as a wearable device in quantifying PA in a sample of 49 older adults and found the potential of the wearable device to enhance PA among care recipients by capturing even the low levels of PA. Furthermore, Jaschinski and Allouch [40] found that most informal caregivers had a positive perception about using ambient assisted living and appreciated the help of ambient assisted living technologies in preventing accidents and alerting them immediately in case of an emergency [40].

There is a greater potential for wearable devices to improve health and health care. Wearable technology can serve as a safe and cost-effective intervention to promote health and healthy behaviors such as PA [28]. Incorporating health-related data obtained from wearables into the electronic health record systems could further assist health care professionals in monitoring individual health status and providing relevant care and support efficiently [25,28,41]. Notably, by connecting or linking to mobile apps, wearables can better facilitate motivating and managing individual health and health care [42]. Furthermore, prior systematic reviews and meta-analysis in this domain have provided evidence regarding the positive influence of using wearable technology in increasing PA among various subgroups of population [43-45]. The use of wearable devices as a health-promoting intervention is associated with increased PA and steps per day and a significant increase in moderate to vigorous minutes per week of PA among patients with cardiometabolic diseases [44]. Other studies indicate that using consumer-based wearable activity trackers as an intervention modality significantly increased daily step count and energy expenditure among wearable users compared with those who do not use these devices among a wide range of healthy populations and populations with CC [43].

Nonetheless, there is the issue of the digital divide related to these innovative technologies, which could worsen the already existing disparities [2,46]. The digital divide pertains to differences between have's and have-not's with information and communication technologies [47]. The gap in access to digital technologies, including wearable devices, can widen the already present health and health care disparities [2]. Evidence shows that the younger, more educated, wealthier, and tech-savvy adults are more likely to use wearables compared with older adults, those with lower education and income, and non–tech-savvy individuals [21,28,48]. Farivar et al [49] explored the extent to which factors were associated with the adoption of wearable devices among older adults by conducting a mixed methods study and found their perceived complexity in using wearable devices as a barrier to adoption. In addition, it was found that cognitive age itself does not considerably affect wearable device use intention, which is moderated by subjective well-being in older adults, indicating that older adults' use intention is influenced by their subjective well-being [49].

Our findings show that informal caregivers with higher income, compared with those with lower income (≤US $20,000), were more likely to engage in PA by meeting the recommended guidelines. A meta-analysis conducted by Pinquart and Sörensen [50] examined correlates of informal caregivers' physical health and found that having higher income was associated with better physical health. They suggested that less access to health care and inadequate health practices may be attributed to the relationship of income with physical health [51]. As one of the socioeconomic indicators, income is considered a correlate of financial resources and tangible well-being that may affect individual's healthy behaviors [51]. Insufficient tangible resources may influence individual health behaviors from financial limitations that can hinder people from making healthy choices, albeit not all those choices are based on income or money [51]. Nonetheless, evidence also suggests that the relation of socioeconomic components, including income, to individual health behaviors is not clear or straightforward [51]. Moreover, other evidence from the United States indicates that use of wearable devices and other digital technologies is greatly impacted by individuals' socioeconomic status [21]. Approximately 31% of the residents of the United States with an annual household income of ≥US $75,000 reported wearing a smart watch or fitness tracker on a regular basis, whereas only 12% of those with an annual household income ≤US $30,000 reported using these devices [21]. Similarly, people with higher educational attainment are more likely to adopt these technologies than those with lower levels of education [21].

Interestingly, our findings also indicated that informal caregivers who assessed their health as fair or poor, when compared with those who rated their health as excellent or very good, were less likely to meet PA recommendations. This finding was in line with that of prior studies that reported positive associations of higher self-efficacy and self-rated health with initiation of exercise, higher PA, and better health-promoting behaviors [52-55]. Thus, these psychosocial factors are important predictors of PA among informal caregivers. Specifically, lower levels of perceived health may actually be a potential barrier to PA [54]. It is also possible that this group of informal caregivers may not have had sufficient time to engage in PA owing to their caregiving burden. Indeed, informal caregivers have challenging circumstances or situations such as financial difficulties, time constraints, and other barriers related to their caregiving role [2]. In this respect, innovative technologies, including wearables, could help reduce the burden associated with caregiving by providing beneficial features (eg, motivation, self-tracking, information gathering and exchange, and communication with a provider), which could potentially help improve individual health and well-being [2]. Notably, they could be used by individuals to further engage them in health-related activities, including PA [30], particularly caregivers who are more likely to have poorer physical and mental health and emotional well-being.

There is a greater need for providing support and help to informal caregivers, given that they play an essential role in the health care system. Incorporating elements of innovative information and communication technologies such as wearables could contribute to beneficial health outcomes. Wearables can help individuals be proactive in monitoring, tracking, and managing their health and health care and can help improve their quality of life [56]. Wearables are becoming more affordable and easier to use for monitoring health-related physical activities or conditions, particularly among older

people. Wearable devices are beneficial to overcome the diverse needs related to aging among older adults [57]. Essentially, health-promoting strategies, such as providing health education materials or counseling, should be provided using these technologies to promote or enhance health and health care [23,58]. To reduce the burden associated with caregiving, training should be offered to them, especially those who are new to caregiving. For example, caregiver stress and burden could be reduced by providing instructions about how to perform tasks such as offering mobility assistance, advocating for medical treatment, administering medications and injections, and using digital technologies and other electronic tools (eg, personal health record tracking and medication support systems) [59,60].

Given that most caregivers have a smartphone, they can download and use mobile health apps for health-related purposes. For example, downloading a pedometer app could help enhance their PA. Moreover, facilitating the use of wearables and making them less noticeable and user-friendly, while providing appropriate operating instructions, could help reduce anxiety about technology use [61,62]. Today, there are different types of products (smartwatches, fitness trackers, smart clothes, implantable gadgets, head-mounted displays, etc) from various manufacturers (Xiaomi, Huawei, Polar, Samsung, Apple, Garmin Ltd, Withings, and Fitbit just to name a few) that are available in the market; the variety of options can be daunting for informal caregivers when making decisions about which wearable device to adopt and use [62,63].

Limitations

Although this study provides novel insights that have implications for health care policy and practice, it has several limitations. First, owing to the cross-sectional nature of the HINTS survey, we were unable to infer causality in the reported associations. Second, despite capturing the relevant variables based on the conceptual and theoretical frameworks, it is possible that there could be a more appropriate conceptual model. However, given that the use and implementation of wearable devices are still developing and in their infancy, unified and better-fitting theories and frameworks related to this field are still being developed [64]. Third, provided that the data used for this study were based on a national survey including the self-reported information, there could be recall bias if the respondents did not provide correct information, and there is a possibility that other types of bias may be introduced, including social desirability bias. Fourth, despite ongoing efforts to improve the HINTS survey response rates [65], these rates have remained low, and there is potential for selection bias; thus, population representativeness and generalizability of the findings could be questionable. Fifth, although we adjusted for several related factors based on the theoretical frameworks and literature review, there may be other factors that were not included in our model. For example, we could not adjust for many contextual factors or attributes possibly associated with the use of wearables or PA. Sixth, no thorough assessment of muscle-strengthening activities was provided in the database, which could have supplemented our evaluation of PA. Finally, other critical information about consistency of wearables use, device features, and quality of engagement of those who used the device during the past 12 months were also not collected in this survey. Thus, we were constrained in our analyses by the information provided in the HINTS data set. All these limitations present an opportunity for our team and other researchers to expand the study in the future. Potentially more prospective studies can be designed to further support the findings of this study. In addition, investigating these associations among groups of caregivers who specifically care for patients with CCs (eg, diabetes, hypertension, cancer, and dementia or Alzheimer disease) will be of particular interest in the caregiving field.

Conclusions

In this study, we used a nationally representative sample of 1273 self-identified informal caregivers in the United States to assess the associations between use of wearables and the status of meeting the current WHO recommendations of moderate-intensity PA for adults (ie, ≥150 minutes of at least moderate-intensity PA per week). We found that informal caregivers who reported wearable use during the past 12 months were modestly more likely to engage in ≥150 minutes of at least moderate-intensity PA per week compared with caregivers who did not use wearables. The results demonstrated the potentials of wearables as a means of increasing PA among informal caregivers, thus their role in health promotion and improving quality of life among this important segment of the population.

Long-term adoption could potentially be critical for the delivery of the benefits promised by wearable technology, and yet, this particular area of research requires further scrutiny [64]. There are several acceptance- and abandonment-related issues that substantially influence long-term wearable use. Some of these factors include device appearance, display and interaction, wearability, perceived usefulness or risks, and other technical issues such as data measurement and presentation [29,64]. Other factors that influence wearable use include development of more personalized devices for various groups of people who have different needs and preferences. Usually, designing of an all-purpose wearable is unreasonable and less impactful and is less likely to have sustained use or benefits over time [29].

There are many other issues related to wearable development and use that need to be properly addressed. A few of these issues include data security and protection, consumer privacy concerns, device accuracy, discoverability risks, ethical issues related to the tracking features of wearables, and the fact that many wearables are not regulated by the United States Food and Drug Administration [22,23,25,29,66]. Furthermore, other issues related to wearable technology adoption such as lack of awareness regarding the health and well-being benefits of wearable device use and their implications for physical and mental health, specifically among caregiving and older adults, need to be particularly addressed [23]. To overcome these challenges and concerns, wearable technology developers, researchers, interventionists, health care providers, and policy makers should work in synergy to design and develop personalized, effective, and validated wearables with an optimum impact on health behavior change and health promotion for the caregiver population [25]. The role of digital divide in the adoption and effectiveness of wearables should be emphasized and addressed [64]. As most health technology

adoptions are lagging among those in low-income and low-education subgroups, the design and development of wearables should overcome the initial and long-term barriers of adoption among this disadvantaged segment of the population.

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Data Availability

The data analyzed for this study were obtained from the National Cancer Institute's Health Information National Trends Survey; it is publicly available for access and download at https://hints.cancer.gov/.

Authors' Contributions

AM and HK conceptualized and developed the initial draft of the manuscript. SK and PD critically reviewed and revised the manuscript and made appropriate edits or changes.

Conflicts of Interest

None declared.

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Abbreviations

CC: chronic medical condition
HINTS: Health Information National Trends Survey
MSA: metropolitan statistical area
OR: odds ratio
PA: physical activity
WHO: World Health Organization

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Corrigenda and Addenda

Correction: Digital Coaching Using Smart Inhaler Technology to Improve Asthma Management in Patients With Asthma in Italy: Community-Based Study

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Related Article:

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In “Digital Coaching Using Smart Inhaler Technology to Improve Asthma Management in Patients With Asthma in Italy: Community-Based Study” (JMIR Mhealth Uhealth 2022;10(11):e25879), the authors noted one error.

In the PDF version of the originally published article, Clementina Columbro’s name was inadvertently included in the list of authors as the fifth author due to a technical error.

The list of authors of the paper and their respective affiliations have now been corrected in the PDF version of the article as follows:

Gabriele Rumi[1], MD; G Walter Canonica[2], MD; Juliet M Foster[3], PhD; Niels H Chavannes[4], PhD; Giuseppe Valenti[5], MD; Rosario Contiguglia[6], MD; Eleni Rapsomaniki[7], PhD; Janwillem W H Kocks[8], PhD; Dario De Brasi[9], MD; Fulvio Braido[10], MD

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The correction will appear in the online version of the paper on the JMIR Publications website on November 25, 2022, 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 has also been resubmitted to those repositories.

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Corrigenda and Addenda

Correction: Frequent Mobile Electronic Medical Records Users Respond More Quickly to Emergency Department Consultation Requests: Retrospective Quantitative Study

Kwang Yul Jung[1,2*], MD; SuJin Kim[2*], BA; Kihyung Kim[2], MS; Eun Ju Lee[3], MS; Kyunga Kim[2,4], PhD; Jeanhyoung Lee[5], ME; Jong Soo Choi[2,5], PhD; Mira Kang[2,5,6], MD, PhD; Dong Kyung Chang[2,5,7], MD, PhD; Won Chul Cha[2,5,8], MD

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In "Frequent Mobile Electronic Medical Records Users Respond More Quickly to Emergency Department Consultation Requests: Retrospective Quantitative Study" (JMIR Mhealth Uhealth2020;8(2):e14487) the authors noted one error.

In the originally published article, an affiliation of author Kwang Yul Jung (Affiliation 2) was inadvertantly excluded.

The corrected version now indicates both the following affiliations of author Kwang Yul Jung:

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[2]Department of Digital Health, Samsung Advanced Institute for Health Science & Technology, Sungkyunkwan University, Seoul, Republic of Korea

The correction will appear in the online version of the paper on the JMIR Publications website on November 8, 2022, 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 has also been resubmitted to those repositories.

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