

Efficacy of StepAdd, a personalized mHealth intervention based on social cognitive theory to increase physical activity among type 2 diabetes patients: protocol for a randomized controlled trial

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Abstract

Background: Increasing physical activity improves glycemic control in type 2 diabetes mellitus (T2D) patients. Mobile health (mHealth) interventions have been proven to increase exercise, but engagement often fades with time. Because use of health behavior theory in mHealth design can increase effectiveness, we developed StepAdd, an mHealth intervention based on the constructs of Social Cognitive Theory (SCT). StepAdd improves exercise behavior self-efficacy and self-regulation through use of goal setting, barrier-identifying and barrier-coping strategies, and automatic feedback functions.

Objective: In this study, we aim to investigate the efficacy and safety of StepAdd, a mobile health exercise support system for T2D patients.

Methods: This is a randomized, open-label, multi-center study targeting 160 T2D patients from five institutions in Japan with a 24-week intervention. The intervention group will record daily step counts, body weight (BW), and blood pressure (BP) using the SCT-based mobile application (app) StepAdd and receive feedback on these measurements. In addition, they will set weekly step count goals, identify personal barriers to walking, and define strategies to overcome these barriers. The control group will record daily step counts, BW, and BP using a non-SCT-based placebo app. Both groups will receive monthly consultations with a physician who will advise patients on lifestyle modifications and usage of the app. The 24-week intervention period will be followed by a 12-week observational period to investigate the sustainability of the intervention's effects.

The primary outcome is between-group difference in the change of HbA1c value at 24 weeks. The secondary outcomes include other health measures, measurements of steps, measurements of other behavior changes, and assessments of app usage. The trial began in January 2023 and is intended to conclude in December 2025.

Results: As of September 5, 2023, we have recruited 44 patients. We expect the trial to conclude by October 8, 2025, with the follow-up observation period concluding by December 31, 2025.

Conclusions: This trial will provide important evidence on the efficacy of an SCT-based mHealth intervention in improving physical activities and glycemic control in type 2 diabetes patients. If this study proves the intervention to be effective and safe, it could be a key step towards the integration of mHealth as part of the standard treatment received by diabetes patients in Japan. Clinical Trial: Trial Registration: jRCT2032220603

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Original Manuscript

Original Paper

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Efficacy of StepAdd, a personalized mHealth intervention based on social cognitive theory to increase physical activity among type 2 diabetes patients: protocol for a randomized controlled trial

ABSTRACT

Background

Increasing physical activity improves glycemic control in type 2 diabetes mellitus (T2D) patients. Mobile health (mHealth) interventions have been proven to increase exercise, but engagement often fades with time. Because use of health behavior theory in mHealth design can increase effectiveness, we developed StepAdd, an mHealth intervention based on the constructs of Social Cognitive Theory (SCT). StepAdd improves exercise behavior self-efficacy and self-regulation through use of goal setting, barrier-identifying and barrier-coping strategies, and automatic feedback functions. A single-arm pilot study of StepAdd among 33 patients with type 2 diabetes showed a large increase in step-count (mean change of 4,714 daily steps, or +86.7%) along with strong improvements in BMI (mean change of -0.3 kg/m²) and HbA1c (mean change of -0.79 percentage points).

Objectives

In this study, we aim to investigate the efficacy and safety of StepAdd, a mobile health exercise support system for T2D patients, via a larger, longer, and controlled follow-up to the pilot study.

Methods

This is a randomized, open-label, multi-center study targeting 160 T2D patients from five institutions in Japan with a 24-week intervention. The intervention group will record daily step counts, body weight (BW), and blood pressure (BP) using the SCT-based mobile application (app) StepAdd and receive feedback on these measurements. In addition, they will set weekly step count goals, identify personal barriers to walking, and define strategies to overcome these barriers. The control group will record daily step counts, BW, and BP using a non-SCT-based placebo app. Both groups will receive monthly consultations with a physician who will advise patients on lifestyle modifications and usage of the app. The 24-week intervention period will be followed by a 12-week observational period to investigate the sustainability of the intervention's effects.

The primary outcome is between-group difference in the change of HbA1c value at 24 weeks. The secondary outcomes include other health measures, measurements of steps, measurements of other behavior changes, and assessments of app usage. The trial began in January 2023 and is intended to conclude in December 2025.

Results

As of September 5, 2023, we have recruited 44 patients. We expect the trial to conclude by October 8, 2025, with the follow-up observation period concluding by December 31, 2025.

Conclusions

This trial will provide important evidence on the efficacy of an SCT-based mHealth intervention in improving physical activities and glycemic control in type 2 diabetes patients. If this study proves the intervention to be effective and safe, it could be a key step towards the integration of mHealth as part of the standard treatment received by diabetes patients in Japan.

Trial Registration: jRCT2032220603

Keywords: digital therapeutics, behavior change, social cognitive theory, exercise, type 2 diabetes, mobile application, randomized controlled trial

INTRODUCTION

Worldwide, about 537 million people in the 20-79 year age range have diabetes [1]. Diabetes is a serious public health concern with a considerable impact on health expenditures and human life, causing 4.2 million deaths per year [2, 3]. Diabetes is a disease that is difficult to cure once it develops, and if left untreated causes complications such as cardiovascular disease and microvascular complications [4].

Exercise has been proven to improve glycemic control and other metabolic parameters, including low-density lipoprotein cholesterol, visceral adipose tissue and blood pressure [5]. Diabetes patients are recommended to commit to a minimum of 150 minutes of moderate to vigorous physical activity per week. As walking has been rated as the most favored form of physical activity by sedentary groups, it is a suitable form of exercise for diabetes patients, who typically have lower physical activity volume [6, 7]. The recommended 150 minutes of activity translates into taking at least 7,500 steps per day, of which 3,000 steps should be at moderate to vigorous intensity [8]. Although physical exercise has been proven effective in improving blood glucose, reducing cardiovascular risk factors, and improving cardiorespiratory fitness in type 2 diabetes patients, lack of motivation has been reported to be a barrier [9]. It is difficult for patients to change their current exercise behavior by themselves [9]. It has also been reported that adherence to physical activities is lower than adherence to medication regimens [10].

Mobile health (mHealth) interventions such as mobile phone applications that support self-management have proven to be effective in increasing physical activity of patients [11, 12] and improving glycemic control [13, 14]. According to the American College of Sports Medicine, online fitness programs, exercise-related digital services, and use of mobile phones are increasingly popular in the worldwide exercise community [15]. Recent meta-analyses found a moderate-to-large positive effect in daily step changes due to use of smartphone apps that focus on physical activities [16, 17]. Although mHealth is effective, patients lose motivation to engage with the intervention after some time [18, 19]. Personalization of intervention components has been shown to increase patient motivation and engagement in using the app [20]. Several studies have found that tailored interventions are more effective in changing health behavior than non-tailored interventions [21, 22].

While several studies evaluating the effectiveness of personalized interventions have reported an increase in the physical activity levels of users [23, 24], work to-date generally does not use a theory-based framework with mHealth. In particular, social cognitive theory (SCT), with a human agency model in which individuals proactively self-reflect, self-regulate, and self-organize, offers a powerful framework that could support improved mHealth interventions [25, 26]. SCT has been used to understand behaviors relating to physical activity due to its emphasis on the dynamic interactions between the individual, the environment, and behavior [27]. SCT-based interventions were found to be effective at changing physical activity behaviors among people with prediabetes [28].

To address this research gap, we developed a personalized smartphone-based mHealth intervention, StepAdd, to improve physical activity levels and diabetes control among patients with type 2 diabetes by using the SCT framework. In 2021, we conducted a pilot study of StepAdd among 33 type 2 diabetes patients attending Mitsui Memorial Hospital in Japan using a pre-post evaluation design over 12 weeks. The results show very high retention (97.0%), a very large increase in mean daily steps (from 5,436 to 10,150 steps per day, an 86.7% increase), and resulting positive changes in BMI (mean change of -0.3 kg/m²) and HbA1c (mean change of -0.79 percentage points) [29]. Growth in step count continued throughout the intervention, as did growth in step count goals. The step goal achievement rate remained steady and high throughout the intervention. With strong positive impacts and strong, on-going engagement in this pilot study, we concluded that StepAdd warranted a deeper study.

The current trial aims to investigate the efficacy of StepAdd, also known as diabetic kidney disease – exercise therapy (DKD-ET), in a longer (24 week), randomized controlled trial. The specific research objectives and hypotheses are as follows:

Objective 1:

To investigate the efficacy of StepAdd in improving physical activity levels, as measured via daily step count.

We hypothesize that, at the end of the intervention, the intervention group will achieve a statistically significant increase in daily step count relative to the counts of the control group.

Objective 2:

To investigate the efficacy of StepAdd in reducing HbA1c levels.

We hypothesize that, at the end of the intervention, the intervention group will achieve a statistically significant reduction in the primary outcome, HbA1c levels, relative to HbA1c levels in the control group.

Objective 3

To assess the effect of StepAdd in improving seven self-care behaviors (walking duration, adherence to diabetes self-care, self-management behavior to enhance and maintain physical activity, self-regulation of physical activity, self-efficacy to achieving targeted daily steps, self-efficacy to deal with barriers in achieving targeted daily steps, and self-efficacy for health promoting behaviors) and ten health indicators (FBG, eGFR, BMI, BP, HDL, LDL, TG, locomotive syndrome, diabetes related emotional distress, and diabetes-dependent quality of life).

We hypothesize that, at the end of the intervention, the intervention group will achieve a statistically significant improvement in the seven self-care behaviors and ten health indicators.

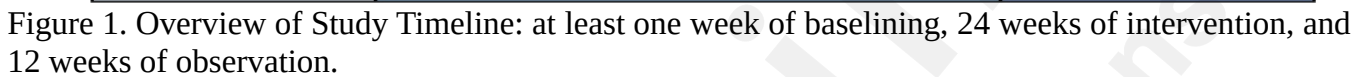
METHODS

Study design

This study is an open label, multi-center (Textbox 1), confirmatory, two-armed randomized controlled trial to study the efficacy of an mHealth intervention, StepAdd, in promoting exercise behavior among T2D patients. The conduct and reporting of the trial will follow the CONSORT guidelines. This study (Figure 1) begins with recruitment, a baseline measurement period (nominally two weeks, but at least seven days), and randomized assignment to intervention and control groups. The patients in the intervention group will use the SCT-based StepAdd smartphone application to measure weight, BP, and daily steps, receive personalized feedback, and develop updated step goals. The patients in the control group will use a placebo smartphone application that simply measures and reports weight, BP, and daily steps. Both groups will receive monthly consultations with their physician. The intervention will last for 24 weeks and is followed by a 12-week observational period. This study will be conducted across three years, from January 1, 2023, to December 31, 2025.

Textbox 1. Participating institutions: five medical centers within Japan

University of Tokyo Hospital Akita University Hospital Yokohama City University Hospital Yokohama City University Medical Center Yokohama Rosai Hospital
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This mHealth intervention uses a pedometer, a body weighing scale, a blood pressure monitor, and a smartphone with an mHealth app, StepAdd. The app is an iOS application on an iPhone that communicates with the StepAdd server. An administrative screen is used by a medical professional (either a physician or a clinical research coordinator who is overseen by a physician). Pedometer count, blood pressure, and body weight are measured at home. The pedometer count is synchronized with the app continuously during the day, and the blood pressure and body weight are synchronized with the app daily when patients open the app at the time of measurement. The app interacts with the patient to establish personalized goals, provide personalized feedback, and define and assess the efficacy of patient-specific coping skills (Figure 2). This app was developed in collaboration with foo.log Co., Ltd, a software development company. The control group uses a placebo app supporting the same measurements but without personalized goals and feedback (Table 1).

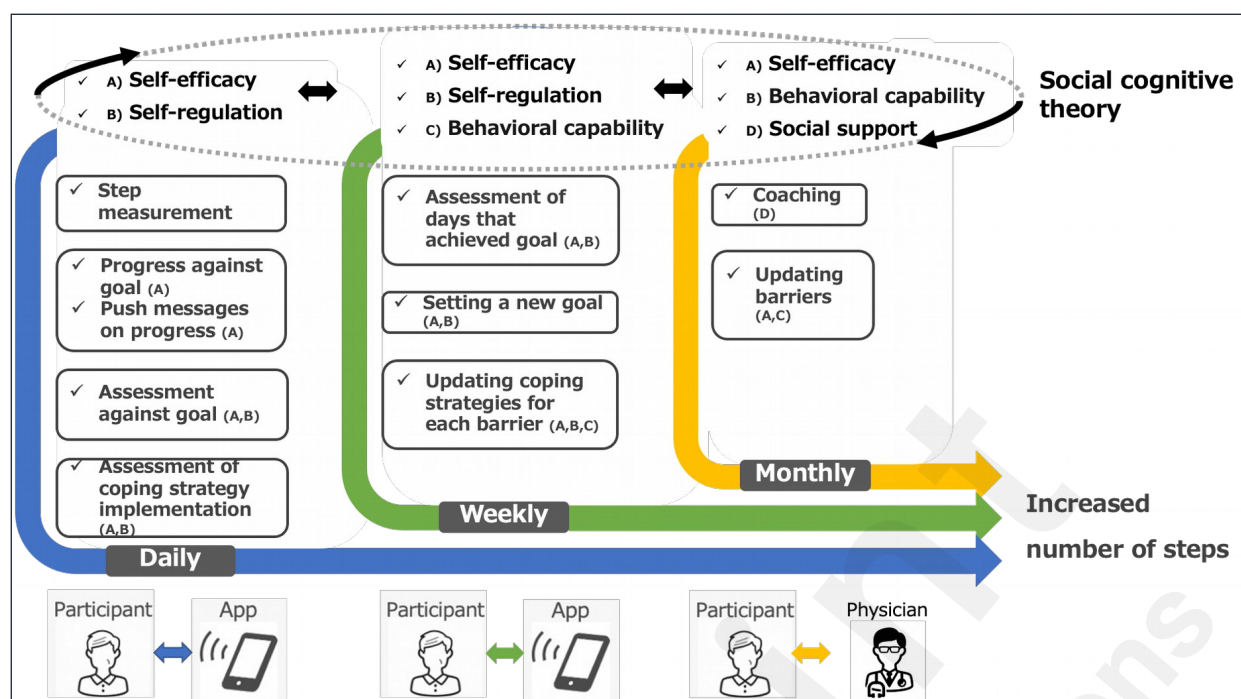


Figure 2 StepAdd's process for implementing SCT-based personalization on daily, weekly, and monthly timelines (based on the figure in [29])

Table 1. Features of the trial's StepAdd and placebo apps showing additional features provided to the intervention group.

Features	StepAdd app	Placebo app
Display, record, and upload step count, BW, BP	Yes	Yes
Reminders to measure BW and BP and to carry pedometer	Yes	Limited reminders to carry pedometer
Review of step count, BW, BP	Yes	No
Exercise instructions	Yes	No
Goal Setting	Yes	No
Coping strategies to overcome barriers in achieving step goals	Yes	No
Reminders about coping strategies	Yes	No
Display of recorded health data that were registered by physicians from the administrative screen	Yes	No
Daily reflection assistance	Yes	No
Weekly reflection assistance	Yes	No
Record on whether tasks agreed with healthcare professional are completed	Yes	No

Personalized feedback	Yes	No
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The intervention uses the framework of SCT [25, 26]. The intervention incorporates the SCT constructs most used in physical activity research: self-efficacy, self-regulation, behavioral capability, and social support [30]. Self-efficacy is an individual's belief in their ability to perform a particular behavior successfully. Individuals are less likely to engage in a behavior if they do not believe they are capable of producing the desired effects. Sources of self-efficacy include mastery experience (the successful accomplishment and mastering of a desired behavior) and verbal persuasion (receiving verbal encouragement by others for performing a behavior). Self-regulation, one of the constituent concepts of SCT closely linked with behavior change, is a dynamic feedback loop by which an individual sets a target goal, and by comparing this goal to their present state, is motivated to change their behavior to achieve the goal [31]. Motivation does not originate from the goals themselves, but from the individual analyzing their own behavior with reference to their goal [32]. Self-regulation includes behaviors such as setting personal goals and planning courses of action to achieve them, and it is often motivated by expected positive outcomes. Behavioral capability is a person's actual ability to perform a behavior through essential knowledge and skills. Social support involves identifying others who will provide encouragement in the form of moral support, participation in the behavior, and accountability [33].

SCT constructs integrated in this app focused on a self-regulated walking habit using goal setting and perceived self-efficacy [34]. Users set small, progressive, and realistic goals for daily step counts (self-efficacy and goal setting), track and monitor daily step count performance (self-observation), and evaluate their own progress against the goals (self-judgment). The belief that one's progress is acceptable, along with the anticipated satisfaction of meeting a goal, enhances self-efficacy and motivation (self-reaction) [34]. The intervention provides social support through monthly meetings with a physician who examines usage of the app and provides advice, verbal encouragement, and support on the participants' exercise behavior (behavioral capability and social support).

The app proposes the target number of daily steps for the following week according to the achievement of the current week's step count against goals. Our algorithm [29] increases, maintains, or decreases the suggested goal based on the number of days in the previous week in which the user achieved their goal. Increases are either 300 or 500 steps, depending on past goal achievement levels. The patient may choose to decrease their goal by decrements of 200 steps if they are not confident in being able to complete the goal for five or more days. In this way, the app recommends goal adjustments according to the user's self-efficacy in goal achievement. Personalized goal setting also enhances self-regulation through forethought (setting a goal and deciding on goal strategies); performance control (employing goal-directed actions and monitoring performance); and self-reflection (evaluating one's goal progress and adjusting strategies to ensure success) [35].

The app provides automated feedback with individualized advice. Status against the daily goal is available continuously on the app. Self-regulation is enhanced as patients are able to self-monitor their behavior through the personalized feedback. The feedback also enhances self-efficacy as it acts as a means of verbal persuasion, which is a source of self-efficacy [25, 26]. The app automatically communicates with the patients through push notifications four times a day (at 11:00, 13:00, 16:00, and at 18:00) to communicate the achievement against the step goals. For example, if the target number of steps have not been reached at 11 o'clock, the message "The number of steps registered by 11 o'clock is (participants' registered number of steps). The additional number of steps required is (target number of steps-current number of steps) to achieve your goal" appears on the app. The day's achievement against the goal is shown at 18:00. If the participant has reached the target step goal, a message "Today's steps have significantly exceeded your goal! Congratulations. You're in good

shape tomorrow. Don't get tired.” appears on the app. At the end of the week, the app provides feedback by displaying the number of days in the week that the step goals were achieved (Figure 3).



Figure 3 Example of end-of-week feedback (with English translation) showing daily and weekly performance against goals

Individualized coping planning enhances self-regulation by allowing patients to evaluate possible barriers to achieving their step goals. Each week participants select or input one to three barriers that prevented them from achieving the targeted number of steps, and for each they suggest a solution, or coping strategy, that could be useful to overcome the barrier (Figure 4). The coping strategies can be selected from a literature-based list of solutions to common barriers to walking [36-39] or can be freely described by the participants. At the end of each day, participants use the app to report on how many coping strategies they implemented that day. At the end of each week, the app provides feedback on coping strategy use by displaying the average number implemented per day.

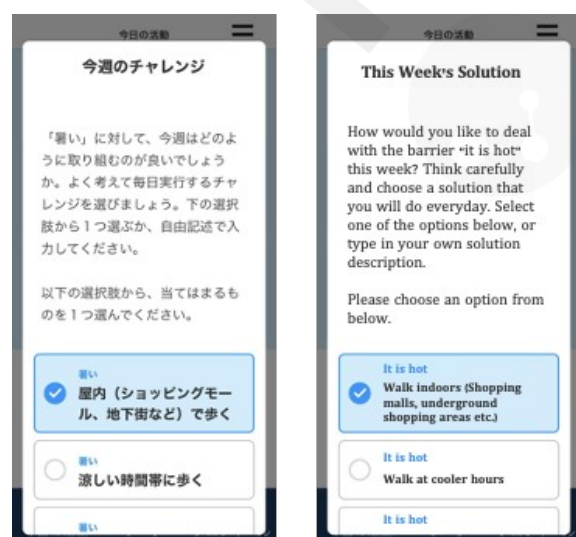


Figure 4: Example of personalized coping planning strategy on the app (with English translation) showing how patients select the strategy to use for the upcoming week

Patient recruitment

Patients will be recruited at five medical institutions in Japan: University of Tokyo Hospital, Akita University Hospital, Yokohama City University Hospital, Yokohama City University Medical Center and Yokohama Rosai Hospital. Recruitment will be conducted by attending physicians during patients' regular consultations at outpatient clinics. Recruitment will be conducted across two years starting from January 1st 2023 and ending in December 31st 2024.

In order to detect a 0.35% difference in the primary outcome (change in HbA1c), assuming a standard deviation of 0.74% as seen in a prior study [40, unpublished data], and to achieve a two-sided significance level of 0.05 and a statistical power of 80%, the minimum sample size is 72 patients per group [41]. Based on an assumed dropout rate of 10%, we are targeting recruiting a total sample of 160 patients (80 in the intervention group, 80 in the control group.)

All participants will receive a thorough written and verbal explanation concerning participation. We will subsequently obtain written informed consent from all study participants before screening for eligibility to participate in the study. If findings concerning efficacy and safety that may affect patient consent are discovered at any points during the trial, we will swiftly disclose this information to participants and acquire their renewed consent.

In order to focus on patients who are likely to benefit and also likely to be capable of participating, we will recruit patients who meet all the inclusion criteria (Table 2) and, to ensure that patients can safely and effectively participate in the intervention, do not meet any of the exclusion criteria (Table 3) We will use a transtheoretical model (TTM) questionnaire to categorize the participants who are currently at the contemplation stage (willing to change health behavior within the next six months), preparation stage (willing to change health behavior within the next month) or action stage (has made modifications to health behavior) [42]. In our previous study, patients who were in the contemplation and preparation stages of TTM were more likely to prefer to use smart-phone-based self-management tools than those in the pre-contemplative stage [43]. For this reason, we targeted patients who are in the contemplation, preparation, or action stage of achieving the target goal of 10,000 steps a day.

Table 2. Inclusion criteria of the study, focusing on patients who are likely to benefit from the intervention and are likely to be capable of participating.

Criteria
(1) Diagnosed with Type 2 Diabetes
(2) Being in the contemplation, preparation, or action stage of the transtheoretical model (TTM) to achieve the target step count of 10,000 steps / day
(3) $7.5\% \leq \text{HbA1c} \leq 10\%$ at the time of consent acquisition
(4) No change in antidiabetic medication within 8 weeks of the time of consent acquisition
(5) $18 \leq \text{Age}$
(6) Systolic blood pressure less than 180 mmHg and diastolic blood pressure less than 110

mmHg at the time of consent acquisition
(7) eGFR 45mL/min/1.73m ² or more recorded at least once in the past 12 weeks before the time of initial registration (V0)
(8) Urine albumin creatinine ratio < 300mg/gCr for the past year (52 weeks) on at least one occasion before V0
(9) BMI 22 kg/m ² and above
(10) No incidences in the 12 weeks before V0 of severe hypoglycemic attacks where assistance by others was required
(11) No symptoms of a possible hypoglycemic attack (including palpitations, tremors, dizziness, light-headedness, anxiousness, loss of consciousness, sweating, pale face, tachycardia, headache, drowsiness, blurred vision, convulsion) observed in the 12 weeks before V0
(12) Able to attend consultations at designated times during the trial
(13) Fully informed about participation in this study, and has given free and voluntary written consent based on a thorough understanding of the study

Table 3 Exclusion criteria, focusing on patients who may not be able to participate safely or whose participation may interfere with the effectiveness of the study

Criteria
(1) Walked an average of $\geq 10,000$ steps a day in the four weeks before V0 (must be verifiable by pedometer, etc.)
(2) Wearing a pacemaker
(3) Using continuous glucose monitoring (but do not exclude if self-monitoring of blood glucose or intermittently scanned-continuous glucose monitoring was conducted eight weeks or more before V0)
(4) Diagnosed with hyperthyroidism and have received treatment other than thyroid hormone replacement in the year before V0
(5) Diagnosed with a moderate to severe heart condition that requires exercise restriction as assessed by a physician
(6) Require exercise treatment restrictions as assessed by a physician at V0, decision made with reference to "Cases in which exercise therapy should be prohibited or restricted" in the Guidelines for Diabetes Treatment (Japan Diabetes Society, 2022-2023)
(7) Hb < 10g/dL for the 12 weeks before V0
(8) Serum albumin ≤ 3.0 g/dL in the 12 weeks before V0
(9) Diagnosed with preproliferative retinopathy or retinopathy of a later stage within the year before V0
(10) Cannot undergo exercise treatment
(11) Pregnancy, including any possibility of or intention of pregnancy
(12) Participation in other trials at the time of initial registration (V0)
(13) Impaired cognitive function as determined by the investigator or sub investigator
(14) Any other reason that the patient is classified as unfit for participation by the investigator or sub investigator (a record must be kept of the reason the patient was determined to be inappropriate)

We will provisionally register patients who meet the eligibility criteria. We will then provide them with a step counting device and a smartphone running just the step-counting part of the placebo app. We will ask patients to record their daily step count for a baseline period (nominally two weeks, but at least seven days), and then we will measure their HbA1c level at the end of the screening period. We will enroll patients who were able to measure their step count for seven or more days during the baseline period (to ensure we study patients able to adequately participate in the study) and who continue to have an HbA1c level of 7.5% or above (to ensure patients continue to have high HbA1c after the screening period). (We believe that the two-week trial will have no significant effect on outcomes.) We will then use the electronic data records to randomize eligible participants one-to-one to either the intervention or the control group using the covariate-adaptive randomization by minimization method to ensure covariance balance for age (<65, ≥65), sex, HbA1c (<8.5%, ≥8.5%), and institution [44].

Intervention process

The study (Table 4) includes ten events (V0-V9), a 24-week continuous measurement phase (M), and a 12-week follow-up observation phase. Initial measurements will be made at event V0. At V0, we will provide each participant with an NFC-enabled pedometer (A&D, UW-204NFC) and an iPhone (iPhone 8 with iOS16) prepared with the placebo app configured for step count only. We will direct the participants to wear the pedometer throughout the day except during sleep. We will use the step count gathered during V1 to confirm eligibility and to set a step count baseline.

Table 4 Study Events: one measurement period and ten visits spanning approximately 37 weeks

Event	Focus	Time	Key Activities
V0	Physical baseline, initial registration	Enrollment, ≥7 days prior to start of intervention	Collect consent Collect demographic information: date of birth, gender, smoking and drinking status, medical history, diet and exercise habit, household living condition, employment, usage of smartphones, habit of step count measurement, and stage of behavior change according to the transtheoretical model of change regarding walking 10,000 steps a day. Collect physical data: blood testing measuring HbA1c, fasting blood glucose (FBG), LDL cholesterol, HDL cholesterol, triglyceride (TG) and eGFR; urinalysis; height, body weight and blood pressure measurements. Collect medication and combination therapy status Assess health literacy Conduct surveys (Table 5) Distribute pedometer and placebo-equipped phone
V1	Step count baseline	From V0 until the day before V2 (at least 7 days)	Patients record daily steps and determine step count baseline
V2	Registration, allocation,	Beginning of	Measure HbA1c Finalize registration and allocation

	start of intervention	intervention (end of week 0)	Distribute BP monitor and scale Activate full placebo and StepAdd features Collect medication and combination therapy status Check for adverse events
M	On-going measurement	From V2 through V8	Daily measurements via app Intervention only: daily feedback, weekly feedback, and weekly personalized goal setting via app Check for defects
V3	Hospital visit 1	End of week 4	Check app usage and equipment Check for adverse events Intervention: coach goals, coping strategies Collect medication and combination therapy status
V4	Hospital visit 2	End of week 8	Check app usage and equipment Check for adverse events Intervention: coach goals, coping strategies Collect medication and combination therapy status
V5	Interim hospital visit	End of week 12	Collect physical data: blood testing measuring HbA1c, fasting blood glucose (FBG), LDL cholesterol, HDL cholesterol, triglyceride (TG) and eGFR; urinalysis; body weight and blood pressure measurements. Check app usage and equipment Check for adverse events Intervention: coach goals, coping strategies Collect medication and combination therapy status Conduct surveys (Table 5)
V6	Hospital visit 4	End of week 16	Check app usage and equipment Check for adverse events Intervention: coach goals, coping strategies Collect medication and combination therapy status
V7	Hospital visit 5	End of week 20	Check app usage and equipment Check for adverse events Intervention: coach goals, coping strategies Collect medication and combination therapy status
V8	Intervention end	End of week 24	Collect physical data: blood testing measuring HbA1c, fasting blood glucose (FBG), LDL cholesterol, HDL cholesterol, triglyceride (TG) and eGFR; urinalysis; body weight and blood pressure measurements. Collect medication and combination therapy status Check for adverse events Conduct surveys (Table 5) Assess usefulness and usability
V9	Followup end	End of week 36	Collect physical data: blood testing measuring HbA1c, fasting blood glucose (FBG), LDL cholesterol, HDL cholesterol, triglyceride (TG) and eGFR; urinalysis; body weight and blood pressure measurements. Collect medication and combination therapy status Check for adverse events Conduct surveys (Table 5)

Table 5 Surveys: nine surveys assessing diabetes-related behaviors and outcomes

Survey	Content
Problem Areas in Diabetes (PAID)	20 items to assess diabetes-related emotional distress [45].
Locomo 25	25-question risk assessment to evaluate musculoskeletal disorders such as walking disability, difficulty in daily living, or suffering pain on body [46].
Evaluation Scale for Self-Management Behavior related to Physical Activity of type 2 diabetic patients (ES-SMBPA-2D)	Assessments of: (I) Self-management behavior to enhance daily physical activity (II) Self-management behavior to maintain the level of physical activity [47].
Steps achieved	Self-Efficacy Scale relative to achieving targeted daily steps [48].
Dealing with barriers in achieving targeted daily steps	Self-Efficacy Scale relative to dealing with barriers in achieving targeted daily steps [49].
Physical Activity Self-Regulation scale (PASR-12), Japanese version	Addresses self-monitoring, goal setting, eliciting social support, reinforcement, time management, and relapse prevention, rated from 1 (never use strategy) through 5 (use strategy very often). Scores are the sum of the two individual item scores and summed self-regulation subscale scores for a measure of overall self-regulation [50].
SDSCA (The Summary of Diabetes Self-Care Activities Measure), Japanese version	Assesses diabetes self-care activities [51]
Health behavior “active coping behavior with disease”	Self-Efficacy Scale for health behavior “active coping behavior with disease” Subscale [52].
Audit of Diabetes-Dependent Quality of Life (ADDQOL), Japanese version	Assesses diabetes-dependent quality of life [53]

Following randomization, we begin the intervention. We will provide participants a Bluetooth-enabled sphygmomanometer (A&D, UA-651BLE Plus) and a Bluetooth-enabled weighing scale (A&D, UC-352BLE) (in addition to the already-provided pedometer and phone). For the control group, we will enable BP and weight measurement functions in the placebo app. For the intervention group, we will replace the placebo app with StepAdd, and define initial goals and barriers. Both the intervention and control group will watch a video concerning lifestyle modification, self-management of diabetes and effect of exercise on glycemic control.

The main part of the intervention is daily measurement by all patients throughout phase M. We will direct participants to measure their body weight and blood pressure daily upon awakening and wear the pedometer throughout the day except during sleep. All the participants will log the measurement data by syncing the recording devices (scale, sphygmomanometer, pedometer) to the app, rather than by manually inputting the data. This data is then uploaded to the server and made visible to healthcare professionals via the administrative screen. Intervention group participants receive personalized feedback on their step count performance four times a day. At the end of each week, intervention group participants review their weekly step count performance on the app, determine their personal barriers to achieving step goals, and identify possible coping strategies. StepAdd then provides a personalized step goal recommendation for the following week.

Every four weeks (events V3-V7), both groups will meet with a physician who will advise patients on lifestyle modifications and usage of the app and, for the intervention group only, help with goals and coping strategies. Baseline measurements (other than collection of some background information) are repeated at the interim (V5), at the end of the intervention (V8), and at the end of the followup observation period (V9). We will collect equipment at V8, prior to the followup observation period. The purpose of the observational period is to assess whether intervention-induced effects are maintained after the end of the intervention.

During the study, we will not restrict the use of supplements and drinks that can affect blood glucose and BP. In both the intervention and control groups, diabetes treatment details, such as changes or additions of oral diabetes medications, insulin, GLP-1 receptor agonists, and changes in medication dosage, can be changed at the discretion of the attending physician.

If patients discontinue the trial or stop using app, we define this as discontinuation, and we will collect measurements within seven days of this discontinuation. If participation in the study is discontinued during the intervention period, we will collect V8 measurement items. If participation in the study is discontinued during the observation period, we will collect V9 measurements items, except for urinalysis.

Monitoring, quality control and data management

An auditor independent from departments involved in the trial, including those responsible for monitoring, will inspect the medical institution and other facilities involved to ensure the trial is conducted appropriately.

Ethical considerations

This trial will be conducted in compliance with the Declaration of Helsinki, the Pharmaceutical and Medical Device Act, Ministerial Ordinance on Good Clinical Practice (GCP) for Medical Devices, and all other guidelines in relation to these regulations (jRCT2032220603). This study was approved by the Institutional Review Board of the University of Tokyo School of Medicine (approval number: 2022012-11DY). We will obtain written informed consent from all study participants. All patient data will be anonymized. Patients will be compensated 7,000 Japanese yen (approximately 50 USD) for each visit to the hospital.

Outcome Measures

Primary outcome

The primary outcome of this study is the between-group differences in the change of HbA1c value between baseline (V2) and either the end of the intervention period (week 24 (V8)), or, for patients who discontinue prior to V8, the point of discontinuation. Reduction of HbA1c by 0.35 percentage points is considered to be clinically significant [54, 55].

Secondary outcomes

Secondary outcomes (Table 6) include health measures, measurements of steps, measurements of other behavior changes, and assessments of app usage. We will also assess safety outcomes such as hypertension requiring medical assistance (assessed from the system records), subjective hypoglycemia, pain in the lower back and lower extremities (tarsus, thighs, knees, calves, shins, ankles, feet), and any other adverse events (all assessed via patient interviews).

Table 6: Secondary outcomes investigated in the study: 22 areas spanning health outcomes, exercise outcomes, other behavior changes, and app assessments

Secondary Outcomes	
	Health outcomes
1	HbA1c (%) 1. Change in HbA1c 2. Proportion of patients with HbA1c < 7%
2	FBG (mg/dL) more than 5 hours after a meal
3	eGFR (L/min/1.73m ²)
4	BMI (kg/m ²)
5	Body weight measured at home (kg)
6	Systolic and diastolic BP (mmHg) 1. BP measured at hospital 2. BP measured at home
7	HDL (mg/dL), LDL (mg/dL), TG (mg/dL)
8	Concomitant medication intake (type of medication, daily dosage or weekly dosage for weekly formulation) 1. Change in diabetes medication intake (either increased, unchanged or reduced) 2. Introduction of new medications to treat diabetes, hypertension or dyslipidemia
9	Diabetes-related emotional distress (assessed using PAID) [45]
10	Diabetes-dependent Quality of Life (assessed using ADDQoL) [53]
	Exercise outcomes

11	Daily step count
12	Walking duration
	Other behavior changes
13	Locomotive syndrome (assessed using Locomo 25) [46]
14	Diabetes self-care (assessed using Japanese version of SDSCA (The Summary of Diabetes Self-Care Activities Measure)) [51]
15	Self-management behaviors related to physical activity (assessed using evaluation scale for self-management behaviors related to physical activity of type 2 diabetic patients (ES-SMBPA-2D) [47]
16	Self-regulation of physical activity (assessed using Japanese version of Physical Activity Self-Regulation scale (PASR-12) [50]
17	Changes in walking self-efficacy 1. Self-efficacy for achieving targeted daily steps [48] 2. Self-efficacy for dealing with barriers in achieving targeted daily steps (assessed using Self-Efficacy Scale of Walking Behavior) [49]
18	Changes in self-efficacy in health promoting behavior (assessed using 'positive coping behavior towards illness' subscale within Self-efficacy Scale for Health Promoting Behaviors) [52]
19	Health Literacy (HLS-14) [56]
	App assessments
20	App usage 1. Recording rate of BW, step count, BP and its change 2. Goal achievement rate 3. Goal increment rate 4. Goal reduction rate 5. Average number of coping planning strategies implemented per day 6. Number of barrier identifications
21	System feasibility and usability (only for the intervention group)
22	Number of mails, SMSs, and calls to encourage registration

Note:

Item 1.1 includes both differences between week 0 (registration at V2) and week 12 (V5) (or point of discontinuation, if earlier) and between week 0 (registration at V2) and week 36 (V9) (or point of discontinuation, if earlier) which are compared within group and between group, and also includes a difference between week 0 (registration at V2) and week 24 (V8) (or point of discontinuation, if earlier) which are compared within group.

Item 1.2 includes all three proportions which are compared between group: latest HbA1c up to week 12 (V5) (or point of discontinuation, if earlier) less than 7%, latest HbA1c up to week 24 (V8) (or point of discontinuation, if earlier) less than 7%, and latest HbA1c up to week 36 (V9) (or point of discontinuation, if earlier) less than 7%.

Items 2-4, 6.1, 7.9, 10, 12-18 include all three differences between provisional registration (V0) and week 24 (V8) (or point of discontinuation, if earlier), between provisional registration (V0) and week 12 (V5) (or point of discontinuation, if earlier), and between provisional registration (V0) and week 36 (V9) (or point of discontinuation, if earlier) which are compared between groups.

Item 8 includes assessment at week 12 (V5), week 24 (V8), week 36 (V9) (or point of discontinuation, if earlier) respectively, and it will be compared between groups.

Items 5, 6.2, and 11 include differences between the start of intervention (V2) (or from baseline period (V1) for steps) and week 4 (V3) and differences between each visit and each subsequent visit, which are compared between groups. Also, they include measurements at each period (between visits) which are to be compared between groups. Item 11 also includes difference between baseline (V1) and 2 weeks before week 12 (V5) (or point of discontinuation, if earlier) and week 24 (V8) (or point of discontinuation, if earlier) which are compared within group and between groups.

Item 19 will be assessed at provisional registration (V0).

Item 20 includes comparisons of the differences over the first period of the intervention (from week 0 (V2) to week 4 (V3)) and differences over each subsequent period (between subsequent visits) which are compared between groups (item 20.1 only) and within group (all parts of item 20). Items 20.2-20.6 will only be examined for the intervention group.

Item 21 will be assessed for the intervention group only, at week 24 (V8) (or point of discontinuation, if earlier).

Item 22 will be assessed at week 24 (V8) (or point of discontinuation, if earlier).

Item 20 will be calculated as follows:

1. Number of days where measurements for BW, step count, and BP are recorded / total number of days *100
2. Number of days step goal was achieved / total number of days *100
3. Number of days step goal was increased / total number of reset times *100
4. Number of days step goal was reduced / total number of reset times *100
5. Total number of coping strategies implemented over the period / total number of days
6. Number of barriers identified every 4 weeks

Statistical analysis

In this study we define three analysis populations: the full analysis set (FAS), the per protocol set

(PPS), and the safety analysis set (SAS). The FAS is the set of all patients whose data were obtained at least once after randomization. We will follow the Intention-to-treat (ITT) principle and analyze data based on the assigned group in the FAS analysis. The PPS is the FAS population with exclusion of patients who were found to have violated the eligibility criteria after randomization, or who did not use the app over a three-week period. The SAS is the set of all patients who used the StepAdd app or the placebo app at least once after randomization. In the safety analysis using the SAS, we will analyze data based on the apps actually used by patients regardless of allocation. The FAS will be the primary analysis population and the PPS will provide supportive results. All safety analyses will be conducted in the SAS.

Data on patients' characteristics will be presented as mean, SD, minimum, 25 percentile, median, 75 percentile, and maximum for continuous variables and as frequency and proportion for categorical variables.

In the primary analysis, we will perform between-group comparison of the change in HbA1c from week 0 (V2) to week 24 (V8) (or point of discontinuation, if earlier) using analysis of covariance including baseline HbA1c (i.e., HbA1c at week 0 (V2)) as a covariate in the FAS. If participants discontinue the study, the latest measurement of HbA1c before V8 will be used.

We will also conduct two subgroup analyses with one classification by HbA1c at week 0 (V2) (either $<8.5\%$ or $\geq 8.5\%$) and the other classification by BMI at time of initial registration (V0) (either <25 or ≥ 25). We will conduct subgroup analysis on the primary outcome in each analysis set to investigate whether the efficacy of StepAdd is consistent between these subgroups.

In the secondary analysis, the change in HbA1c at week 12 (V5) and week 36 (V9) will be analyzed as in the primary analysis. The proportion of HbA1c less than 7% at week 24 (V5), week 24 (V8), and week 36 (V9) (or point of discontinuation, if earlier) will be compared between groups by Fisher's exact test. The change from baseline in the step counts, various laboratory test values, and questionnaires at week 12 (V5), week 24 (V8), and week 36 (V9) (or point of discontinuation, if earlier) will be analyzed as the primary endpoint. Changes in diabetes medications, classified as weakened, unchanged, or strengthened, will be compared between groups by the Cochran-Mantel-Haenszel test. The proportion of new medications added will be compared between groups by Fisher's exact test. Change in application data (step counts, weight, blood pressure) and their recording rates will be evaluated between each visit based on the week 0 (V2) to week 4 (V3) period and compared between groups by t-test. The McNemar test will be used for within-group comparison of the proportion of people who walked 10,000 steps or more in the two weeks before the intervention and the two weeks before week 24 (V8). A paired t-test will be used for within-group comparison over the week 0 (V2) to week 4 (V3) period for goal achievement rate, goal increment rate, goal reduction rate, average number of coping planning strategies implemented per day, and the number of barrier identifications.

As an exploratory analysis, we will use linear regression to investigate the relationship in the intervention group between the average number of coping strategies implemented per day and improvement in HbA1c. The analysis will use the average number of coping strategies implemented per day and baseline HbA1c as explanatory variables and the change in HbA1c as the response

variable. The change from baseline to week 12 (V5), week 24 (V8), and week 36 (V9) (or point of discontinuation, if earlier) will be evaluated.

We will conduct statistical analysis of safety outcomes. We will compare the proportion of incidences of hypoglycemia, joint pain, significantly elevated blood pressure (145/95 mmHg or higher), and exacerbations of joint pain between groups using Fisher's exact test. Other adverse events will be recorded using the Japanese version of the Medical Dictionary for Regulatory Activities categories for Preferred Term and System Organ Class and their incidence proportions will be compared between groups using Fisher's exact test. The severity of each incidence will be categorized into three grades (low, moderate, and high) and their between-group comparison will be conducted using the Cochran-Mantel-Haenszel test.

RESULTS

Recruitment began on January 1, 2023. As of September 5, 2023, we have recruited 44 patients. We expect the trial to conclude by October 8, 2025, with the follow-up observation period concluding by December 31, 2025. We anticipate concluding analysis by March 30, 2026.

DISCUSSION

We have designed this study based on the foundational concept that this is a behavioral change intervention, albeit one where we are measuring medical outcomes. We base the intervention on a specific theory of behavioral change, in this case SCT, to give a framework to the intervention, ensuring clarity on the targets of the intervention, and keeping the focus on these targets so as to avoid scatter-shot ideas on how and where to intervene. We identified a specific and actionable target behavior, walking more, and designed a measurement and feedback system around this focused behavior. This focused approach brings clarity to the researchers and to the patients. The focus lets us determine if this specific intervention increases walking behavior while also assessing any resulting changes in physical parameters such as BMI and ultimately assessing changes in health. It is not sufficient to show that some behavior intervention leads to HbA1c improvement – we need to understand the steps in between, in particular the behavior response, to fine tune the intervention to expand on aspects that work and trim out aspects that do not. We have designed this trial to provide evidence on the intermediate stages.

Our study uses objectively measured data for all primary and many secondary outcomes. The intervention employs wireless technology which allows step count, BW and BP measurements to be synced automatically to the app. These simple passive features make for easy-to-use objective measurements, especially for older patients. Daily monitoring of blood glucose has been shown to have low measurement rates and to not be preferred by patients, so we have not included it in this intervention [57].

We chose HbA1c level as our primary outcome, as it is regarded as both a global standard for measuring glycemic control and an appropriate indicator for the effectiveness of diabetes treatment [58]. According to The Japan Diabetes Society's treatment guideline, diabetes patients should aim to lower their HbA1c level to below 7% to prevent the development of any complications [59].

Therefore, we decided to study the proportion of patients who achieved an HbA1c level of below 7% in addition to studying the absolute change in HbA1c levels.

In this study, we have elected to use a “formidable” control [60] using a fairly high-functioning placebo app. We have initial confirmation of proof of concept from the pilot, and now we want to show whether or not our specific behavior change intervention methods are superior to simply giving patients access to their step count, body weight, and blood pressure. There is evidence that simply giving patients a pedometer increases their activity level [61], so there is some risk that the study will induce a response in the control group that may prevent statistical proof of any superiority of the StepAdd intervention. Most people who want a pedometer already have access to one in their smartphone, and we think this risk is modest. By giving the placebo group a functional app, albeit one lacking StepAdd’s functionality, we have designed the study to give strong proof of the success of StepAdd, if in truth it is effective.

Many behavior interventions show solid short-term gains that then fade [62]. Our StepAdd pilot [29] showed results that continued to improve throughout the study, with no sign of a fade. The current study expands the trial time to 24 weeks with a 12 week observation period in order to see if the pilot results hold true over a longer period. Behavior change maintenance is theorised as an outcome of active and on-going self-regulation, and habit development follows a period of successful self-regulation of a new behavior [63]. Our objective is to change behavior in a sustainable way, such that the new pattern of behavior becomes a habit that can be sustained over the long haul.

A key to our approach is ensuring the patients receive a strong introduction to the mechanics of the intervention and the StepAdd app. Patients have busy lives, and we work to make it clear and easy for them to meet the demands of the intervention. By providing training on the intervention and the app, and by ensuring that all messaging in the intervention is simple and focused, we maximize the likelihood that the patients will use the tools of the intervention just as we intend them to.

Another key part of the approach is focusing first on the patients that the intervention will serve. We designed the intervention for a specific target set, not all patients, and customized the intervention to meet their needs and accommodate their preferences. We have found that it is essential to design with cultural background and patient preference in mind, as we did in the StepAdd pilot [29]. Another key to our approach is applying it only to patients who already are motivated to change their behavior. We filter based on TTM stage, and we have found this approach to be highly effective [43, 29]. Our intervention is designed for high-motivation patients in need of some help implementing their desired behavior – low motivation patients are in need of an entirely different intervention focused on improving their motivation. We have found that large proportions of diabetes patients in Japan have high motivation, with one study showing that 92% are in the contemplation-through-action stages of TTM [64]. There is a very large pool of patients who would benefit from this targeted intervention. Exercise has been shown to improve health in patients with chronic kidney disease [65], and a recent meta-analysis confirms that exercise and diet programs improve the health of obese diabetes patients, including improving BMI and HbA1c [66]. This study is a multi-center randomized controlled trial, and this increases the generalizability of the findings to diabetes patients throughout Japan. Our techniques are general, and there is every reason to believe these methods could be applied to increase exercise for patients with other diseases and in countries throughout the world.

The study has limitations. The results of our trial may be specific to the population studied and may not fully generalize to other populations. Our participants will likely be older people of Japanese ethnicity. There are differences between Japanese and other populations in lifestyles and in the

pathophysiology of T2D. The study is limited to patients able to use mobile phones, so there may be biases due to users' digital literacy. Conversely, results may differ with a younger population [67], as it has been reported that younger populations are able to complete tasks more successfully on mHealth apps [68] and have higher satisfaction compared to their older counterparts [69]. Participants will not be blinded to randomization, so social desirability bias may affect the results. We do not engage on or control for dietary changes, and changes in dietary behavior during the study may affect our results. Our baseline measurement of step count is based on providing pedometers to participants, and the resulting measurements may be higher than the true pre-study step count, as studies have found providing a pedometer increases step count by > 2,000 steps [63], at least in the short term. This effect is mitigated by our two-arm trial and the length of our trial, but it may lead us to underestimate increases in step count and therefore overestimate the per-step impact on health outcomes.

This trial will provide important evidence on the efficacy of an SCT-based mHealth intervention in improving physical activities and glycemic control in type 2 diabetes patients. If this study proves the intervention to be effective and safe, it could be a key step towards the integration of mHealth as part of the standard treatment received by diabetes patients in Japan. Our findings will inform future research on using theory-based behavior change techniques and may lead to practical use by exercise professionals in the real world [64].

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Data availability

Aggregate data analyzed in this study may be made available upon reasonable request by contacting the corresponding author via the e-mail address provided.

Conflicts of Interest

The study was supported by Raxi Co., ltd. Patent resulted from this research work is issued to Raxi Co., ltd. and The University of Tokyo.

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Abbreviations

ADDQOL - Audit of Diabetes-Dependent Quality of Life

App – Application

BMI – Body mass index

BP – Blood pressure

BW = Body weight

DKD-ET - Diabetic kidney disease – exercise therapy

eGFR – Estimated glomerular filtration rate

ES-SMBPA-2D - Evaluation Scale for Self-Management Behavior related to Physical Activity of type 2 diabetic patients

FAS – Full Analysis Set

FBG – Fasting blood glucose

GLP-1 – Glucagon like peptide 1

HbA1c – Hemoglobin A1c

HDL – High density lipoprotein

ITT – Intention to treat

LDL – Low density lipoprotein

mHealth – Mobile health

NFC – Near field communication

PAID - Problem Areas in Diabetes

PASR-12 - Physical Activity Self-Regulation scale

PPS – Per Protocol Set

SAS – Safety Analysis Set

SCT – Social Cognitive Theory

SDSCA - The Summary of Diabetes Self-Care Activities Measure

T2D – Type 2 diabetes mellitus

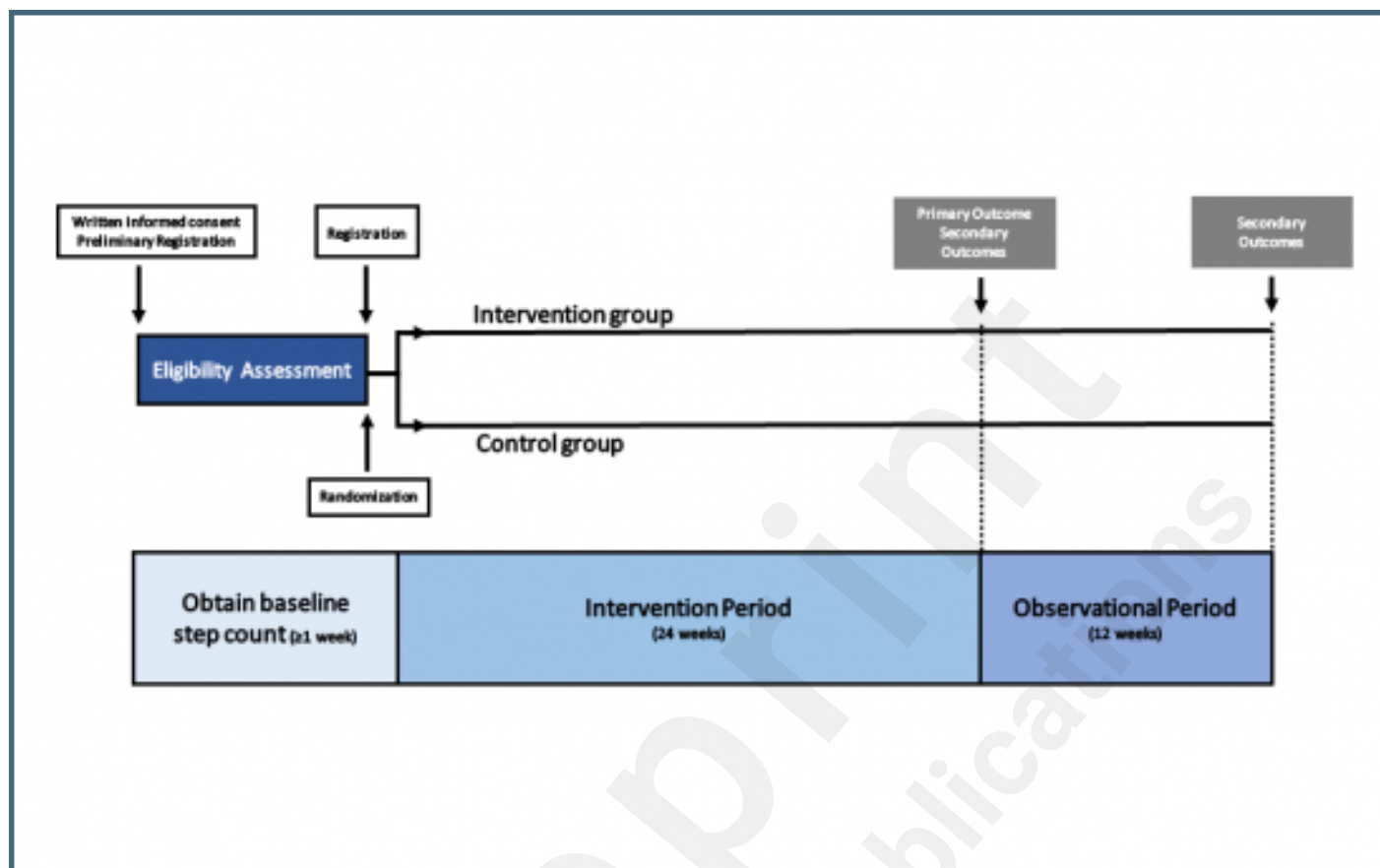
TG – Triglyceride

TTM – Transtheoretical Model

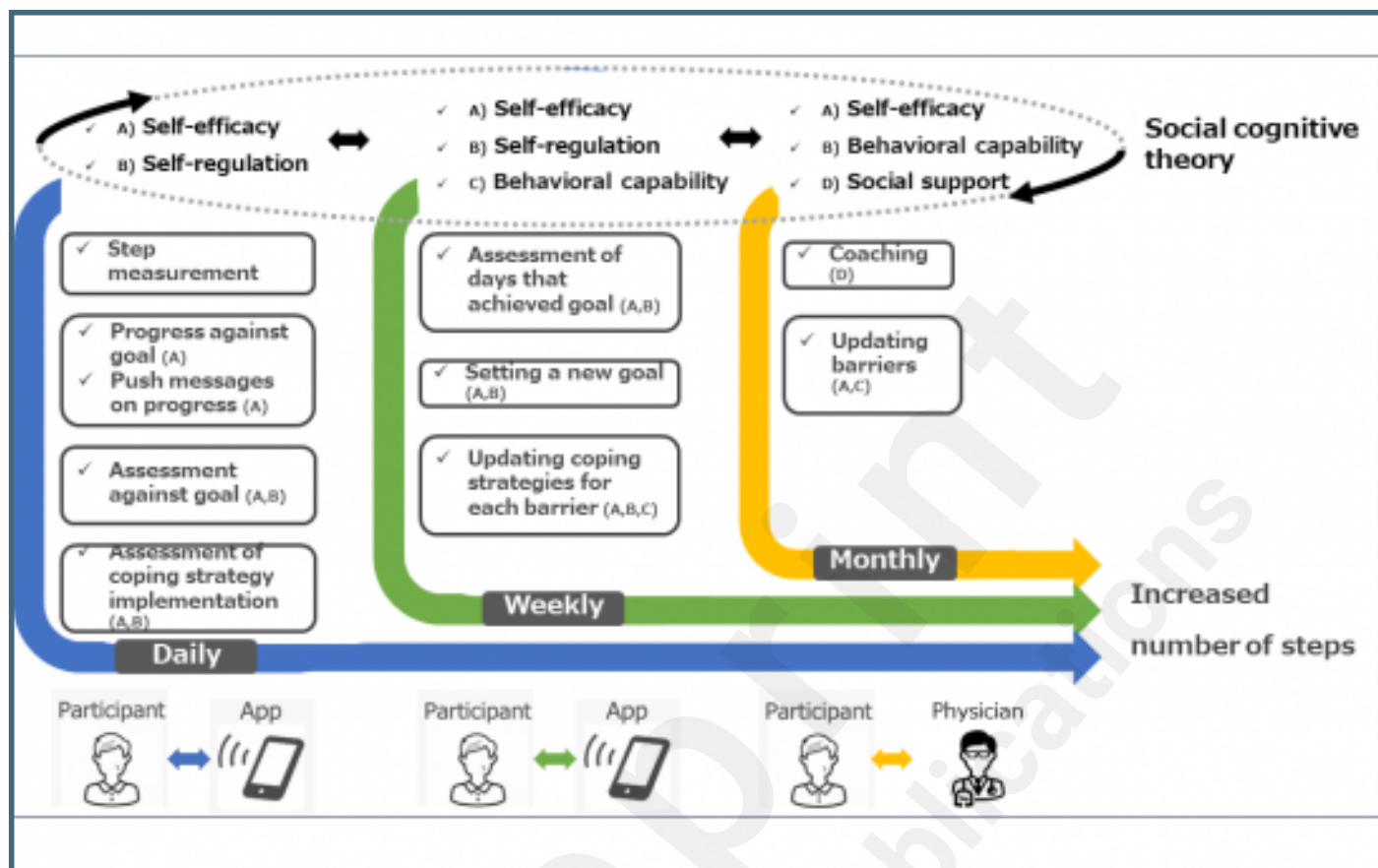
Supplementary Files

Figures

Overview of Study Timeline.



StepAdd's process for implementing SCT-based personalization.



Example of end-of-week feedback (with English translation).



Example of personalized coping planning strategy on the app (with English translation).

