

Efficacy of BedTime, a personalized mHealth intervention to increase sleep duration among short-sleeping type 2 diabetes patients: Protocol for a pilot randomized controlled trial

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Abstract

Background: There is a strong association between sleep duration and glycemic control in type 2 diabetes (T2D) patients, but there is a lack of convincing evidence of a causal link. Improving sleep is seeing increasing emphasis in clinical T2D treatment guidance, and there is a need for effective sleep intervention methods that can scale up to affordably serve large populations through use of mobile health (mHealth).

Objective: In this study, we aim to pilot an intervention approach that extends sleep duration via changing bedtime behavior to investigate its efficacy among short-sleeping (6 hours or less per night) T2D patients and establish robust evidence that extending sleep causes improved glycemic control.

Methods: This is a randomized, single-blinded, multi-center study targeting 70 T2D patients from 9 institutions in Japan with a 12-week intervention. We apply the Theory of Planned Behavior (TPB) to develop a sleep extension intervention, BedTime, targeting TPB's constructs of perceived and actual behavioral control. The pilot intervention combines wearable actigraphy devices with text messaging controlled by human operators. The intervention and control groups will record bedtime, sleep duration, and step count using an actigraphy device, with time-in-bed (TIB) assessed via sleep diaries. The intervention group will in addition receive weekly bedtime goals, receive daily feedback on their bedtime performance relative to those goals, identify personal barriers to an earlier bedtime, and choose strategies to overcome these barriers. The 12-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 at 12 weeks. The secondary outcomes include other health measures, measurements of sleep (bedtime, TIB, sleep duration, total sleep time, sleep quality), measurements of other behavior changes, and assessments of the usability of the intervention approach. The trial began on February 8, 2024, and is intended to conclude in February 2025.

Results: As of June 5, 2024, we have recruited 36 patients. We expect the trial to conclude by November 26, 2024, with the follow-up observation period concluding by February 18, 2025.

Conclusions: This trial will provide important evidence on the causal link between increased sleep duration and improved glycemic control in short-sleeping T2D patients. It will also test the efficacy of our bedtime behavior change intervention in improving sleep duration by piloting using human operators, with the goal of future implementation via an mHealth smartphone application. If this study proves the intervention to be effective, it could be a key step towards the development and deployment of sleep-focused mHealth as part of the standard treatment received by T2D patients in Japan. Clinical Trial: jRCT1030230650

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Original Manuscript

Original Paper

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Abstract

Background: There is a strong association between sleep duration and glycemic control in type 2 diabetes (T2D) patients, but there is a lack of convincing evidence of a causal link. Improving sleep is seeing increasing emphasis in clinical T2D treatment guidance, and there is a need for effective sleep intervention methods that can scale up to affordably serve large populations through use of mobile health (mHealth).

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Results: Patient recruitment ended on August 29, 2024 with 70 participants recruited. The intervention period concluded on December 6, 2024. The observation period is scheduled to conclude on February 26, 2025.

Conclusions: This trial will provide important evidence on the causal link between increased sleep duration and improved glycemic control in short-sleeping T2D patients. It will also test the efficacy of our bedtime behavior change intervention in improving sleep duration by piloting using human operators, with the goal of future implementation via an mHealth smartphone application. If this study proves the intervention to be effective, it could be a key step towards the development and deployment of sleep-focused mHealth as part of the standard treatment received by T2D patients in Japan.

Trial Registration: 1030230650

Protocol version: 3.0, 14 June 2024

Keywords: digital therapeutics, behavior change, theory of planned behavior, sleep duration, type 2 diabetes, 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]. Type 2 diabetes (T2D) 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].

T2D treatment guidelines include pharmacological and lifestyle modification elements. Lifestyle modifications have historically included diet and exercise changes, but recently the importance of improving the sleep of T2D patients has gained prominence [5, 6]. Some T2D patients suffer from sleep disorders, including obstructive sleep apnea (OSA), restless leg syndrome (RLS), and

insomnia. For these patients, an appropriate approach is treatment of the underlying disorder [7]. Sleep quality is associated with risk of T2D [8], and interventions to improve sleep quality have been shown to be effective [9]. Many T2D patients do not get sufficient sleep – they have *short sleep*. Definitions of short sleep vary from study to study, from 6 or fewer hours per night down to less than 4.5 hours per night [10]. This problem is widespread, with data indicating that 39.4% of T2D patients in Japan sleep <6.4 hours per night [11].

There is strong evidence that short sleep is associated with T2D risk and worse glycemic control. Short sleep is associated with higher HbA1c levels in Japanese T2D patients [11], with meta-analysis indicating a 0.23% difference in HbA1c due to short sleep [12]. Prospective studies have shown increased risk of T2D due to short sleep [8]. There are plausible biological mechanisms, with sleep extension leading to lower energy intake [13] and sleep restriction leading to worsened insulin sensitivity [14].

Surprisingly, there is a lack of strong evidence for causality – that intervening to improve sleep duration in short-sleeping T2D patients without sleep disorders causes improvements in HbA1c levels. Recent meta-analyses [15, 16] found scant and conflicting evidence on effect of sleep intervention on glycemic control. Studies have examined an intervention for T2D patients with insomnia [17, 18]. A study examined an educational intervention for T2D patients, including short sleepers, but results from a published abstract [19] are unclear, and no paper has been published. Two related studies used cognitive behavior therapy to improve HbA1c by improving sleep quality, not duration [20, 21]. There is a lack of strong evidence that increasing sleep duration among short-sleeping T2D patients without sleep disorders causes improvements in HbA1c.

Numerous studies have successfully increased sleep duration in various populations. A recent meta-analysis of 42 studies found that extending time in bed has the largest potential to change sleep, with direct interventions (directly scheduling a longer period in bed) yielding a 1:23h increase in sleep duration [22].

Mobile health (mHealth) interventions such as mobile phone applications that support self-management have proven to be effective in increasing physical activity, reducing body weight, [23, 24] and improving glycemic control [25, 26], but to our knowledge there have been no applications of mHealth to improving the sleep duration of short-sleeping T2D patients without sleep disorders. Personalization of intervention components has been shown to increase patient motivation and engagement in using the app [27]. Several studies have found that tailored interventions are more effective in changing health behavior than non-tailored interventions [28, 29]. Interventions that are based on behavior change theory have been shown to be more effective than those not based on theory [30], with interventions based on the theory of planned behavior (TPB) being especially effective [31]. TPB focuses on intention and actual behavioral control as determining behavior, with perceived behavioral control (similar or identical to Bandura's self-efficacy) playing a central role in determining intention [32, 33].

To address the lack of evidence of improvements in glycemic control caused by improvements in sleep duration, we developed a pilot of a personalized mHealth intervention, BedTime, to increase sleep duration and assess the impact on glycemic control among short-sleeping patients with T2D. The intervention uses the TPB framework to induce a change in behavior of earlier bedtimes. The current trial aims to investigate the efficacy of the BedTime approach in a pilot 12 week single-blind randomized controlled trial. The specific research objectives and hypotheses are as follows:

Objective 1:

To investigate the efficacy of the BedTime approach in moving patients to an earlier bedtime, as measured via daily bedtime reporting, and increased sleep duration, as measured via daily actigraphy.

We hypothesize that, at the end of the intervention, the intervention group will achieve statistically significant changes in bedtimes and sleep durations relative to the bedtimes and sleep durations of the control group.

Objective 2:

To investigate the efficacy of the BedTime approach 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.

Methods

Study overview

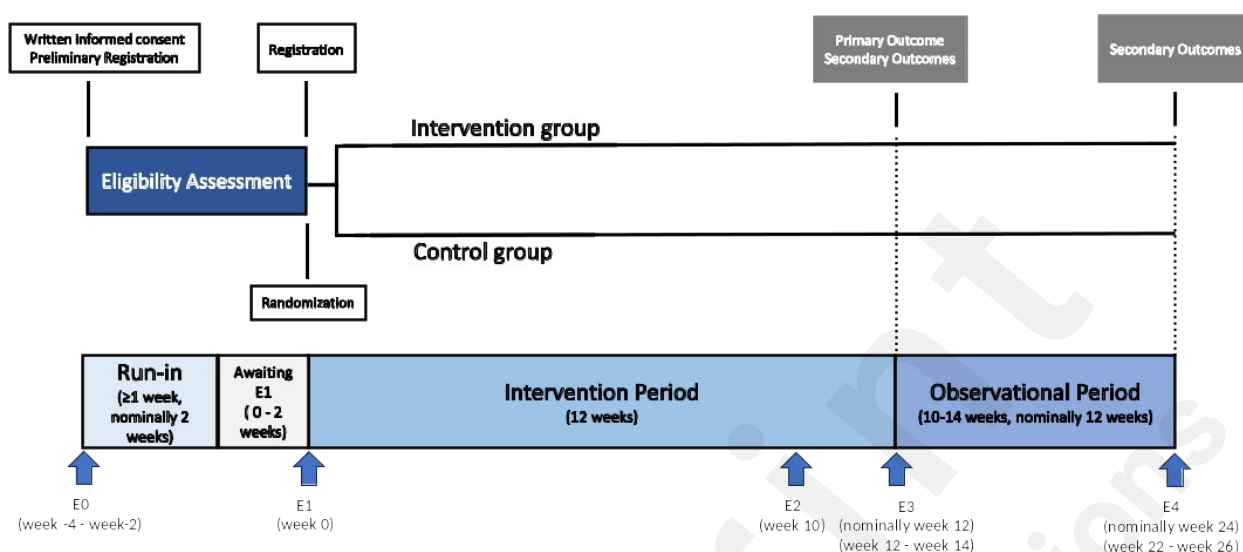
This study is a single-blinded, multi-center (Textbox 1), pilot, two-armed randomized controlled trial to study the efficacy of an mHealth intervention approach, BedTime, in promoting earlier bedtime behavior and increased sleep duration among short-sleeping T2D patients. The conduct and reporting of the trial will follow the CONSORT guidelines. This study (Figure 1) begins with recruitment (E0), a baseline measurement period (nominally two weeks, but at least 7 days), and randomized assignment to intervention and control groups (E1). The patients in the intervention group will record daily bedtime, sleep duration, and step count using an actigraphy device, with time-in-bed (TIB) assessed via sleep diaries. They will receive weekly bedtime goals, receive daily feedback on their bedtime performance relative to those goals, identify personal barriers to an earlier bedtime, and define strategies to overcome these barriers. The control group will record daily bedtime, sleep duration, and step count using an actigraphy device, with time-in-bed (TIB) assessed via sleep diaries but will receive no feedback and have no assigned goals. During week 10 of the intervention period (E2), intervention group will complete a Theory of Planned Behavior (TPB) questionnaire. The intervention will last for 12 weeks, followed by end-of-intervention assessments on primary outcome and secondary outcomes (E3). After the intervention period, an observation period whose length, nominally 12 weeks, depends on the date of the final visit (E4) which may fall anywhere within 10 to 14 weeks of the end of the intervention period. This study will be conducted across one year, from February 8, 2024, to January 22, 2025.

Textbox 1. Participating institutions – 11 medical centers in Japan

- The University of Tokyo Hospital
- Mitsui Memorial Hospital
- Meiji Yasuda life Insurance Company Tokyo Hospital
- Kobe University Hospital
- Akita University Hospital
- Tokai University Hospital
- Okayama Saiseikai General Hospital
- Sawaki Internal Medicine and Diabetes Clinic
- Yokota Medical Clinic

- Aikawa Comprehensive Internal Medicine Clinic
- Yokohama Rosai Hospital

Figure 1. Overview of study timeline.



Intervention design

Some features of the intervention are common to both the control group and the intervention group, while others are unique to the intervention group (Table 1). This m-Health intervention uses a physical activity monitoring system (iAide2, Tokai) and a researcher-designed paper diary for both the intervention and control group patients. The iAide2 measures activity intensity levels, skin temperature, and pulse rate [34, 35] to assess step count and sleep, with minute-by-minute assessment of wake/sleep [36, 37]. The iAide2 provides timely behavior feedback (via a wirelessly connected Event button and near-real-time access to data) to researchers via an administrative screen. During the 12 week intervention period, control group and intervention group patients wear the iAide2 device at all times other than when bathing and push its Event button at their bedtime every day. The patients record bedtime/risetime each day in the paper diary. For the intervention group, the diary includes additional pages implementing aspects of the intervention. We define bedtime as the time when one starts trying to sleep and risetime as the time when one stops trying to sleep. The diary information is used to calculate Time in Bed (TIB), the length of the interval between risetime and bedtime. The intervention is designed to cause patients to have an earlier bedtime, with the expectation that this will increase TIB and thus increase sleep duration (the time inside the TIB interval in which the patient is asleep).

Table 1. Intervention features for the intervention group and control group.

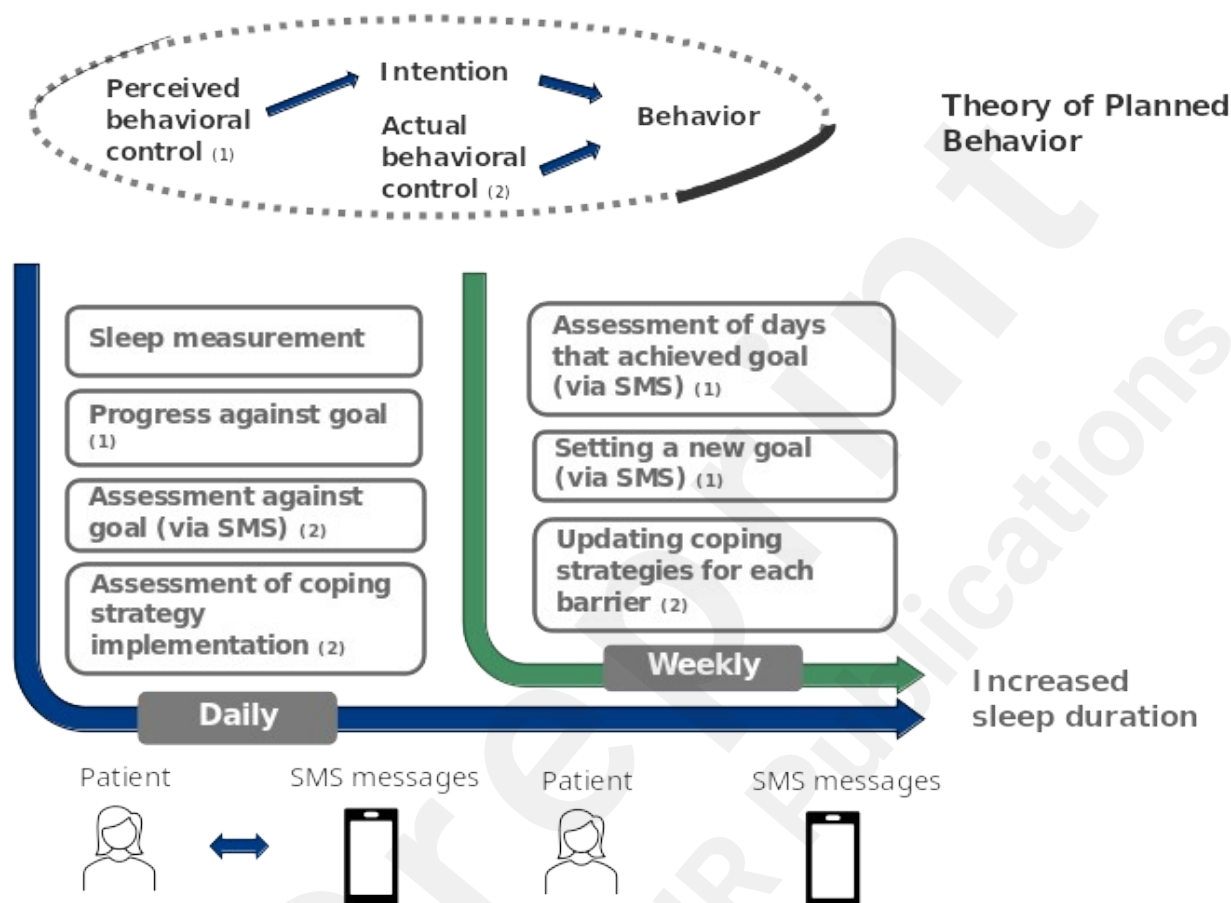
Features	Intervention group	Control group
iAide2		
• Press Event button to send bedtime	Yes	Yes
• Measure daily sleep and steps (without providing this information to patients)	Yes	Yes

Diary		
• Enter bedtime and risetime	Yes	Yes
• Define barriers and coping strategies, report the number of coping strategies implemented	Yes	No
• TPB questionnaire at E2	Yes	No
SMS		
• Diary reminder	Yes	Yes
• Low battery message	Yes	Yes
• Daily feedback, target bedtime	Yes	No
• Request for a reply message when patients forget to press the Event button	Yes	No
Surveys and questionnaires		
• Screening at E0	Yes	Yes
• Sleep and transtheoretical model questionnaire at E0, E3 and E4	Yes	Yes
• Feedback survey	Yes	No
• TPB questionnaires at E1	Yes	No
• Ask if taking any medication that may affect one's sleep at E0, E1, E3 and E4	Yes	Yes
• Obtain information about medications, including T2D treatments and other drugs, either by asking the patients or by checking their medical records at E0, E1, E3 and E4	Yes	Yes
• Measure height at E0, and measure weight and blood pressure at E0, E1, E3, and E4	Yes	Yes
• Ask about any adverse events or malfunction in iAide2 at E1, E3, and E4	Yes	Yes
• TPB questionnaires at E3 and E4	Yes	Yes

For the intervention group, the intervention implements daily and weekly messaging implementing a TPB-based intervention on perceived behavioral control and actual behavioral control (Figure 2.) The researcher or clinical research coordinator (CRC) who is under the supervision of the researcher will define a baseline bedtime and an initial goal for an earlier bedtime. They will also help patients

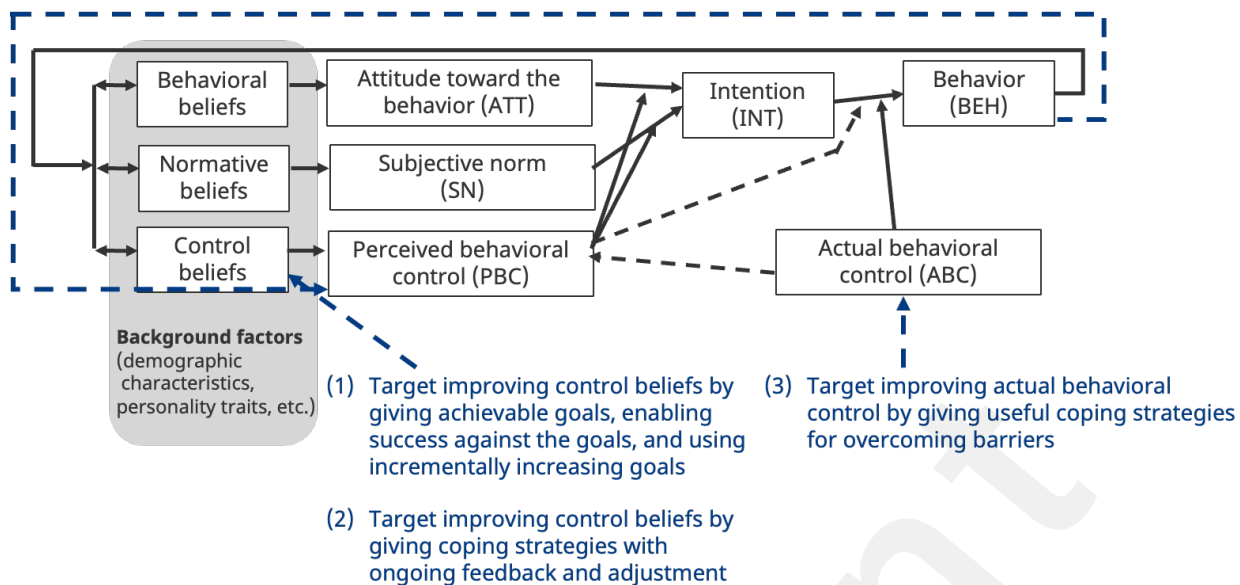
identify barriers to an earlier bedtime and determine coping strategies. Patients in the intervention group will receive a daily assessment of their performance against their target bedtime via SMS (Short Message Service) and will record whether they used their coping strategies every day. They will also receive weekly assessments of performance against the goal along with an updated target bedtime via weekly SMS messages and will decide on coping strategies for the upcoming week.

Figure 2. BedTime's process for implementing TPB-based personalization



The intervention uses the framework of TPB (Figure 3) [32, 33]. TPB models human behavior as being driven by Intention (INT) to do the behavior as well as by the ability to do the behavior, actual behavioral control (ABC). Behavior is likely to occur only when the person has both a high intention of performing the behavior and a high actual ability to perform the behavior. Intention, in turn, is affected by the person's personal attitude toward the behavior (ATT), their assessment of the beliefs of others important to them (subjective norms, SN), and their assessment of their ability to perform the behavior (perceived behavioral control, PBC). Each of these three drivers of intention (ATT, SN, and PBC) are in turn driven by the person's beliefs about them. The stronger the positive behavioral, normative, and control beliefs, the more likely someone is to intend to carry out the behavior. Actually performing the behavior depends on both intention and the actual behavioral control (ABC). ABC is difficult to measure, and researchers generally use measurements of PBC as a proxy for ABC in predicting behavior [32, 38].

Figure 3. TPB applied to the BedTime intervention



The BedTime intervention is designed to influence PBC via changes in control beliefs. The primary mechanism to improve control beliefs, and thus PBC, is by giving patients achievable goals, thereby allowing them to achieve success against goals and build positive self-mastery. We implement achievable yet growing goals using a simple algorithm based on our prior work [39]. Our algorithm increases, maintains, or decreases the suggested target bedtime based on the number of days in the previous week in which the user achieved their goal. Increases are either 5, 10 or 15 minutes and decreases are either 5 or 10 minutes, depending on past target bedtime achievement levels.

The secondary mechanism to improve control beliefs is engaging in daily self-reflection on barriers and coping strategies, leading to patients feeling that their behavior is under their control. These mechanisms are similar to or identical to the mechanisms of improving self-efficacy in social cognitive theory [32]. In addition to affecting PBC, the barrier and coping strategy intervention may improve ABC by providing useful coping strategies, though this is expected to have a relatively minor impact because the provided coping strategies will not necessarily be novel or ground-breaking to the patients. Each week participants select or write 1 to 3 barriers to achieving the targeted bedtime, and for each they suggest a solution, or coping strategy, that could be useful to overcome the barrier (Table 2). The coping strategies can be selected from a literature-based list of solutions to common barriers to going to bed early [40-60] or can be freely described by the participants. At the end of each day, participants use the diary to report on how many coping strategies they implemented that day.

Table 2: Example of personalized coping planning strategy (with English translation)

Japanese		English translation	
Barriers	Coping strategies	Barriers	Coping strategies
□□□□□□□□□□□□□□□□□□□□	□□□□□□□□□□ 2 □□□□□□□□□□	I eat dinner late and still have things to do.	Finish dinner at least 2 hours before bedtime.
□□□□□□□□□□□□□□□□□□□□ □	□□ 1□2 □□□□□□□□□□□□□□	I take a bath late and still have things to do.	Take a lukewarm bath 1-2 hours before going to bed.

□□□□□□□□□□	□□□□□□□□□□□□□□□□ □□□□□□□□□□□□□□	I have work to do before bed	Tell your boss about your doctor's orders to get more sleep and negotiate an earlier finish time.
□□□□□□□□□□□□□□□□ □□□□	□□□□□□□□□□□□□□□□ □□□□□□□□□□□□□□	I'm late coming home from work, so I still have things to do.	Tell your boss about your doctor's orders to get more sleep and negotiate an earlier finish time.
□□□□□□□□□□□□□□□□	□□ 1 □□□□□□□□□□□□□□□□ □□□	There are things I haven't gotten around to yet, such as housework.	Plan your schedule so that you leave an hour before bedtime.
	□□□□□□□□□□□□□□□□ □□□□□□□□□□□□		Make a to-do list and commit to doing it the next day instead of at bedtime.
	□□□□□□□□□□□□□□□□ □□□□□□□□□□□□□□□□		Do housework with the help of others based on your doctor's instructions to get more sleep
□□□□□□□□□□□□□□□□	□□□□□□□□□□□□□□□□ □□□□□□□□□□ 30 □□60 □□□□□□ □□□□□	I need to manage hyperglycemia or hypoglycemia at bedtime	Measure your blood sugar 30 to 60 minutes before bedtime to ensure that any necessary dietary or medication therapy is completed by bedtime.
□□□□□□□□□□□□□□	□□□□□□□□□□□□□□ 10 □□□□□□ □□□□□□□□□□	I need a little more "me" time.	Incorporate several 10-minute breaks during the day for "me" time.

The intervention provides daily individualized feedback via an SMS message (Table 3). These messages, which were typically sent between 12 PM and 6 PM, tell the patient whether they went to bed earlier or later than their target bedtime on the prior night, with an encouraging tone. This timing ensures that participants receive feedback well before their usual bedtime, allowing sufficient time to adjust their nightly activities in response to the feedback messages. The exact time of the SMS message delivery vary slightly due to the manual nature of the SMS message sending process.

At the end of the week, the intervention provides feedback via an SMS message which reports the number of days in the week that the goal was achieved.

Table 3 Example of daily feedback (with English translation)

Situation	SMS message	English translation
Last night, bedtime was earlier than the target bedtime which is 10 minutes earlier than the baseline bedtime.	□□□□□□□□□□ 10 □□□□□□□□□□□□□□ □□□□□□□□□□□□□□□□! □□□□□□□□□□ □□□□□□□□□□□□	Last night you achieved your goal of going to bed at least 10 minutes earlier. Great job! You're taking action to improve your health!
Last night, bedtime was 15 minutes later than the goal bedtime of 30 minutes earlier than the baseline	□□□ 15 □□□□□□□□□□□□□□30 □□□□□□ □□□□□□□□□□□□□□□□□□□□□□□□□□□□ □□□□□□□□□□□□□□□□□□□□□□□□□□□□ □□ □□□□□□□□□□□□□□□□□□□□□□□□□□ □□□□□□□□□□ □□□□□□□□□□□□□□□□□□	You went to bed 15 minutes later than your goal last night. You didn't reach your goal of going to bed 30 minutes earlier than your baseline bedtime. Try your best to reach your

bedtime.		target bedtime tonight. You can do it! Review your chosen coping strategy and think about your bedtime tonight. Sleeping early will improve your health!
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Patient recruitment

Patients will be recruited at 9 medical institutions in Japan (Textbox 1). Recruitment will be conducted by attending physicians during patients' regular consultations at outpatient clinics. Recruitment will be conducted from February 8th, 2024 to July 30, 2024.

In order to detect a 0.3% difference in the primary outcome (change in HbA1c), assuming a standard deviation of 0.41% (the average of the standard deviation seen in two prior studies [17, 61], and to achieve a two-sided significance level of 0.05 and a statistical power of 80%, the minimum sample size is 31 patients per group. Based on an assumed dropout rate of around 10%, we are targeting recruiting a total sample of 70 patients (35 in the intervention group, 35 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.

We will use survey instruments as part of our inclusion and exclusion criteria (Textbox 2). 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 (Textbox 3) and, to ensure that patients can safely and effectively participate in the intervention, do not meet any of the exclusion criteria (Textbox 4), building on the methods of a prior study [62]. We anticipate recruiting a participant cohort with a roughly equal distribution by sex and an average age in the late 50s. We also include women undergoing menopausal transition who meet the study's inclusion and exclusion criteria.

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) [63]. 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 [64]. For this reason, we targeted patients who are in the contemplation, preparation, or action stage of increasing their sleep duration by one hour per day.

Textbox 2. Screening surveys

- STOP-J (Snoring, Tiredness, Observed apnea, high blood Pressure screen, Japanese version)
 - Screening for obstructive sleep apnea [65]
- ISI-J (Insomnia Severity Index, Japanese version)
 - Screening for insomnia [66]
- IRLSQ-J ver.2.2 (International Restless Legs Syndrome Study Group Rating Scale,

Japanese version)

- Screening for restless legs syndrome [67]
- AUDIT-C-J (Alcohol Use Disorders Identification Test - Consumption, Japanese version)
 - Screening for alcohol use disorder [68, 69]
- PHQ-8-J (Patient Health Questionnaire-8, Japanese version)
 - Screening for major depression [70, 71]
- TTM (transtheoretical model) Sleep Questionnaire
 - Assess TTM stage [63] relative to sleeping 7 or more hours nightly

Textbox 3. Inclusion criteria of the study, selecting patients who are likely to benefit from the intervention and are likely to be capable of participating.

At the time of consent acquisition (E0)

- Diagnosed with T2D and attending the hospital/clinic
- HbA1c is 7.5% or higher at the time of obtaining consent
- A short-sleeper - self-reports an average sleep duration in the prior month of 6 or fewer hours
- In the contemplation, preparation, or action stage of TTM for the action of sleeping 7 hours or more per day
- Willing and able to wear a wristband-type measuring device on the non-dominant wrist during the research period
- Has and uses a mobile phone capable of sending and receiving SMS text messages
- Able to attend consultations at designated times during the research period
- 18 or older in age
- Fluent in spoken and written Japanese
- Does not have impaired cognitive function as determined by the investigator or sub investigator
- Can undergo sleep treatment, as determined by the investigator or sub investigator
- Fully informed about participation in this study, and has given free and voluntary written consent based on a thorough understanding of the study

Textbox 4. Exclusion criteria, focusing on patients who may not be able to participate safely or whose participation may interfere with the effectiveness of the study.

Exclusion criteria at the time of consent acquisition (E0)

- BMI is greater than 35.0 kg/m²
- Age is 76 years or older
- A shift worker, or someone who sometimes sleeps in a way other than with a single major sleep period at night
- A caregiver (of a child or adult) who needs to wake up during the night
- At high risk of obstructive sleep apnea (OSA) (STOP-J score of 3 or higher)
- At high risk of insomnia (ISI score of 15 or higher)
- Possibility of restless legs syndrome (RLS) (IRLS score of 1 or higher)
- High possibility of depression (PHQ-8 score of 10 or higher)
- Taking medications that affect sleep
- Changed T2D medication within the past 8 weeks
- Currently participating in another clinical research program
- A heavy user of alcohol (AUDIT-C-J score of 4 or higher for females, and 6 or higher for males)

- Has severe chronic pain (due to cancer, etc.)
- Has a diagnosed clinical sleep disorder
- Has an uncontrolled psychiatric disorder
- Pregnant at the time of consent acquisition
- Any other reason why the patient is classified as unfit for participation by the investigator or sub investigator

Exclusion criteria before allocation (E1)

- Recorded both bedtime and risetime in diary fewer than 7 days during the trial period
- Recorded the event button of the iAide2 fewer than 7 days during the trial period
- Recorded fewer than 7 days of valid iAide2 data showing sleep duration, as judged by the investigator or sub-investigator

We will provisionally register patients who meet the eligibility criteria at E0. At E0, we will provide each participant with an actigraph (iAide2). We will direct the participants to wear the actigraph 24 hours a day except when bathing, to press the Event button at bedtime, and to record bedtimes and risetimes in the diary. We will exclude patients who were unable to press the Event button for 7 or more days during the run-in or were unable to complete the diary for 7 or more days during the run-in period to ensure we study patients able to adequately participate in the study. We will use the data gathered during the run-in period to confirm eligibility and to set a sleep and step baseline. 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 ($<8.5\%$, $\geq 8.5\%$), and institution [72]. The random allocation will be carried out by the Internet Data and Information Center for Medical Research (INDICE) cloud, provided by the University Hospital Medical Information Network (UMIN), an internet-based central randomization system. A research co-investigator will access the UMIN INDICE cloud and enter the necessary baseline information. The allocation result for each participant will be securely generated by the system immediately before the participant is assigned to either intervention or control group. The process is designed to ensure that researchers cannot access or predict the allocation result in advance, preventing any potential bias.

Intervention process

The study (Table 4) includes 5 events (E0-E4), a 2-week run-in period, a 12-week intervention period, and a 12-week observation period. Initial measurements will be made at event E0. We will use questionnaires to assess sleep behavior and solicit patient feedback (Textbox 5).

Table 4. Study events—1 measurement period and 4 visits spanning approximately 26 weeks.

Event	Focus	Time	Key activities
E0	Physical baseline assessments and initial registration	Enrollment— ≥ 7 days before the beginning of the intervention	Collect consent Collect demographic information: age, sex, date of T2D diagnosis, smoking and drinking habits, macrovascular disease, diabetic retinopathy, periodontal disease,

			tinea pedis, diabetic neuropathy, other medical history Collect physical data: Hemoglobin levels, Alb, uric acid, BUN, eGFR, Cre, fasting blood glucose, HbA1c, LDL-C, HDL-C, triglycerides, Urine specific gravity, urinary protein, UACR, height, body weight, and BP measurements Collect medication status Conduct screening surveys (STOP-J, ISI-J, IRLSQ-J ver.2.2, AUDIT-C-J, PHQ-8-J, TTM Sleep Questionnaire) Conduct PSQI-J survey Distribute actigraph (iAide2) and run-in period diary
Run-in	Baseline	From E0 for 2 weeks	Patients record daily bedtime and risetime, with automated (blinded) measurements of sleep parameters and step count
E1	Registration, allocation, and beginning of the intervention	Beginning of the intervention	Verify that run-in diary and iAide recording do not cause exclusion Finalize registration and allocation Collect medication status Intervention only: Conduct surveys (TPB Questionnaire, SRB Questionnaire) Distribute intervention diary or control group diary Check for malfunctions or adverse events during run-in
intervention period	Ongoing measurement	From E1 for 12 weeks	Patients record daily bedtime and risetime, with automated (blinded) measurements of sleep parameters and step count Intervention only: daily feedback, weekly self-set barriers and coping strategies via diary, weekly personalized target bedtime setting via SMS
E2		End of 10 weeks from E1	Intervention only: Conduct TPB Questionnaire via diary

E3	End of the intervention	End of 12 weeks from E1	Collect physical data: Hemoglobin levels, Alb, uric acid, BUN, eGFR, Cre, fasting blood glucose, HbA1c, LDL-C, HDL-C, triglycerides, Urine specific gravity, urinary protein, UACR, body weight, and BP measurements Collect medication status Conduct surveys (TTM Sleep Questionnaire, TPB Questionnaire, SRB Questionnaire, PSQI-J) Intervention group: Conduct survey (Feedback survey) Collect actigraph (iAide2) and intervention period diary Check for malfunctions or adverse events
E4	End of follow-up	End of 24 weeks from E1	Collect physical data: Hemoglobin levels, Alb, uric acid, BUN, eGFR, Cre, fasting blood glucose, HbA1c, LDL-C, HDL-C, triglycerides, Urine specific gravity, urinary protein, UACR, body weight, and BP measurements Collect medication status Conduct surveys (TTM Sleep Questionnaire, TPB Questionnaire, SRB Questionnaire, PSQI-J)

Textbox 5. Assessment questionnaires and surveys

- TPB (theory of planned behavior) Sleep Questionnaire
 - Assess individual components of TPB [32, 33] relative to implementing an earlier bedtime
- SRB Questionnaire
 - Self-assessment of sleep over the past two weeks
- PSQI-J
 - Assess sleep quantity and quality [73, 74]
- Feedback survey
 - Collect feedback on the intervention.

Following randomization, we begin the intervention. For the intervention group, before providing any explanation of the intervention, the researcher or CRC will administer the TPB Sleep Questionnaire and the SRB Questionnaire. The researcher or CRC will then distribute a diary which is customized for the intervention group. The researcher or CRC will average the bedtimes during the

run-in period to determine a baseline bedtime, after discussing with the patient to determine if any bedtimes should be excluded as due to unusual circumstances. The researcher or CRC will tell patients that their ultimate goal is to make bedtime one hour earlier than the baseline bedtime, while for the first week the goal is to have a bedtime that is ten minutes earlier than the baseline bedtime. The researcher or CRC will provide support to identify what barriers are hindering the patients from going to bed early and assist them in determining up to three coping strategies tailored to those barriers for the first week. During this process, the researcher or CRC will facilitate discussions using the list in the diary as a reference. The patients can either choose from the list or write down their own coping strategies in the diary. For the control group, the researcher or CRC will provide patients a diary like that used in the run-in but covering 12 weeks. The researcher or CRC will tell control-group patients to continue recording bedtime and risetime, just as they did during the run-in period. The intervention period is 12 weeks, from E1 to E3. We will send messages reminding both groups to use the diary at the end of weeks 1 and 10. We will collect all equipment including the diary at E3, prior to the follow-up observation period.

For the intervention group, we will provide daily and weekly feedback. The researchers will check receipt of the Event time and, if the Event is absent, send a reminder asking the patient to report their bedtime to us via SMS. If we don't have a bedtime via an Event report or SMS, we will treat the night as a failure to achieve the target bedtime. At E2, 10 weeks after E1, we will send a reminder to answer the TPB Sleep Questionnaire in the diary.

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, T2D treatment, such as oral T2D medications, insulin, GLP-1 receptor agonists, and medication dosage, can be changed at the discretion of the attending physician. We will collect information on T2D-related medication and medication affecting sleep at E1, E3 and E4.

Discontinuation is defined as patients expressing a decision to discontinue or failing to record data for a contiguous period of 7 or more days. If participation in the study is discontinued during the intervention period, we will attempt to collect E3 measurement items. If participation in the study is discontinued during the observation period, we will attempt to collect E4 measurements items.

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 approval

This trial will be conducted in compliance with the Declaration of Helsinki, Pharmaceutical and Medical Device Act, Ministerial Ordinance on Good Clinical Practice for Medical Devices, and all other guidelines in relation to these regulations (jRCT1030230650). This study was approved by the institutional review board of the University of Tokyo School of Medicine (approval number 2023336NI). We will obtain written informed consent from all study participants. All patient data will be pseudonymized. Patients will be compensated JPY 30,000 (approximately US \$200) at the end of E4.

The participant information materials and informed consent form are available from the corresponding author upon request. Any subsequent amendments to the protocol will be submitted for further review and approval of the institutional review board. Study findings will be disseminated through peer-reviewed publications and conference presentations.

Outcome Measures

Primary outcome

The primary outcome of this study is the between-group differences in the change of HbA1c value between baseline (E0) and either the end of the intervention period at week 12 (E3), or, for patients who discontinue prior to E3, the point of discontinuation. Reduction of HbA1c by 0.3 percentage points is considered to be clinically significant [75, 76].

Secondary outcomes

Secondary outcomes (Table 5) include health measures, measurements of bedtime and sleep, measurements of other behavior changes, and assessments of actigraph and diary 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 5. Secondary outcomes investigated in the study

	Outcomes

Differences in changes	1. HbA1c (%) (only after the end of the observation period) ^a 2. Weight (kg) ^a 3. BMI (kg/m ²) ^a 4. Systolic blood pressure/diastolic blood pressure (mmHg) ^a 5. eGFR (ml/min/1.73m ²) ^a 6. Fasting blood sugar (mg/dL) ^a 7. LDL-C (mg/dL) ^a 8. HDL-C (mg/dL) ^a 9. Neutral fat (mg/dL) ^a 10. UACR (mg/gCr) ^a 11. PSQI-J ^a
Differences in the measured values	12. Survey on past bedtimes ^a
Difference in proportions	13. Behavior change questionnaire ^a
	14. Elements of the bedtime questionnaire (Attitude (ATT), Subjective Norm (SN), Perceived Behavioral Control (PBC), Intention (INT)) ^b 15. Sleep time calculated from iAide2's sleep data and diary data ^c 16. Time in bed (TIB) calculated from bedtime and wake-up time recorded in diary for each period ^c 17. Bedtime recorded in diary for each period and bedtime sent from iAide ^c 18. Steps recorded by iAide2 ^c 19. Achievement rate of target bedtime ^d 20. Number of barriers and coping strategies set and implemented in the diary for the intervention period ^d 21. Percentage of use of each drug ^e 22. Percentage of new additions for each drug since consent was obtained ^f 23. Changes in antidiabetic drugs since consent was obtained (strengthened, unchanged, attenuated) ^f

^a Evaluate the differences after the end of the intervention period (at 12 weeks) and after the end of the observation period (at 24 weeks) from the time of consent acquisition

^b Evaluate the differences in the measured values for the following items at 10 weeks and after the end of the observation period (24 weeks)

^c Evaluate the difference in the average change from the trial period in the two weeks before the end of the intervention period

^d Evaluate the rates weekly during the intervention period, for intervention group

^e Evaluate the differences in percentages at the time of consent acquisition, at the time of actual registration, after the end of the intervention period, and after the end of the observation period

^f Evaluate the difference in proportions after the intervention period and after the observation period

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 primary outcome was obtained. 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 had 7 or more contiguous days of not using the iAide2, or who took medications that affect sleep. The SAS is the set of all patients who used the iAide2 at least once after randomization. In the safety analysis using the SAS, we will analyze data based on the intervention 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 baseline (E0) to week 12 (E3) (or point of discontinuation, if earlier) using analysis of covariance including baseline HbA1c (i.e., HbA1c at E0) as a covariate in the FAS. If participants discontinue the study, the latest measurement of HbA1c before E3 will be used.

We will also conduct two subgroup analyses with one classification by HbA1c at baseline (E0) (either $<8.5\%$ or $\geq 8.5\%$) and the other classification by Age at time of initial registration (E0) (either <65 or ≥ 65 years). We will conduct subgroup analysis on the primary outcome in each analysis set to investigate whether the efficacy of BedTime is consistent between these subgroups.

In the secondary analysis, the change in HbA1c at week 12 (E3) and week 24 (E4) will be analyzed as in the primary analysis. The proportion of HbA1c less than 7% at week 12 (E3) and week 24 (E4) (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 (E3) and week 24 (E4) (or point of discontinuation, if earlier) will be analyzed as the primary endpoint. Changes in T2D 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. A paired t-test will be used for within-group comparison over the week 0 (E1), week 10 (E2), week 12 (E3), and week 24 (E4) for change in TPB Questionnaire measurements. Changes in TPB Questionnaire measurements and SRB Questionnaire measurements will be compared between week 12 (E3) and week 24 (E4) by t-test. A paired t-test will be used for within-group comparison over the week 0 (E1) to week 12 (E3) 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 (E3) and week 24 (E4) (or point of discontinuation, if

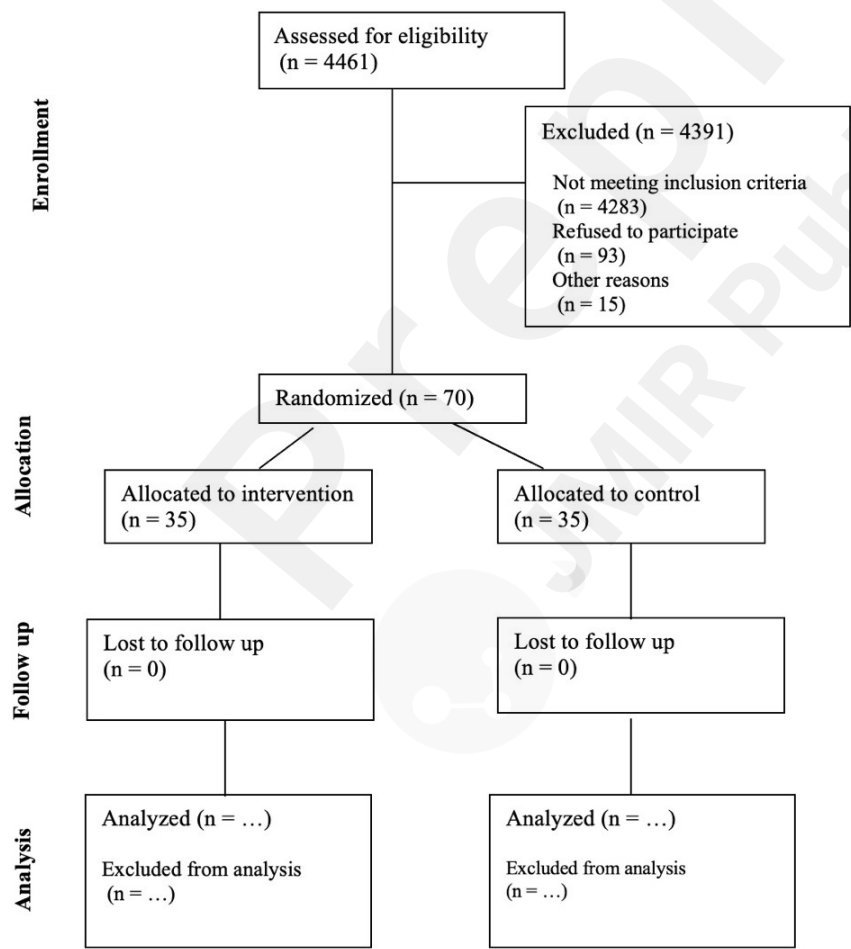
earlier) will be evaluated.

We will conduct statistical analysis of safety outcomes. We will calculate the frequency, number of cases, and percentage of individuals experiencing adverse events during the trial period, intervention period, and observation period. For the intervention and observation periods, compile the data separately for each group and compare the percentages between groups using Fisher's exact test.

Results

Recruitment began on February 8, 2024, and ended on August 29, 2024. The intervention period concluded on December 6, 2024. The observation period is scheduled to conclude on February 26, 2025. We anticipate concluding analysis by March 30, 2025. We will thoroughly review all the collected data and data entry before commencing analysis.

Figure 4. CONSORT Flow Diagram Depicting Enrollment, Allocation, Follow-Up, and Analysis Phases



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 TPB, 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, going to bed earlier, 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 changes sleep behavior while also assessing any resulting changes in sleep 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 study 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 sleep and step count to be synced automatically to the server. These simple passive features make for easy-to-use objective measurements, especially for older patients.

Participants will be blinded to group assignment, so social desirability bias will not affect the results. To achieve that, the patients will not be told that this study involves random assignment to two groups, nor will they know that it is a study aimed at advancing bedtime for the intervention. Patients are informed that the study aims to examine the relationship between self-management of lifestyle habits (including exercise and sleep) and blood glucose control in patients with type 2 diabetes, and that various information on lifestyle factors, including sleep, will be collected. This approach minimizes the risk of the control group unblinding themselves by identifying the lack of intervention. We believe that maintaining blinding provides a significant scientific benefit, as it reduces potential bias and enhances the validity of the study findings.

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 T2D treatment [77]. According to The Japan Diabetes Society's treatment guideline, patients with T2D should aim to lower their HbA1c level to below 7% to prevent the development of any complications [78]. 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. We recognize that the duration of T2D may influence the primary outcome. While our recruitment process does not explicitly stratify participants based on disease duration, this information is collected during participant registration. This data will be incorporated into the analysis to account for its potential impact on study outcomes.

In this study, we have elected to use a “formidable” control [79] using the same devices as those used in the intervention group. This study is an initial confirmation of proof of concept, and we want to show whether our specific behavior change intervention methods are superior to simply having patients record bedtime and risetime. There is evidence that simply giving patients a pedometer increases their activity level [80]. This leads to some concern that recording bedtime and risetime in the control group may similarly induce a response that could hinder statistical proof of any superiority of the intervention. By giving the control group the iAide and diary, but not giving them the intervention functionality, we have designed the study to give strong proof of the success of the

intervention, if in truth it is effective.

Many behavior interventions show solid short-term gains that then fade [39]. This study includes an observation period of the 12 weeks following the intervention period in order to see if any intervention benefit persists or fades. Behavior change maintenance is theorized as an outcome of active and on-going self-regulation, and habit development follows a period of successful self-regulation of a new behavior [81]. 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. 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 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 a previous study [39]. We acknowledge that general socioeconomic background may influence sleep patterns. While our recruitment strategy does not explicitly target specific socioeconomic groups, the institutions involved in the study serve patient populations with typical demographics representative of the general community.

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 [39, 63]. 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 T2D patients in Japan have high motivation, with one study showing that 92% are in the contemplation-through-action stages of TTM in dietary behavior change [82]. There is a very large pool of patients who would benefit from this targeted intervention. This study is a multi-center randomized controlled trial, and this increases the generalizability of the findings to T2D patients throughout Japan. Our techniques are general, and there is every reason to believe these methods could be applied to increase sleep duration 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. Our baseline measurement of sleep is based on providing actigraphs and sleep diaries to participants, and the resulting measurements may be higher than the true pre-study sleep levels. This effect is mitigated by our two-arm trial and the length of our trial, but it may lead us to underestimate increases in sleep duration and therefore overestimate the per-hour-of-sleep impact on health outcomes.

This trial will provide important evidence on the efficacy of a TPB-based mHealth intervention in improving sleep duration and glycemic control in T2D 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 T2D patients in Japan.

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Data Availability

The datasets generated during and/or analyzed during this study can be obtained from the corresponding author on reasonable request.

Conflicts of Interest

None declared.

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Abbreviations

ABC– Actual behavior control

Alb – albumin

ATT– Attitude toward the behavior

BMI – Body mass index

BP – Blood pressure

BUN – Blood urea nitrogen

BW = Body weight

Cre – Creatinine

eGFR – Estimated glomerular filtration rate

FAS – Full Analysis Set

FBG – Fasting blood glucose

GLP-1 – Glucagon-like peptide 1

HbA1c – Hemoglobin A1c

HDL-C – High density lipoprotein cholesterol

INT – Intention

ITT – Intention to treat

LDL-C – Low density lipoprotein cholesterol

mHealth – Mobile health

PBC– Perceived behavior control

PPS – Per Protocol Set

SAS – Safety Analysis Set

SN – Subjective norm

T2D – Type 2 diabetes mellitus

TPB – Theory of planned behavior

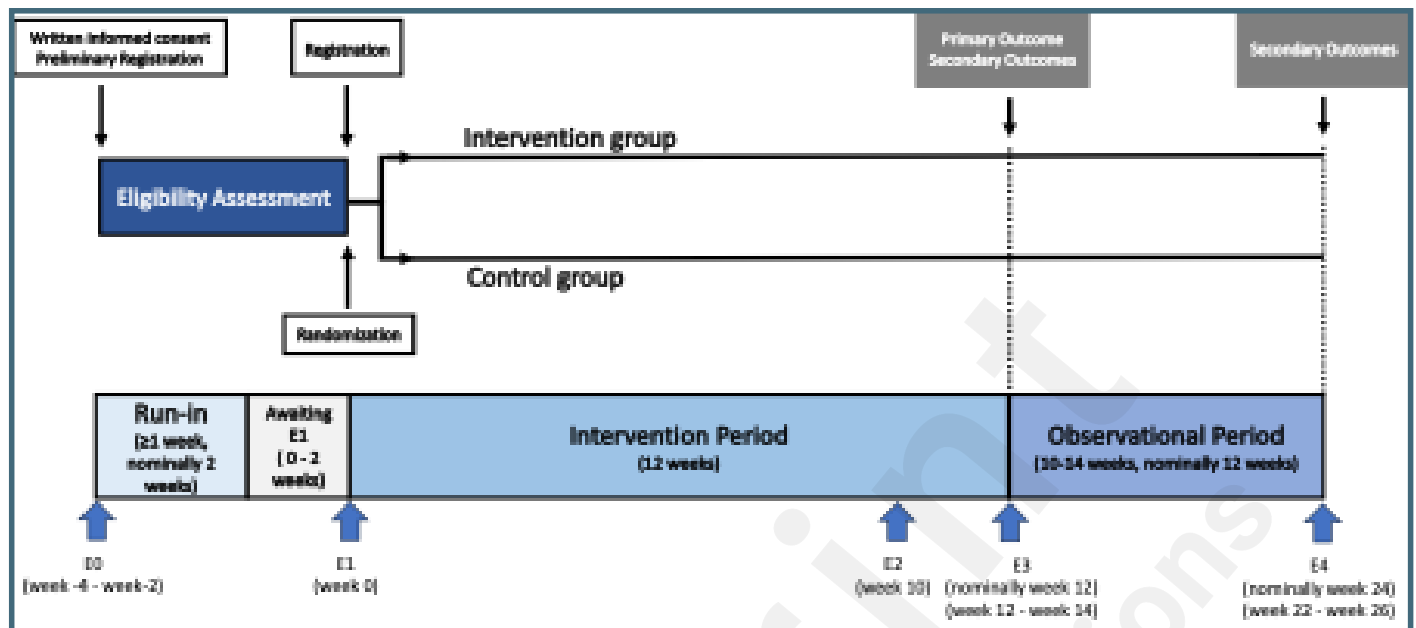
TTM – Transtheoretical Model

UACR – Urine albumin-to-creatinine ratio

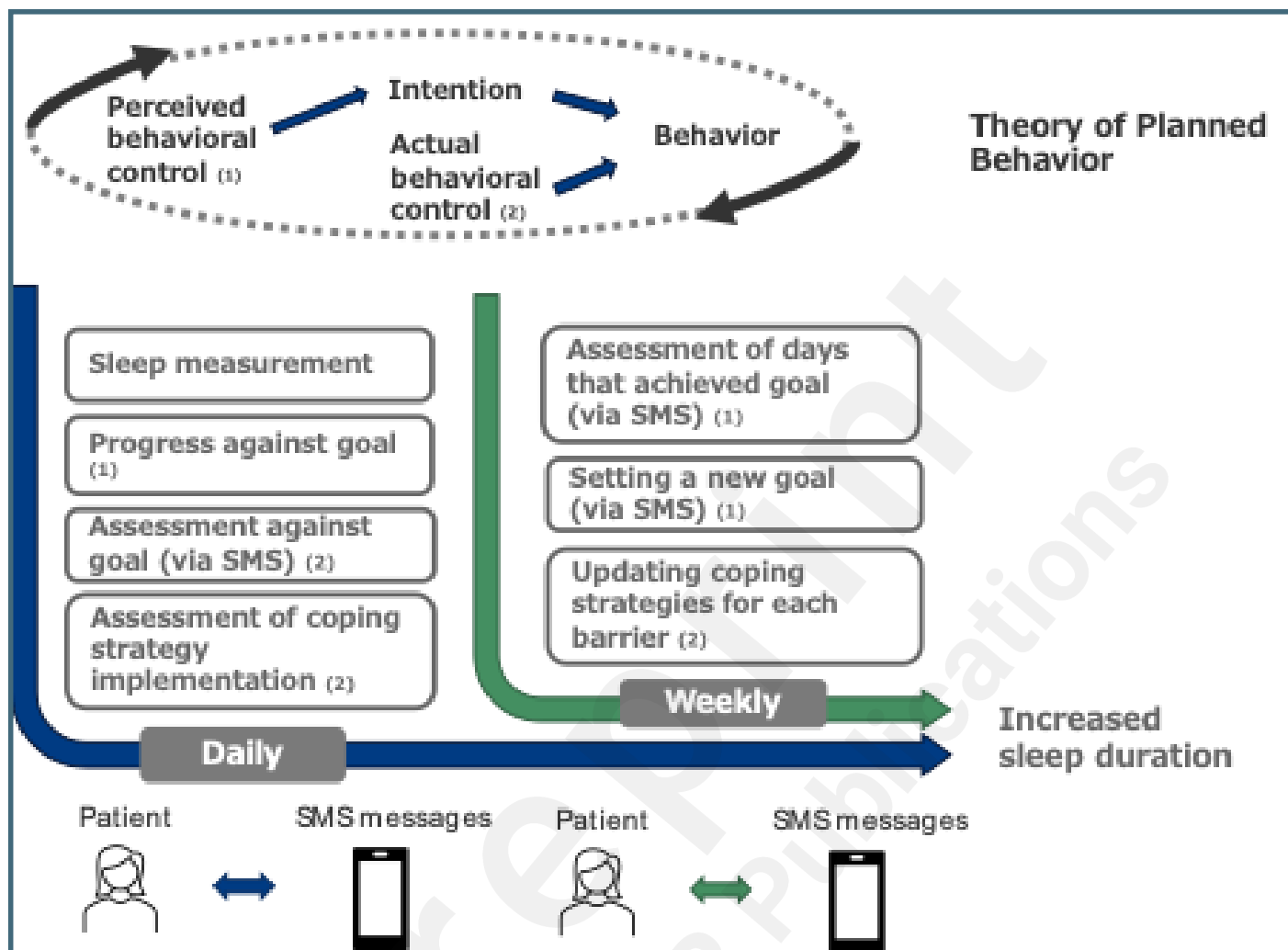
Supplementary Files

Figures

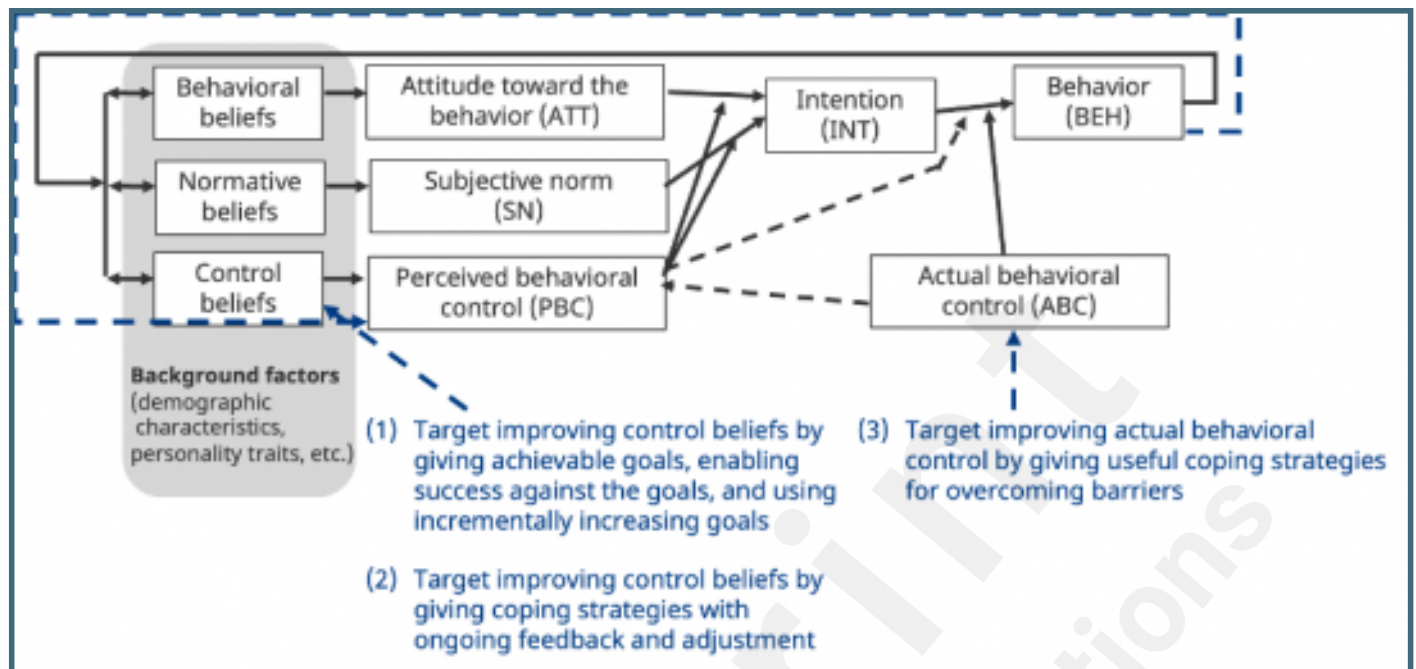
Overview of study timeline.



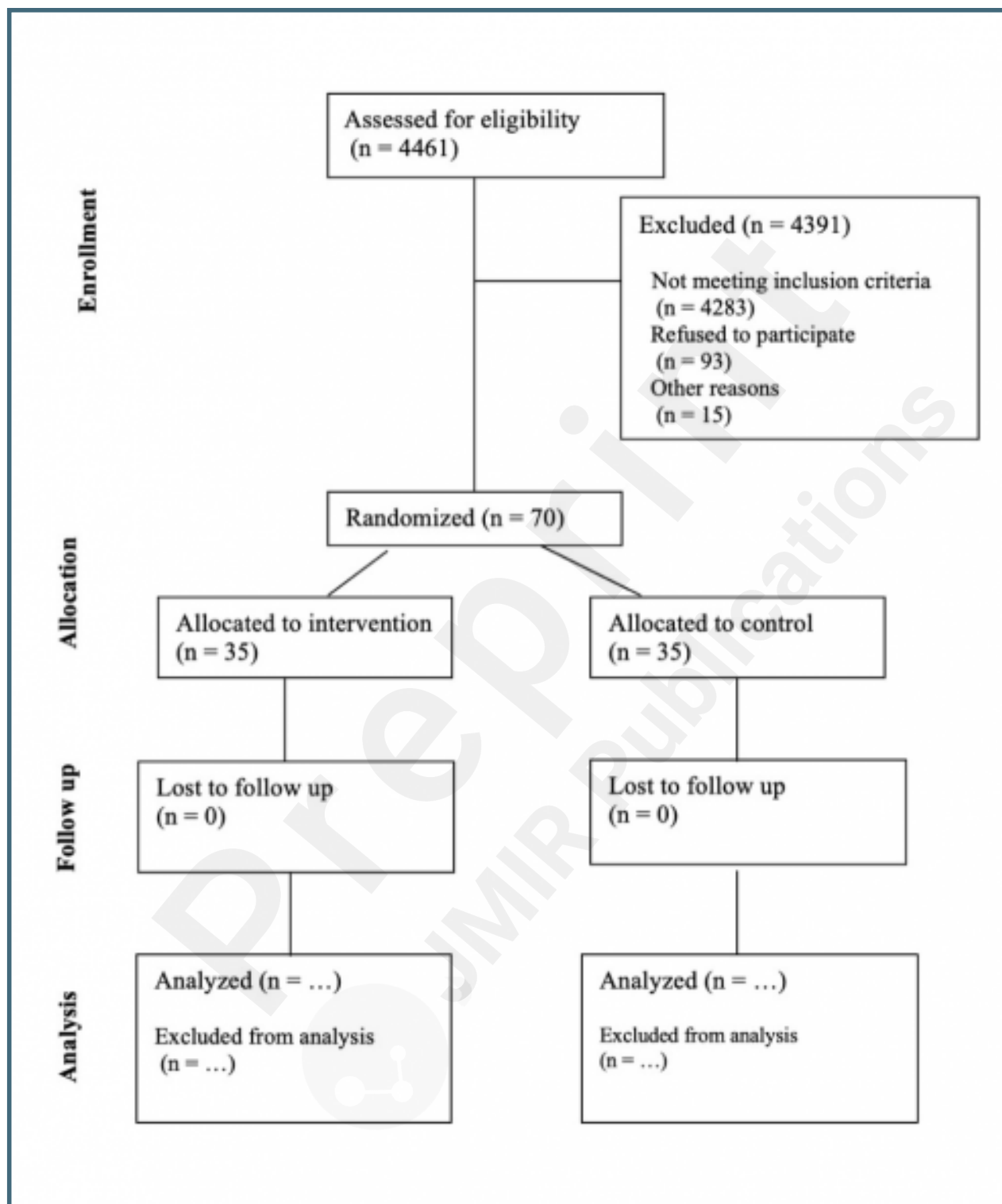
BedTime's process for implementing TPB-based personalization.



TPB applied to the BedTime intervention.



CONSORT Flow Diagram Depicting Enrollment, Allocation, Follow-Up, and Analysis Phases.



CONSORT (or other) checklists

SPIRIT checklist.

URL: <http://asset.jmir.pub/assets/10726c0acc926f2bbbd7b78e5770f011.pdf>

