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Development of a Small Steps for Big Changes Diabetes Prevention App: Application of the Development Phase of FASTER

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Abstract

mHealth technologies are being continually used to supplement diabetes prevention programs. Given the thousands of mHealth apps on the market and lack of an evidence base, there has been a call for more thorough development and evaluation of apps targeting diabetes prevention behaviors. This paper presents a case study on the development of an mHealth app to support participants in the Small Steps for Big Changes diabetes prevention program, using the Framework for Accelerated and Systematic Technology-based intervention development and Evaluation Research (FASTER). The design process followed the 5 stages within the development phase of FASTER (*Empathize, Define, Ideate, Prototype, and Test*) and broadly consisted of a needs assessment, literature review, end-user feedback and heuristic evaluation. Additionally, the app behavior change scale was consulted to ensure that the resulting app included evidence-based techniques to maximize its potential of behavior change. This systematic process resulted in the development of an app consisting of evidence-based behavior change techniques likely to elicit behavior change. This paper is the first to use the FASTER to develop a diabetes prevention app (or app of any type) and confirms the usability and usefulness of the framework within the complex area of preventative medicine. The systematic development of the Small Steps for Big Changes app will be followed by thorough validation coupled with usability and effectiveness evaluations in the next two phases of the FASTER.

Keywords Mobile health · User-centered design · Diabetes prevention · Health promotion

Introduction

Prediabetes, a condition which increases type 2 diabetes risk by up to 70% (Nathan et al., 2007), will affect approximately 587 million adults globally by the year 2045 (Hostalek, 2019). Type 2 diabetes is a leading cause of disability around the world (James et al., 2018) and is associated with decreased productivity and increased economic burden, accounting for 12% of global health expenditures in 2018 (Zhang & Gregg, 2017). In Canada, one in every two individuals will be diagnosed with diabetes in their lifetime with an associated annual treatment cost of $30 billion (Kern, 2018). This increasing prevalence and burden highlight the need for effective and accessible diabetes prevention care.

Landmark diabetes prevention programs have shown that more than half of type 2 diabetes cases can be prevented or delayed through intensive diet and physical activity interventions (Knowler et al., 2002; Li et al., 2008; Lindström et al., 2003). That being said, these diabetes prevention programs are costly and time intensive, decreasing their utility in terms of widescale implementation (Eddy et al., 2005; Glasgow et al., 2003). Additionally, rural communities, which have notably high rates of prediabetes (Kern, 2018), often do not have access to trained staff, facilities, and resources, thereby limiting the ability of these communities to host diabetes prevention programs. This lack of access creates a service gap between those most at risk, and prevention programs tailored for use in metropolitan areas. Technological developments and widespread adoption may help to narrow that gap. Digital approaches can reach a wider audience due to their accessibility and availability (Glasgow et al., 2001) and have been increasingly used in behavior change interventions (Marcolino et al., 2018).

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mHealth Interventions

Mobile health (mHealth) technologies provide an opportunity to empower individuals to play an active role in their own care via smart phone mobile applications (herein referred to as apps) (Istepanian & Al-Anzi, 2018). The popularity of mHealth apps has risen as a result of increased access to the internet. An estimated 97% of adults worldwide had access to a mobile phone in 2015, with 43% using the internet (ITU, 2015). This number of internet users increases to over 94% in high-income countries such as Canada (ICT, 2017). This growth in internet connectivity has created an opportunity for technologies to supplement healthcare by providing patients with a convenient means to access and self-manage their conditions. In the first quarter of 2020, there were approximately 44 thousand mHealth apps within the Google Play store, this is roughly 20 thousand more mHealth apps than the first quarter of 2015 (Statista, 2020). Given the growing integration of apps in daily life, mHealth apps provide an avenue to make diabetes prevention programming more accessible for individuals without access to traditional in-person diabetes prevention programs.

In terms of type 2 diabetes, reviews of the literature have suggested that mHealth technologies may be associated with clinically meaningful weight loss (Grock et al., 2017; Joiner et al., 2017); however, these programs have been primarily conducted with high socio-economic status participants within metropolitan areas and include a range of mHealth technologies including text messaging, apps, DVDs, videoconferencing, and email. In a recent review of mHealth apps relating to type 2 diabetes prevention, 15 apps were assessed using the Mobile App Rating Scale (MARS), none of which had evidence available for their efficacy in diabetes risk reduction behaviors (Ranjani et al., 2021). The MARS is a validated app rating scale which consists of 5 overarching categories (engagement, aesthetics, functionality, information, and subjective quality; Stoyanov et al., 2015). When assessing diabetes prevention apps using the MARS, all apps scored highly on the MARS, with the categories *Aesthetics and Functionality* driving these ratings (Ranjani et al., 2021). Authors concluded that future research is required to develop diabetes prevention apps using evidence-based content, coupled with behavior change techniques effective in diabetes risk reduction behaviors such as diet and physical activity (Ranjani et al., 2021).

The Current Study

This work aims to develop an mHealth app for use in the Small Steps for Big Changes diabetes prevention program. Small Steps for Big Changes is a brief 3- to 4-week diabetes prevention program which utilizes evidence-based behavior change and motivational interviewing techniques (MacPherson et al., 2020) to provide client-centered counseling and supervised exercise sessions to improve dietary and physical activity behavior change (Bean et al., 2020a, b, c; Jung et al., 2020). Within this program, participants are provided with tailored heart rate zones and are taught how to gauge their exercise intensity during both high-intensity interval training and moderate-intensity continuous training (Bean et al., 2020a, b, c; Jung et al., 2020). All participants are provided with the option to use commercially available mHealth apps to self-monitor their diet and/or physical activity (MacPherson et al., 2022). While previous Small Steps for Big Changes participants have noted that mHealth technologies are important facilitators to long-term behavior change maintenance following program completion (Bean et al., 2020b), they have also expressed a desire for more comprehensive platforms in which they can receive ongoing support and information (Bean et al., 2020a). As such, this work aims to develop a diabetes prevention app tailored to Small Steps for Big Changes participants using the first phase of the Framework for Accelerated and Systematic Technology-based intervention development and Evaluation Research (FASTER) (Wang et al., 2021).

The FASTER consists of three phases to develop and generate rigorous evidence appropriate for technology-based interventions (Wang et al., 2021). The three phases include: (I) development, (II) progressive usability and feasibility evaluation, and (III) scaled evaluation and implementation. Throughout all phases, FASTER includes guiding principles believed to be imperative to the effective development of mHealth interventions: engagement with end-users, transdisciplinary collaboration, ethical development and implementation, and continued process evaluation and reporting. This work highlights the first application of the FASTER for app development.

Methods

Overview of FASTER Phase I: Development

The development phase is split into 5 stages adopted from the Design School at Stanford University's "Design Thinking": *Empathize, Define, Ideate, Prototype, and Test.* In the Empathize stage, researchers are encouraged to complete activities to determine end-user needs and preferences within the specific implementation context while also examining the broader context. The information gathered within this step is then used within the Define stage to specify the problem in detail (describing what the problem is, where it occurs, who performs it, and other stakeholders). Following this, the Ideate stage recommends that the research team

develop a logic model to describe the proposed mechanisms of action within the mHealth intervention and how intervention components are anticipated to influence short- and long-term outcomes. The logic model then directly leads to the Prototype and Test stage in which the research team focuses on rapidly creating iteratively improving upon mHealth intervention prototypes to refine the requirements with end-users.

Empathize

Needs Assessment

To determine user needs for the app, a needs assessment was conducted with the research team consisting of behavior change researchers and Small Steps for Big Changes coaches where they were asked: 1) what features they would like to see in a Small Steps for Big Changes app, 2) what features they think would be of benefit to Small Steps for Big Changes clients, 3) what information they would like tracked for research purposes, 4) how they think the app should look, 5) what steps can be made to ensure user privacy, and 6) how they think the app can be developed to improve equity, diversity, and inclusion within diabetes prevention care. All suggestions were collated and weighted equally at this stage.

Literature Review

Concurrent to this needs assessment, two authors (MM and BG) reviewed research evidence for physical activity apps to garner a broader understanding of the field. Medline, CAB direct, and PsycInfo were searched for terms relating to mobile phone applications and physical activity (see Table 1 for Medline search). Given the large number of reviews which have already been conducted on physical activity apps, inclusion was limited to review articles of any type (e.g., systematic, scoping, rapid review, and qualitative meta-synthesis) which were assessing physical activity apps and were published in the last 5 years. All data was narratively summarized.

Table 1 Medline search terms

Category	MeSH term	Key words
Mobile phone application	Cell phone/or "cell phone use"/or mobile applications/	App.ab,ti or Mobile phone.ab,ti or Smartphone.ab,ti
Physical activity	Exercise/or physical fitness/or fitness trackers/	physical* activ*.ab,ti or exercise*.ab,ti or fitness.ab,ti

MeSH terms and key words for a single topic were searched with the Boolean term "OR", and the categories were searched with the Boolean term "AND." Additionally, the search was limited to only those articles with "review" in the title

Define

Following a review of the literature, and based on the existing evidence and experiences within Small Steps for Big Changes, a problem statement as it relates to this specific context was defined. By understanding the specific Small Steps for Big Changes context, further ideation, prototyping, and testing was able to be tailored to the target audience.

Ideate

The logic model for this app was developed using the COM-B model—a widely used theoretical framework to aid in understanding the antecedents for health behaviors. Within the COM-B, it is proposed that an individual needs sufficient Capability (physical and psychological), Opportunity (physical and social), and Motivation (reflective and automatic) in order to perform a Behavior (Michie et al., 2014). To develop a logic model linking app features with COM-B domains, all potentially relevant behavior change techniques (BCTs) were identified by collating those found in the literature review and BCTs already in use within Small Steps for Big Changes (MacPherson et al., 2020). A BCT is defined as an "observable, replicable and irreducible component of an intervention designed to alter or redirect causal processes that regulate behavior; that is, a technique is proposed to be an 'active ingredient'" (Michie et al., 2011).

Following BCT identification, two reviewers (MM and NG) independently assessed each BCT using the APEASE (*Affordability, Practicability, Effectiveness, Acceptability, Side-effects/Safety,* and *Equity*) criteria (Michie et al., 2014). The APEASE criteria allowed researchers to critically appraise each BCT to ensure that only those BCTs which are most likely to be successfully implemented and elicit change are included. Once a final list of BCTs deemed appropriate for integration into the app was identified, two reviewers (MM and NG), with verification from the team, grouped app features into broader app categories and created a logic model for each app category linking the app features with BCTs, COM-B components, and behavior change outcomes.

Prototype/Testing

Ratings

Wireframes with all candidate components (identified in the Empathize stage) were presented to the same team who conducted the initial needs assessment as well as members of the

Small Steps for Big Changes Patient Advisory Council (PAC) in order to identify the priority in which to develop specific components and begin planning for future phased development of the app. Wireframes for the potential components were created and a group of 9 individuals (5 members of the research team and 4 members of the PAC) were asked to identify if they felt each of the features should be included in Phase 1 development, Phase 2 development, if the feature would be nice but is not a necessity, or if the feature is not necessary. Number and percentage of participants were reported for each app feature and each development phase.

Rankings

To further assist in identifying the development timeline, participants were asked to rank each potential app feature from most to least important. The number and percentage of participants who ranked each feature within the top and bottom 5 of their rankings were summarized. Based on results from end-user ratings and ranking, the phase 1 development app was completed, scored on the app behavior change scale, and underwent a heuristic evaluation.

App Behavior Change Scale

This is a reliable scale that is used to determine the potential of an app to enact behavior change (McKay et al., 2019). This scale consists of 21 items relating to knowledge and information, goal setting and planning, feedback and monitoring, and action planning. Similar to Truelove et al. (Truelove et al., 2020), we used the App Behavior Change Scale as a checklist to ensure that our development addressed all relevant items and has high theoretical potential to change physical activity behaviors.

Heuristic Evaluation

Heuristic evaluations are a commonly used way to evaluate user interfaces and identify usability problems (Kushniruk & Patel, 2004). Within this evaluation, one researcher with expertise in mHealth development (MM) went through a series of app-related tasks using Nielsen's List of 10 Usability Heuristics (Nielsen, 1994). For additional information on these heuristics, see (Kushniruk & Patel, 2004). This list of 10 heuristics was used to evaluate the app and identify usability errors within each heuristic. Each error was then rated on scale from 1 to 4 (1 = cosmetic problem; 2 = minor usability problem; 3 = major usability problem; 4 = usability catastrophe; Kushniruk & Patel, 2004).

Results

Empathize

Needs Assessment

$N = 6$ behavior change researchers and Small Steps for Big Changes coaches completed the needs assessment which resulted in recommendations being made regarding data collection requirements, user interface, and considerations of how to improve the equity, diversity, and inclusion within the app. From these recommendations, the app will include a researcher portal in which data pertaining to the following information can be accessed: exercise modality users are engaging in, time spent in different exercise modalities, compliance with prescribed exercise intensity (measured via rate of perceived exertion or heart rate), adherence to physical activity guidelines (e.g., number of minutes of logged exercise in comparison to Canadas physical activity guidelines), and personal goal attainment (e.g., if dietary and physical activity goals are different from recommendations are they achieving their short term goals).

To improve accessibility of this app, it will include clean and simple designs older and less tech-savvy users can easily navigate, written descriptions at a low-reading level to increase accessibility, both text and video demonstrations when applicable (and closed captioning available for all video content), easy to understand icons and symbols, and multiple-choice options where applicable to reduce user burden in having to type out answers required for research purposes. Finally, to ensure the app is representative of those at risk for developing type 2 diabetes, any actors/models used within app content will be diverse in age, race, and gender, and information provided within the app regarding exercise options will account for people ranging in abilities and cultures (e.g., providing exercise options that not only meet Western ideas but also options such as food foraging to increase activity levels).

Literature Review

Twenty reviews met our inclusion criteria. These reviews included active and sedentary individuals, as well as healthy adults and individuals with or at risk for chronic diseases (such as overweight, obesity, and cardiovascular disease). In general, these reviews reported positive outcomes associated with physical activity app use (Gal et al., 2018; Laranjo et al., 2021; Monteiro-Guerra et al., 2020; Petersen et al., 2019; Pradal-Cano et al., 2020; Romeo et al., 2019; Schoeppe et al., 2016; Silva et al., 2020; Yerrakalva et al., 2019). Specifically, apps were shown

to improve health behaviors (e.g., diet and exercise) and health-related outcomes (e.g., blood pressure, cholesterol levels, body mass index, mental health, health literacy, and blood glucose) (Gal et al., 2018; Jee, 2017; Laranjo et al., 2021; Pradal-Cano et al., 2020; Schoeppe et al., 2016; Wu et al., 2019).

Based on these reviews, physical activity apps tend to be well received by users and have been shown to improve different physical activity metrics in a range of studies with varying participant groups. Apps should be designed using behavior change theories, BCTs, and with end-user satisfaction in mind, considering high-quality and user-friendly graphic designs. Specifically, apps with high-quality and user-friendly graphics, that are easy to use, have high visual appeal, and include personalized or tailored content are consistently found to be well-accepted by users (Bondaronek et al., 2018; Jee, 2017; Laranjo et al., 2021).

BCTs Within Physical Activity Apps

Of the reviews which analysed the use of BCTs (Arigo et al., 2020; Bondaronek et al., 2018; Dounavi & Tsoumani, 2019; Gal et al., 2018; Hosseinpour & Terlutter, 2019; Jee, 2017; Kankanhalli et al., 2019; Laranjo et al., 2021; McGarrigle et al., 2020; Monteiro-Guerra et al., 2020; Petersen et al., 2019; Pradal-Cano et al., 2020; Schoeppe et al., 2016; Yerrakalva et al., 2019), self-monitoring was the most used technique, followed by goal setting, social comparison, feedback, and rewards. Regarding their efficacy and effectiveness, Hosseinpour and Terlutter (Hosseinpour & Terlutter, 2019) suggest that the BCTs' feedback and goal setting may be more effective than other techniques. Additionally, self-regulation techniques have shown higher intervention effectiveness in the promotion of physical activity (Laranjo et al., 2021). However, further research is needed to determine what combination of BCTs is most effective to improve physical activity within an app (Bondaronek et al., 2018).

Privacy and Data Security

All apps should include necessary security checks to ensure the privacy of participants; at a minimum, app developers should include understandable privacy policies to inform users how data will be collected and treated, and what measures are in place to handle and secure personal information (Bondaronek et al., 2018; Pradal-Cano et al., 2020). Despite the importance of user privacy, this is consistently highlighted as a neglected area within physical activity apps. For example, Bondaronek et al. (2018) found that in 29.2% of 65 analyzed apps, the privacy policy was not available, and in more than a half, there was no specification regarding how the data was secured. Security and protection of personal information is a relevant aspect among mHealth apps since it is not completely regulated. However, the Office of Privacy Commissioner of Canada jointly with the Offices of Information and Privacy Commissioner of Alberta and British Columbia developed the "Guidelines of Good Privacy Practices for Developing Mobile Apps" (Canada, 2012), based on the Personal Information Protection and Electronic Documents Act (PIPEDA), the Canadian federal privacy legislation. The essential factor to consider and include in the development of a mobile application is the disclosure of a privacy policy to inform the users about the data collection and utilization, along with the privacy and security measures with which the data is being treated. Other factors to consider are being transparent with the data management; collecting and retaining only necessary information; obtaining meaningful consent; and informing the user at the beginning, during and at the end of the app experience, how the data is being handled to ensure true consent.

Identification of App Features

Based on both the needs assessment and literature review, 14 potential app features were identified (for a description of all features see Table 2) grouped into 6 overarching app categories: exercise tools (exercise timer and videos, 6-min walk test, and heart rate calculator), logging (diet logging and self-reported exercise), reflections (progress tracker and notes), goal setting, FAQ (FAQ, exercise options, and DIY exercise sessions), and social support (prompts, a community hub, and links to Small Steps for Big Changes media). The "notes" feature was added following the prototype and testing phase based on ongoing research within Small Steps for Big Changes.

Define

Primary users of the app resulting from this work will be Small Steps for Big Changes clients who will use the app to bolster their autonomy over their health though use of evidence based BCTs. Secondary users include Small Steps for Big Changes coaches and researchers who will have the opportunity to monitor participant progress over time, and share actionable information to reduce type 2 diabetes risk.

Ideate

A total of 49 BCTs were assessed using the APEASE criteria; 24 of which were identified as suitable for the Small Steps for Big Changes app. Intercoder agreement of BCTs to be included/excluded from the app, as determined by Cohen's kappa and prevalence and bias-adjusted kappa were 0.75 and 0.76, respectively, indicating substantial agreement between coders. BCTs were included from 11 BCT categories (from a

Table 2 App features identified within the needs assessment and literature review

App feature	Description
Community hub	A space where past and current participants can connect with one another, suggest recipes and exercises, and post photos of their progress.
Diet logging	A space for participants to log their diet and monitor their daily vegetable and sugar intake.
DIY exercise session	A resource where participants can build their own exercise session (i.e., they can choose what exercise modality they would like to complete, specific exercises they want included in the session, and timing of intervals) so participants can follow-along to a written template for their exercise session.
Exercise timer	Includes timers which correspond to the exercises participants are asked to complete within the program (e.g., a 1-min high intensity intervals followed by a 1-min active rest, repeated 5 times).
List/video demonstrations of exercises	A resource where participants can get ideas about different exercises that can be done at home, outside, with(out) equipment, and proper form to completing these exercises.
FAQ	A space where participants can view all questions which are frequently asked within the program.
Full length exercise videos	Individual videos which correspond to the exercises modalities participants are asked to complete within the program (high-intensity continuous training and moderate-intensity continuous training).
Goal setting	A space for participants to add in a goal and create new plans on how, when, and where they would like to complete said goals.
HR calculator	As individuals progress through their fitness journey, their tailored HR zones will also likely change based on improved cardiorespiratory fitness. As such, this feature can allow participants to get updated target HR zones over time.
Progress tracking	A space for participants to track and monitor their progress over time. Within this feature participants can keep track of their HbA1c, weight, waist circumference, and blood pressure.
Prompts	Participants will be sent periodic motivational and educational prompts. An bank of theory-based prompts have already been developed with input from Small Steps for Big Changes end-users (MacPherson et al., 2021).
Self-reported exercise	Participants will be able to input details about their completed exercise sessions (e.g., modality, duration, rate of perceived exertion, and enjoyment, notes) to self-monitor their exercise over time.
6-min walk test	The 6-min walk test is a well-established measure of exercise capacity and functional status (Society, 2002). Currently Small Steps for Big Changes participants are asked to complete this test at baseline, 6, and 12 months post program. By integrating this feature into an app, participants can self-administer this test and see whether their total walking distance is increasing over time.
Small Steps for Big Changes links	Small Steps for Big Changes already has a walking group, information videos within the YMCA platform, a recipe hub, and newsletters. This feature will amalgamate all these resources into a single location for ease of use.

potential 19), primarily from the categories *Goals and Planning,* and *feedback and monitoring.*

The logic model was then developed by mapping these BCTs onto the 6 overarching app categories and COM-B domains (see Fig. 1 for a conceptual model highlighting relevant BCTs and COM-B domains, and Fig. 2 for more detailed conceptual models corresponding to each category). This step was completed by two authors (MM and NG) and reviewed by all remaining authors.

Prototype/Testing

Ratings

Features which were most often rated as Phase 1 features include: exercise timer (78%), goal setting (67%), self-reported exercise (67%), full-length exercise videos (56%), progress tracker (56%), heart rate calculator (44%), prompts (44%), and FAQ (44%). Phase 2 app features include Small Steps for Big Changes links (56%), DIY exercise session (44%), and the 6-min walk test (44%). Phase 3 features include diet logging (44%). The following features received equal scores for multiple categories: community hub (44% in both phase 2 and 3) and demonstrations of exercises (44% in both phase 1 and 2). No items were identified as not necessary for the app. See Table 3 for all ratings.

Ranking

When asked to rank the features from most to least important, the following features were ranked within the top 5 most often: exercise timer (78%), full-length exercise videos (78%), demonstrations of exercises (78%) and self-reported exercise (55%). The following app features were consistently ranked within the bottom 5: community hub (78%), diet logging (78%), and FAQ (56%). Final determination of which development phase each feature fell into was based on both the ratings and the rankings and can be found within Table 3. Consultations with a mobile app development company Pathverse (https://pathverse.ca/en/) then took place to facilitate the process of integrating BCTs into these identified app features.

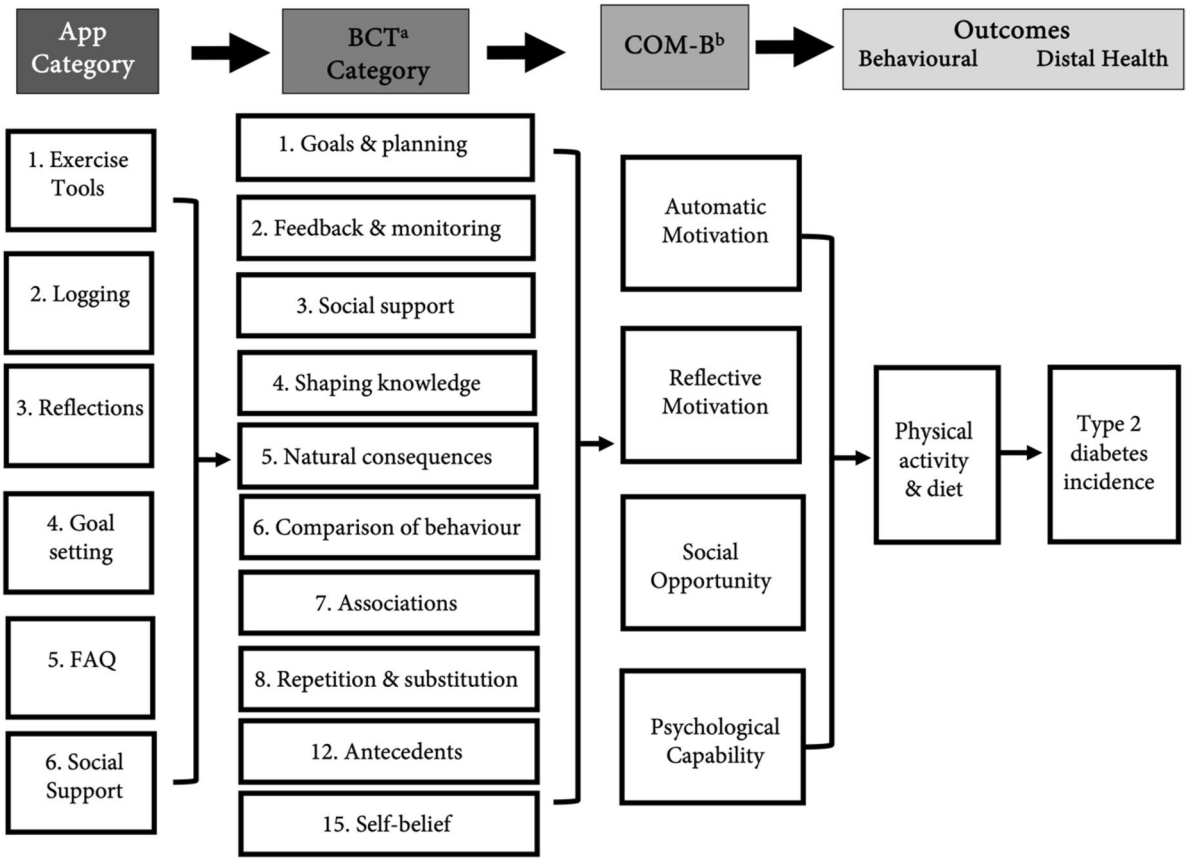


Fig. 1 Broad conceptual model. [a]BCT: behavior change technique; [b]COM-B: capability, opportunity, motivation, behavior

Table 3 App ratings from research team and PAC combined ($n=9$)

App feature	Phase 1	Phase 2	Phase 3	Not necessary	Ranked in top 5	Ranked in bottom 5	Development phase
Community hub	1 (11.11)	4 (44.44)	4 (44.44)	0	0	7 (77.78)	Phase 3
Diet logging	2 (22.22)	1 (11.11)	4 (44.44)	2 (22.22)	0	7 (77.78)	Phase 3
DIY exercise session	3 (33.33)	4 (44.44)	2 (22.22)	0	4 (44.44)	2 (22.22)	Phase 2
Exercise timer	7 (77.78)	2 (22.22)	0	0	7 (77.78)	1 (11.11)	Phase 1
FAQ	4 (44.44)	2 (22.22)	3 (33.33)	0	0	5 (55.56)	Phase 2[a]
Full length exercise videos	5 (55.56)	4 (44.44)	0	0	7 (77.78)	2 (22.22)	Phase 1
Goal setting	6 (66.67)	1 (11.11)	2 (22.22)	0	4 (44.44)	2 (22.22)	Phase 1
HR calculator	4 (44.44)	3 (33.33)	2 (22.22)	0	4 (44.44)	3 (33.33)	Phase 1
List/video demonstrations of exercises	4 (44.44)	4 (44.44)	1 (11.11)	0	7 (77.78)	1 (11.11)	Phase 2
Progress tracking	5 (55.56)	3 (33.33)	0	1 (11.11)	2 (22.22)	1 (11.11)	Phase 1
Prompts	4 (44.44)	3 (33.33)	2 (22.22)	0	3 (33.33)	3 (33.33)	Phase 2
Self-report exercise	6 (66.67)	3 (33.33)	0	0	5 (55.56)	2 (22.22)	Phase 1
6-min walk test	3 (33.33)	4 (44.44)	2 (22.22)	0	2 (22.22)	3 (33.33)	Phase 2
Small Steps for Big Changes links	1 (11.11)	5 (55.56)	3 (33.33)	0	0	6 (66.67)	Phase 2

All valued, *n* (%)

[a]While the FAQ was ranked most commonly in the bottom 5, during initial prototyping it was decided that demonstrations of exercises, Small Steps for Big Changes links as well as the DIY exercise sessions will be integrated into the FAQ feature, as such we decided to make it phase 2 to better align with the rankings of the other features to be integrated

App Behavior Change Scale

Based on the app behavior change scale, the app developed within phase 1 included 11 items out of a total 21 items on the scale, within phases 2 and 3, the app will extend to include a total of 19 items on the scale, indicating a high number of BCTs integrated within the app and a strong potential to enact behavior change (McKay et al., 2019). See Table 4 for examples of app features linked to each item on the App Behavior Change Scale.

Heuristic Evaluation

The one coder completed 6 tasks: 1) input a pre-specified weight, 2) navigate back to the home page, 3) log an exercise session, 4) edit an exercise session, 5) view total exercise minutes, and 6) set a pre-specified goal. A total number of 18 errors were identified, most often falling into the following heuristic categories: match ($n=6$ errors, 33%), user control ($n=6$, 33%), visibility ($n=2$, 11%), aesthetic ($n=2$, 11%), errors ($n=1$, 5%), and flexibility ($n=1$, 5%). This resulted in 8 (44%) errors being classified as a minor usability problem, 9 (50%) errors being classified as a major usability problem, and 1 (5%) being classified as a usability catastrophe. For more information on the errors found, see Table 5. These errors were then presented to the app development team at Pathverse to iterate on the design prior to future feasibility testing.

Discussion

This paper describes the systematic development of the Small Steps for Big Changes diabetes prevention app to improve behavior change adherence and reduce type 2 diabetes incidence. To our knowledge, this is the first app-based intervention developed using the FASTER. FASTER is a relatively recent framework within mHealth development and has been untested within the context of diabetes prevention as well as app development. In this case study, the FASTER provided a systematic process which encouraged the use of multiple data sources and end-user groups to ensure the timely development and uptake of this app in practice.

By bridging the processes for mHealth technology development seen in engineering design (focused on technical development and human factors) with that seen in clinical design (focused on theory, service delivery, and clinical outcomes), FASTER allows for efficient and comprehensive mHealth technology development. Specifically, the FASTER combines concepts from a variety of design process models including the Design School at Stanford University's "Design Thinking" (Institute of Design at Stanford, 2018) and the Medical Research Council's Complex Interventions Framework (Bleijenberg et al., 2018; Craig et al., 2013) to systematically develop and document mHealth technologies. This approach, coupled with the FASTER's guiding principles, allows for the timely and rigorous development based on theory and a variety of end-users. In this research, a series of studies were conducted to (I) identify the priorities of researchers, diabetes prevention coaches, and those at risk for type 2 diabetes within an app, (II) learn what current literature suggests is best practice for mHealth development, (III) narrow down what theory-based BCTs should be included within the app, and (IV) conduct a number of evaluations to iterate on app development. This led to the identification of 15 app features linked to 24 BCTs to bring about change within outcome behaviors of diet and physical activity.

Using the App Behavior Change Scale during the development ensured that the resulting app will maximize the theoretical potential for behavior change. While majority of the items of the scale were integrated into the proposed app features (19 out of 21), further research on the feasibility and effectiveness of the app is warranted. FASTER has 2 additional phases following the development: progressive usability and feasibility evaluation, and scaled evaluation and implementation. Ongoing validation of features such as the 6-min walk test, and overall feasibility is being conducted to progressively refine the app. Following this, the app will be deployed within the Small Steps for Big Changes diabetes prevention program and evaluated with individuals at risk for developing type 2 diabetes and diabetes prevention coaches. Within a scaled evaluation, it is recommended to examine long term intervention adoption, sustained use, and effectiveness (and cost-effectiveness; Wang et al., 2021).

Conclusion

This paper provides an exemplar for how evidence, end-users, and validated assessments can be incorporated into the timely development of an mHealth app aimed to improve behavior change adherence among individuals at risk for developing type 2 diabetes. By using the FASTER to guide development, and integrating evidence-based BCTs, end-user assessments, and reliable app assessments such as the App Behavior Change Scale, we were able to develop an app which is more likely to elicit behavior change and will actually be used in practice as it is based on end-user priorities.

Appendix 1

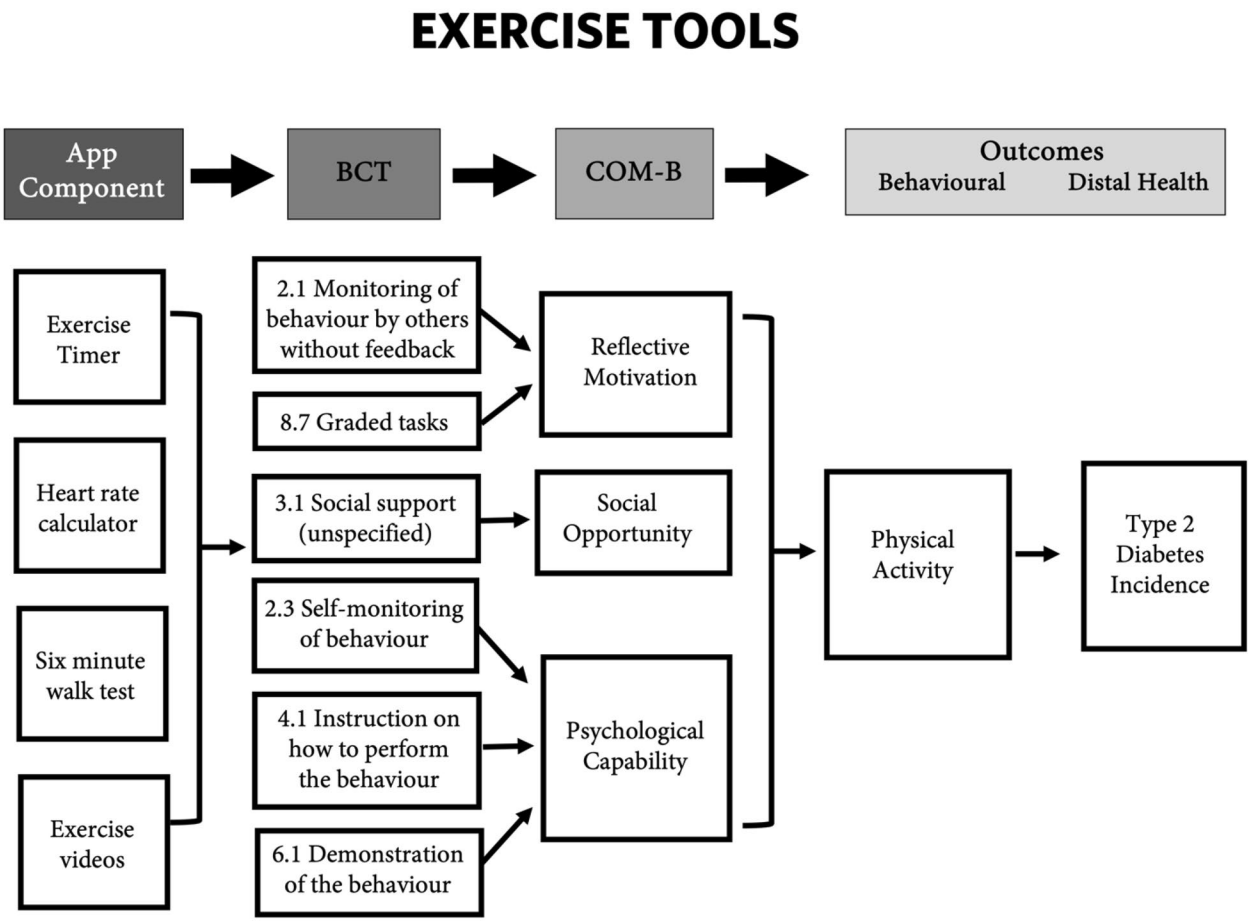


Fig. 2 Detailed conceptual models

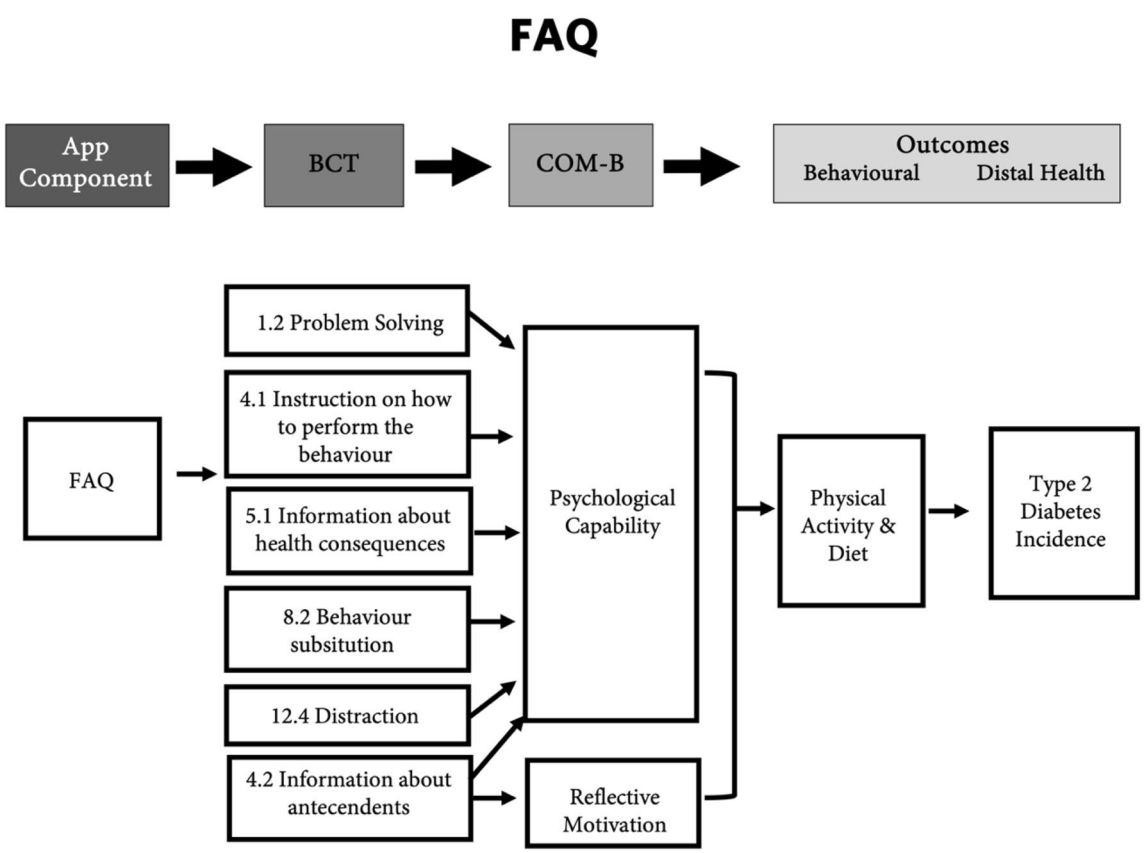


Fig. 2 (continued)

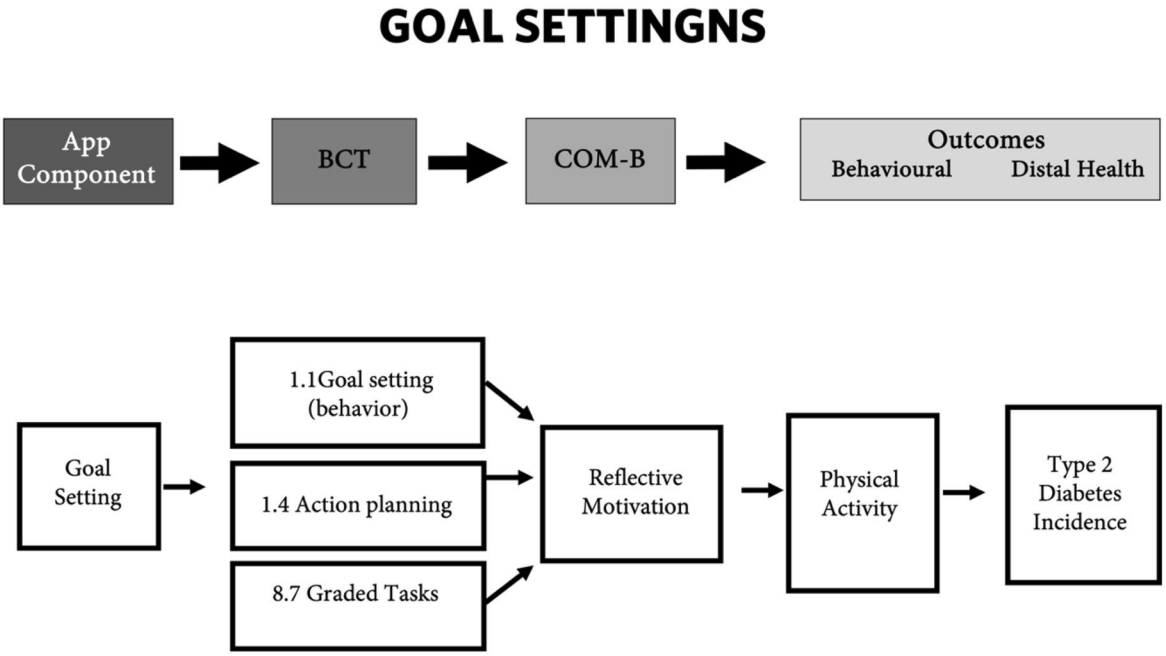


Fig. 2 (continued)

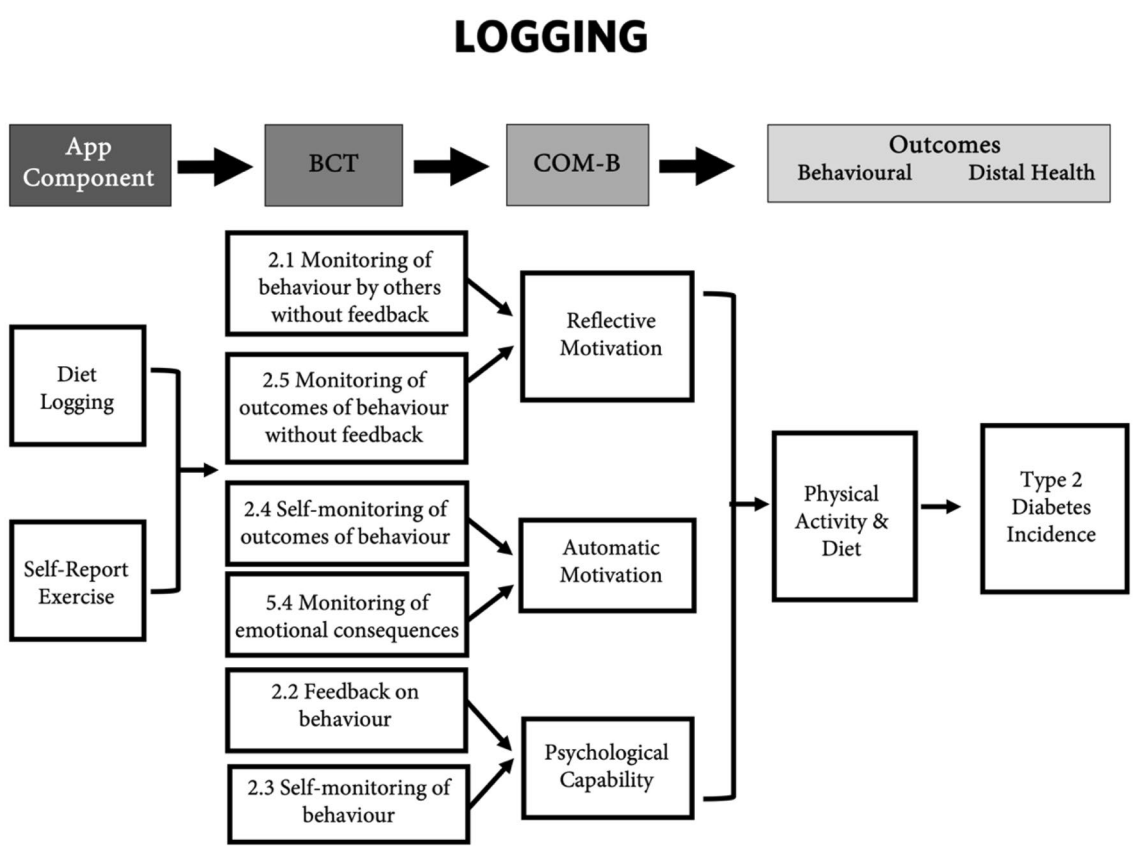


Fig. 2 (continued)

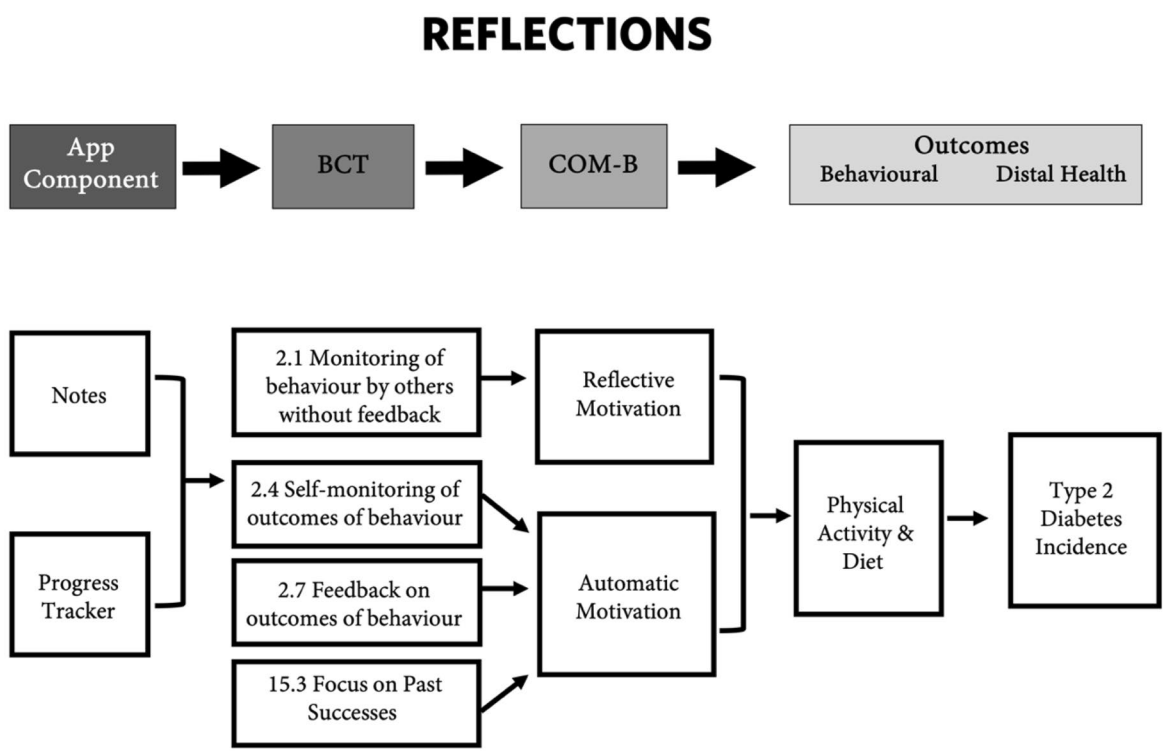


Fig. 2 (continued)

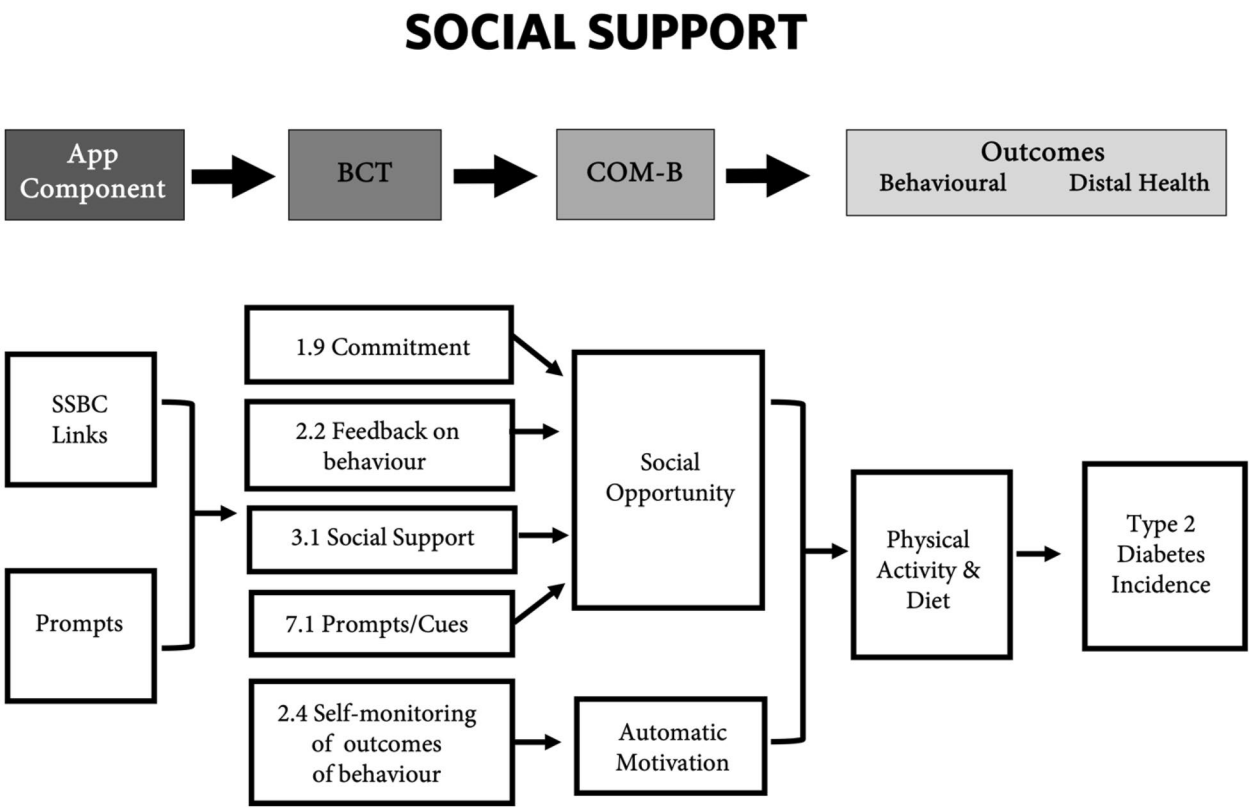
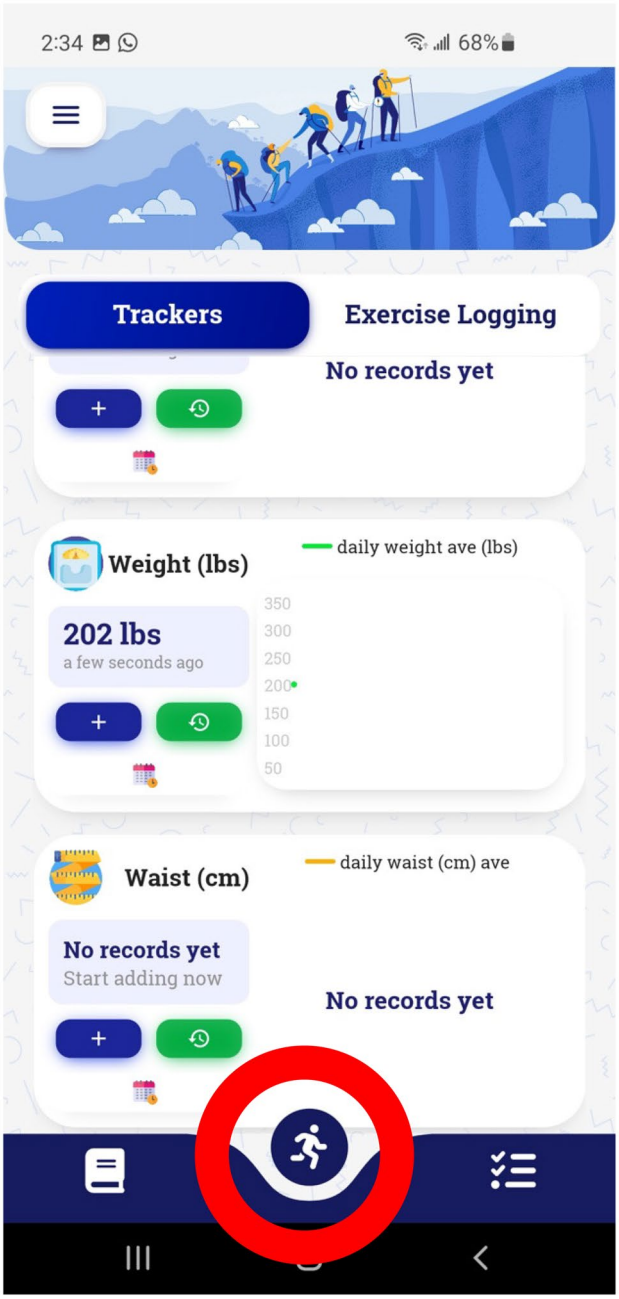


Fig. 2 (continued)

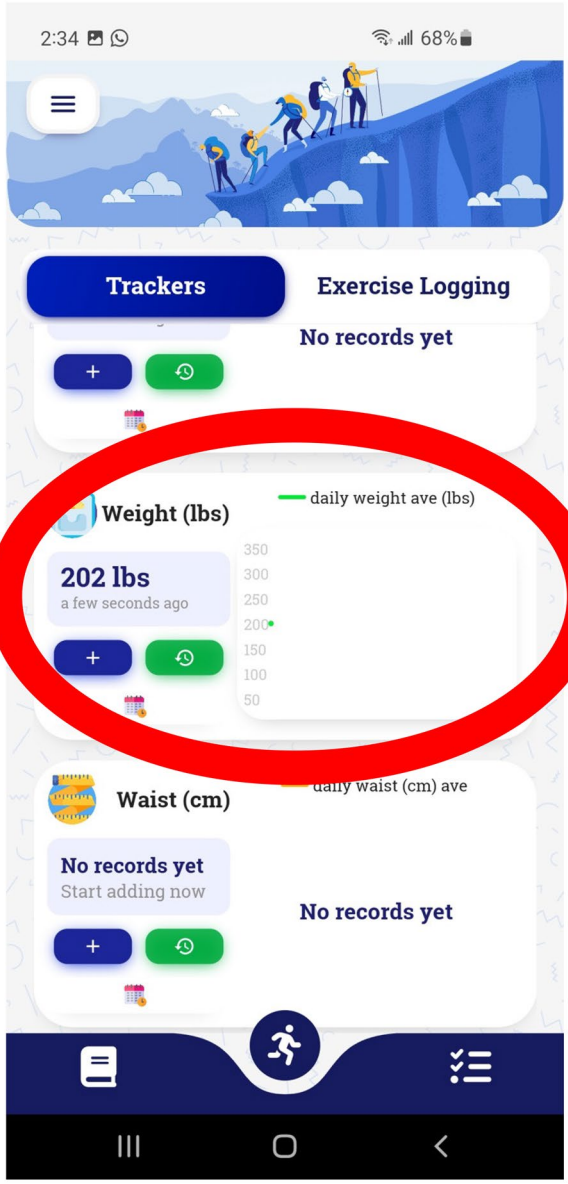
Task 1: Input a Prespecified Weight of 200 lbs

Observations:

- It is not clear that the icon of a person running is where you should go to log weight (among other things).



- The screen for self-monitoring is too small (e.g., when you get to daily weight screen it is hard to read the weight (in light grey and very small font)



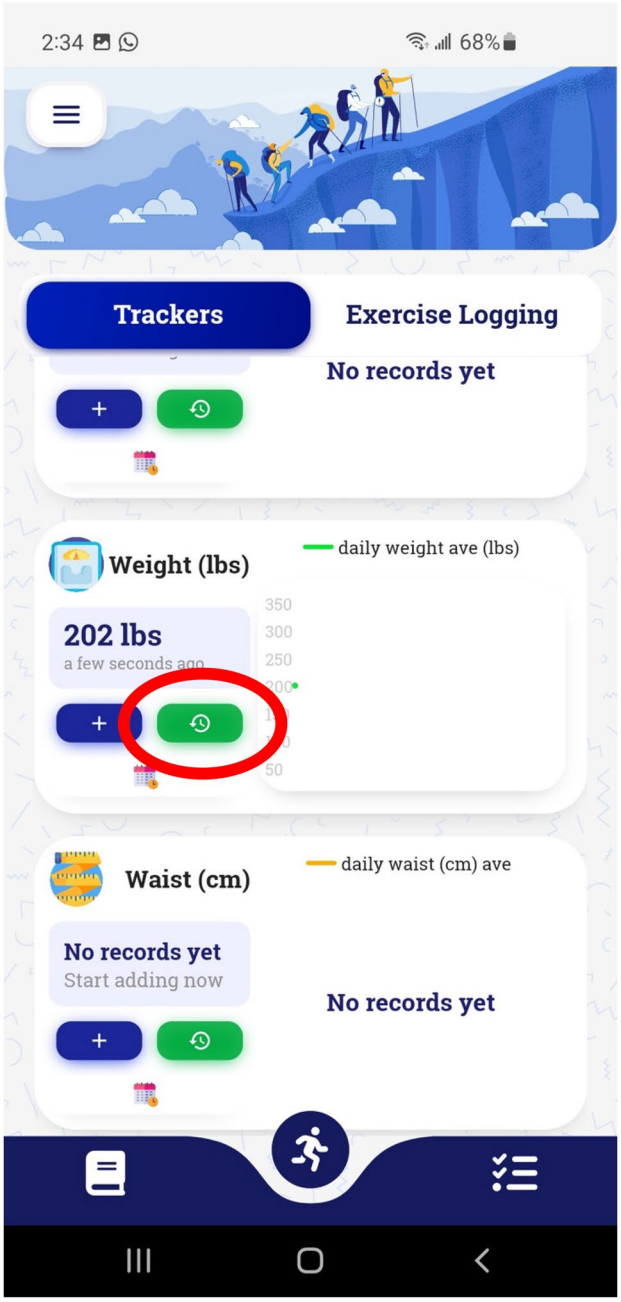
- It is unclear what the green button of the clock with the arrow means until you press it

– You cannot add in another weight while you are on this screen

Task 2: Navigate Back to the Home Page

Observations

- Not clear what we are considering the home screen right now (are the modules the home screen?)

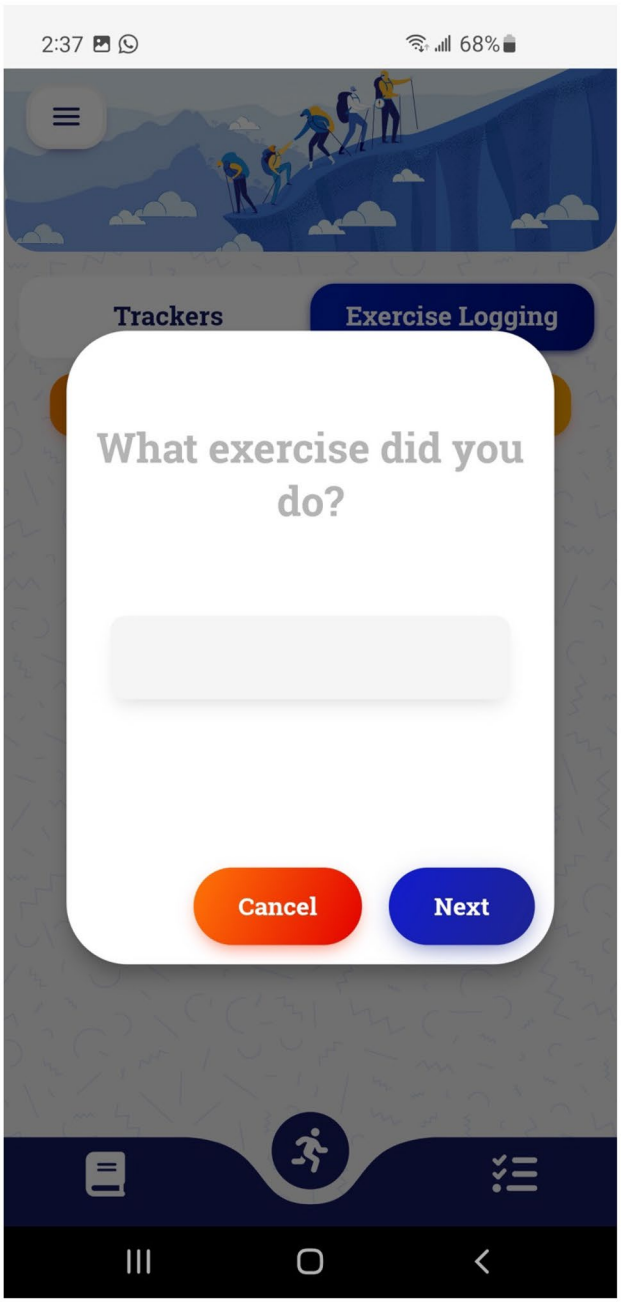


- Clicked on the three lines at the top which allowed me to see the study I am currently in but not click on anything

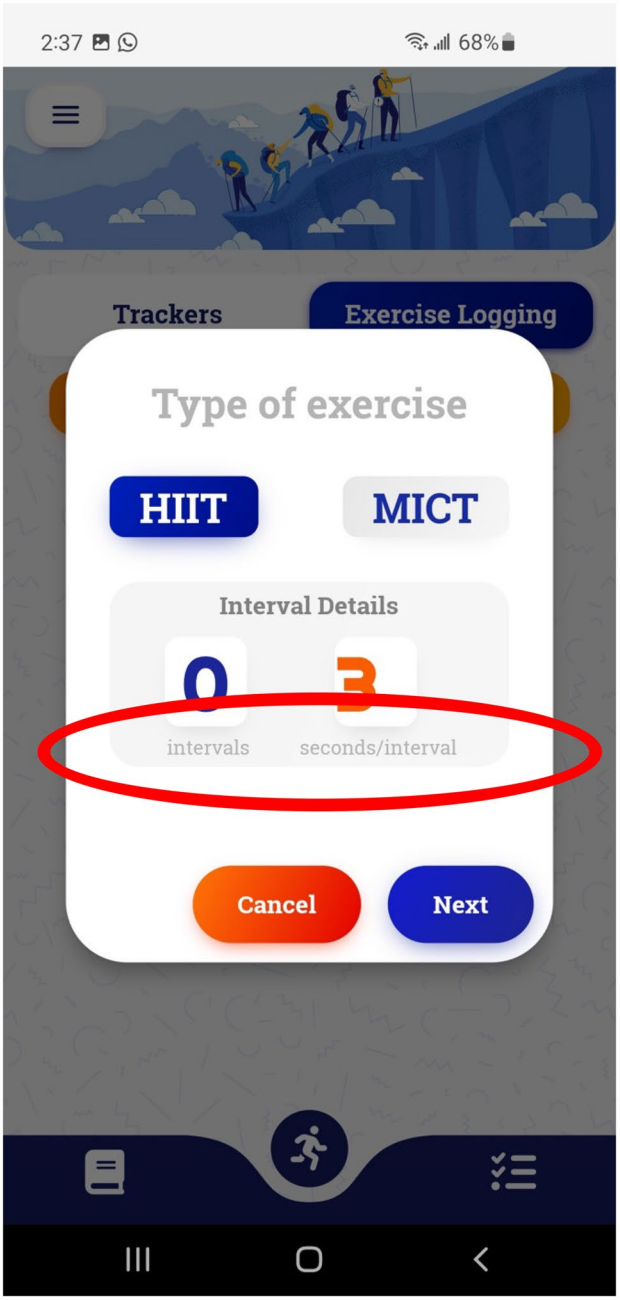
Task 3: Log a 12 min and 30 s HIIT Exercise Session with 5 Intervals at 30 s each

Observations:

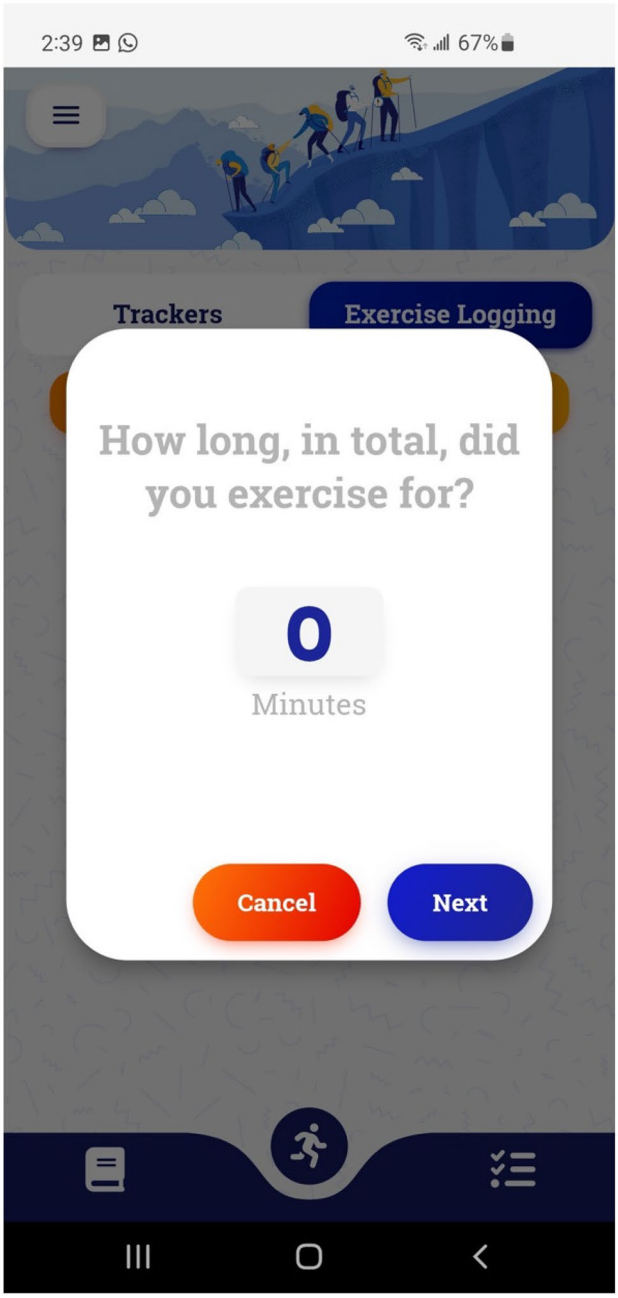
- What exercise did you do? I wanted to put in HIIT but I think this question wants me to say walk or bike or hike… maybe we can add in examples here (what exercise did you do? e.g., walk on the treadmill, bike, etc.)



- Interval details are too small and font is light to be able to clearly see (e.g., number of intervals and seconds/interval)



- Seconds/interval does not provide seconds from 1 to 60 (gives the option to put in 3, 3, 3, 31, 3, 3, 3, 3, 37…
- How long did you exercise for: not clear that I should be scrolling through the numbers and we need to add in another section to add in seconds (should have both minutes and seconds).



- There is no option to go back to a previous screen if I messed up (e.g., I misspelled my exercise and couldn't change it once I clicked next)

Table 4 Examples of app features linked to each item on the app behavior change scale

Scale: item number and question	Definition	Included in app *(phase)?*	Example from Small Steps for Big Changes app
Knowledge and information			
1.1 Does the app have the ability to customize and personalize some features?	Elements of the app can be personalized through specific tools or functions that are specific to the individual using the app.	Y (1)	Users can create personalized goals/action plans.
1.2 Was the app created with expertise and/or does the app provide information that is consistent with national guidelines?	This would be found in the about section or generally in the app.	Y (1)	Created by behavior change researchers.
1.3 Does the app ask for baseline information?	This includes BMI, weight, smoking rate, exercise, or drinking behaviors.	Y (1)	Users can log their weight, waist circumference, HbA1c, blood pressure, and exercise.
1.4 Does the app provide instruction on how to perform the behavior?	The app is clear in telling the person how to perform a behavior or preparatory behaviors, either verbally, through video, or in written form.	Y (2)	The app includes exercise videos with instruction on how to engage in HIIT and MICT.
1.5 Does the app provide information about the consequences of continuing and/or discontinuing behavior?	The app gives the user information about the consequences of behaviour in general, this includes information about the relationship between the behavior and its possible or likely consequences in the general case. This information can be general or personalized.	Y (2)	The FAQ section includes information on the benefits of engaging in dietary and physical activity behavior change.
Goals and planning			
2.1 Does the app ask for willingness for behavior change?	Is there a feature during setup where you describe how ready you are for behavior change?	Y (1)	The app does not specifically ask users their willingness to change their behaviour; however, the assumption was made that participants within the Small Steps for Big Changes diabetes prevention program choosing to download and register for the app are indicative of a user's willingness to change their physical activity behaviors.
2.2 Does the app allow for the setting of goals?	The person is encouraged to make a behavioral resolution. The person is encouraged to set a general goal that can be achieved by behavioral means. This includes sub-goals or preparatory behaviors and/or specific contents in which the behavior will be performed. The behaviour in this technique will be directly related to or be a necessary condition for the target behavior.	Y (1)	Users can set their own diet and/or physical activity goal.
2.3 Does the app have the ability to review goals, update, and change when necessary?	Involves a review or analysis of the extent to which previously set behavioral goals (regardless of short or long) were achieved.	Y (1)	While users cannot change a specific goal once it has been set, they can delete goals, set new goals, and review past goals and mark them as completed.
Feedback and monitoring			
3.1 Does the app give the user the ability to quickly and easily understand the difference between current action and future goals?	Allows user to see how they are tracking against a goal and to see the difference between what they want to do and what they are currently doing. This will give some feedback on where they are at and what they need to change to get to where they want to be.	Y (1)	The user can view their progress towards their weekly activity goal visually within the exercise tracker.

Table 4 (continued)

Scale: item number and question	Definition	Included in app *(phase)?*	Example from Small Steps for Big Changes app
3.2 Does the app have the ability to allow the user to easily self-monitor behaviour?	The app allows for a regular monitoring of the activity.	Y (1)	Users can self-monitor their physical activity manually or they can link the app with their apple health or android health accounts.
3.3 Does the app have the ability to share behaviours with others (including social media or forums) and/or allow for social comparison?	The app allows the person to share his or her behaviours on social media or in forums. This could also include a buddy system or leaderboard.	Y (3)	The "community hub" will allow users to connect with peers.
3.4 Does the app have the ability to give the user feedback—either from a person or automatically?	The app is able to provide the person with feedback, comments, or data about their own recorded behavior. This might be automatic or could be personal.	N	
3.5 Does the app have the ability to export data from the app?	The app allows for the export of information and progress to an external user.	Y (1)	Self-monitoring and goal setting can be exported by the research team.
3.6 Does the app provide a material or social reward or incentive?	App provides rewards for attempts at achieving a behavioural goal. This might include efforts made toward achieving the behavior or progress made in preparatory steps toward the behaviour or in achieving a goal.	N	
3.7 Does the app provide general encouragement?	The app provides general encouragement and positive reinforcement on actions leading to the goal.	Y (2)	Motivational prompts created by MacPherson et al., (M. MacPherson et al., 2021) will be integrated within the app.
Actions			
4.1 Does the app have reminders and/or prompts or cues for activity?	The app prompts the user to engage in the activity. The app has the ability to give notifications or reminders to cue the behaviour.	Y (1)	Users can choose whether they would like to receive reminders when they set a goal.
4.2 Does the app encourage positive habit formation?	The app prompts explicit rehearsal and repetition of the behavior—not just tracking or logging.	Y (2)	Educational prompts created by MacPherson et al., (M. MacPherson et al., 2021) will be integrated within the app.
4.3 Does the app allow or encourage for practice or rehearsal, in addition to daily activities?	App does not have a lock on activities or a number that you cannot exceed daily.	Y (1)	There is no limit on the number of minutes of activity a user can log in a day.
4.4 Does the app provide opportunity to plan for barriers?	The app encourages the person to think about potential barriers and identify ways of overcoming them.	Y (2)	The FAQ section provides users with suggestions on how to overcome common barriers.
4.5 Does the app assist with or suggest restructuring the physical or social environment?	The app prompts the person to alter the environment in ways that it is more supportive of the target behavior.	Y (2)	The FAQ section provides suggestions on how to restructure the environment to promote physical activity.
4.6 Does the app assist with distractions or avoidance?	The app gives suggestions and advice on how the person can avoid situations or distract themselves when trying to reach their goal.	Y (2)	The FAQ section provides information on distractions or avoidance of physical activity.

Table 5 Heuristic evaluation results and notes

Heuristic	Violation	Comment	Severity (1–4)[a]
Visibility	Tasks 1, 6	1. When you have clicked on the clock button you are unable to add in a new weight 2. When setting a goal, you are able to click on the day and it turns green; however, it is unclear why it does that or if it is necessary for you to click that date	1. 2 2. 2
Match	Tasks 1, 2, 3, 6	1. It is unclear that an icon of a person running is the location where I should log weight 2. It is unclear what the green button with the clock and arrow means until you press it 3. It is unclear what we consider to be the "home" screen 4. I clicked on the three lines at the top to see a menu, but it only showed be that I am currently in the small steps study 5. When asked the question "what exercise did you do" I wanted to answer with HIIT, but then the next question asked me if I did HIIT or MICT 6. When asked the question "how long did you exercise for" it was not clear to me that I should be scrolling through the numbers	1. 3 2. 3 3. 3 4. 2 5. 2 6. 3
User control	Tasks 3, 4, 6	1. Seconds/interval does not provide seconds from 1 – 60 2. When adding in an exercise there is no option to navigate back to previous screens 3. I can only delete an exercise session, but cannot edit it 4. Notifications for goal setting should be modifiable (e.g., weekly or daily) 5. It is unclear why there is a character count for goal setting 6. There is no option to account for long and short term goals and set reminders accordingly	1. 4 2. 3 3. 3 4. 2 5. 2 6. 2
Consistency			
Errors	Task 6	1. More specific details should be added to be filled in to decrease potential for errors (e.g., what, when, where, how long)	1. 2
Recognition			
Flexibility	Task 5	1. When I viewed my total exercise minutes (within the tracker screen), my logged exercise does not seem to impact my MVPA goal	1. 3
Aesthetic	Tasks 1, 3	1. The screen for self-monitoring is too small 2. When logging exercise, the interval details are too small and written in too light of a font to clearly see	1. 3 2. 3
Recovery			
Help			

[a] 1 = cosmetic problem; 2 = minor usability problem; 3 = major usability problem; 4 = usability catastrophe

Task 4: Edit an Exercise Session. Change the Number of Intervals in the HIIT Session you Logged to 6

Observations:

- I can only delete an exercise session. Not edit it

Task 5: View Your Total Exercise Minutes

Observations:

- When I viewed my total exercise minutes (within the tracker screen) screen my logged exercise does not seem to impact my MVPA goal… If I log a 12-min exercise should not that count towards my 30 min/day?

Task 6: Create a High Priority Goal to Fill Half Your Plate With Leafy Green Vegetables in Your Next 4 Meals and set a Daily Notification

Observations:

- Can we change the notifications to have different options (e.g., daily, weekly)?
- When I click the date, it turns green but I don't know what does or if I need to click it to create my goal
- Why is there a character count on the goals?
- Can we add in more specific goals?
  - What, when, where, how long?
  - Instead of priority low, medium, high, can we add in a confidence rating once they have created a goal out of 10?

- What if I want my goal to be short term? I want to do this thing for the next three days and I want to receive notifications? I can set daily notifications but I can not set a stop date for them and I can not edit them (so I guess I will receive notifications until I mark the goal as complete?)

Description of Nielsen's 10 Usability Heuristic Categories

Note, these descriptions are directly quoted from (Kushniruk & Patel, 2004).

Heuristic 1: Visibility of system status. This principle states that the user should be informed as to the state of the system at any given moment. The user should know where he or she is in terms of carrying out a procedure using a system (e.g., if patient data are being uploaded, or if the system is currently processing in response to a user request for data retrieval). Users should know if an operation was successfully completed (e.g., a medication was discontinued in a computerized patient record system) or what additional steps are needed in order to complete a task successfully.

Heuristic 2: Match the system to the real World. This heuristic embodies two concepts. First use of the "natural" language of the user (not jargon or computer system terms, particularly if the users are not computer literate) is recommended, e.g., a button with the label "Obtain free sample program" is preferable to a button labeled with the word "Downloads"). Second, it is best to use real-world conventions or natural mappings. A natural mapping refers to the approximation of the real world in the computer system, for example, having a "rewind" button on a computer to indicate backwards navigation maps to the physical rewind button on the common VCR or cassette recorder.

Heuristic 3: User control and freedom. The main concepts embodied in this heuristic, which essentially states that the user should feel he/she is in control of the system (and not the reverse) are the following: (1) provide clearly marked exits, (2) support undo and redo transactions, and (3) make it difficult to perform irreversible actions. Essentially, there should always be a way for users to back out of current actions (e.g., aborting entry of a medication in a computerized patient record system) and that they should not perceive that they are controlled or irreversibly locked into actions or procedures by the system.

Heuristic 4: Consistency and standards. The user interface and basic system operations should be consistent. Ideally, one module of a system should have the same or similar conventions for exiting or entering, or carrying out basic operations. For example, in one part of a CPR system, a user might have to exit by clicking on the corner of a window, while for another module there may be an exit pop-up box. Due to lack of consistency, users may end up being confused and find learning the basic operations of the interface more difficult than if consistent standards for carrying out such a basic operation were employed. Consistency also applies to the general layout and position on the screen of things like menus, exit buttons and other controls, use of standard terminology (e.g., for files, operations like "new," "open," and "close" used throughout the system).

Heuristic 5: Error prevention. This principle states that designers should design interfaces that prevent error from occurring. This includes simplifying screens, avoiding complex modes that may be confusing to users and testing interfaces to ensure that they are simple and easy to use. Interfaces should be designed specifically to decrease the potential for occurrence of slips and mistakes. A slip is defined as an unintentional error in using a system, such as making a typo or pressing the wrong key or selecting the wrong menu item by overshooting and a mistake is defined as an error occurring through conscious deliberation (e.g., resulting from misunderstanding of how to carry out a basic operation with the system such as the sequence of steps to document a medical problem in a CPR system).

Heuristic 6: Minimize memory load—support recognition rather than recall. Based on the psychological principle that human beings rarely are required to remember all of the features of any object by rote memory, this heuristic states that user interfaces should support recognition rather than recall. Consistent with this principle is the psychological finding that people remember and process information in limited number of "chunks" (typically of five plus or minus two items). The implications of this for user interface design is that interfaces should support recognition of a meaningful and limited number of items or chunks (e.g., with a menu consisting of five plus or minus two items versus 50 items in order to support information and recognition processes).

Heuristic 7: Flexibility and efficiency of use. Although all users cannot be satisfied regarding their preferences in the design of a user interface, designers should try to make user interfaces as customizable and flexible as possible. For example, some systems allow experienced users to create shortcuts for common operations or allow users to set up their own preferences for display of screens or information that appears upon the starting up a system.

Heuristic 8: Aesthetic and minimalist design. This heuristic states that often the simplest and most minimal design options are often the best for ensuring usability. For example, adding many features and more items to a user interface will not necessarily make it easier to use and at some point detract from the system's overall usability (there are many examples of Web sites that violate this principle with

too much information presented and too many flashy "add-ons" and features that may detract from actual use). Other approaches to ensuring minimalist design include the "layering" of information, so that rather than providing too much complex information on one screen, information is layered into a number of simple and easier to understand screens.

Heuristic 9: Help users recognize, diagnose and recover from errors. If the user makes a mistake, the system should provide clear and easy to understand information about how to recover from the error. Error messages should be phrased in clear and meaningful language and not by using cryptic statements such as "fatal error #5." Furthermore, error messages should be precise and constructive as well as being "polite." If users make mistakes there should be obvious ways to correct them.

Heuristic 10: Help and documentation. This heuristic states that help should be available to users when needed. This could consist of a list of topics (like a table of contents) giving help about specific topics, such as printing, formatting, etc. Other forms of help include FAQs (frequently asked questions) as well as context sensitive help facilities, designed to adjust their content and advice based on the type of interaction the user needed help with.

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Declarations

Competing Interests The authors declare no competing interests.

Ethics Approval This study was a quality improvement project, as such no ethical approval was required.

Consent to Participate Informed written consent to participate was obtained for this study.

Consent to Publish Informed consent for publication was obtained for this study.

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