Technology-Based Sedentary Reduction Intervention in Patients with Type 2 Diabetes: A Pilot Study

Principal Investigator:
Shelagh Mulvaney, PhD
Associate Professor
School of Nursing, Vanderbilt University
425 Godchaux Hall
21st Avenue South Nashville, TN 37240
Phone: 615-322-1198
Email: shelagh.mulvaney@vanderbilt.edu

Co-Investigators:

Chorong Park, PhD, RN
Assistant Professor
School of Nursing, Vanderbilt University

Mulubrhan Mogos, PhD, MSc
Assistant Professor
School of Nursing, Vanderbilt University

James Muchira, PhD
Assistant Professor
School of Nursing, Vanderbilt University

Jason Jean, DNP
Lecturer of School of Nursing Vanderbilt University
Nurse Practitioner of Vanderbilt University Medical Center

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1.0 Background

Sedentary behavior (SB) is a strong modifiable risk factor for developing type 2 diabetes (T2D) and cardiovascular disease, even after controlling for daily physical activity.[1-3] During sedentary behavior, there is no muscle contraction of the legs, which causes decreasing insulin sensitivity, glucose uptake, vascular dysfunction, and promotes low-grade inflammatory cascades.[4] Despite the important role of sedentary behavior in managing T2D, people with T2D remain highly sedentary. They spend on average 11-15 hours per day sitting,[5,6] which comprises 65-75% of waking time.[5,7,8] Moderate-to-vigorous levels of physical activity or exercise can attenuate cardiometabolic risk, but does not eliminate the increased risk associated with high sedentary time.[1,9] Considering T2D patients' low cardiorespiratory fitness and low activity levels,[10,11] they may be at greater risk than others for the negative cardiometabolic consequences of sedentary behavior.[12] Therefore, there is a pressing need to develop novel strategies to reduce SB and improve daily activity in patients with T2D. Targeting SB, which occupies most of a T2D patient's waking time, can be a new target behavior for secondary prevention in this population.

2.0 Rationale and Specific Aims

Frequent standing/walking can reduce the total SB time and change prolonged patterns to interrupted patterns. Since leg muscles do not contract during SB, sedentary breaks such as standing/walking (requiring muscle contractions) may change physiological pathways and improve cardiometabolic outcomes. A recent meta-analysis found that while controlling for total sedentary time and MVPA time, short sedentary breaks (2-5 minutes of standing/walking for every 20-60 minutes of sitting) were beneficially associated with cardiometabolic markers; adding one break decreases 0.05 unit of BMI, 0.2 cm of WC, 0.002 mg/dl of hsCRP, and 1.8 mmHG of systolic blood pressure (BP).[13,14] Many intervention studies have also shown that breaking prolonged sedentary time with short periods of light PA or standing improves glucose (2-17%) and insulin (15%).[13,15] Moreover, emerging evidence shows that **reducing SB time with frequent breaks is safe[16-18] in other chronic health conditions and applicable to T2D patients.**

SB breaks can be achieved through self-monitoring and prompts from a wearable device. In addition, the use of a smart water bottle may be a promising strategy to naturally break sedentary time due to the impact of increased water intake on kitchen and restroom breaks. A smart water bottle can sync with an activity tracker, which could synergistically motivate the T2D patients to reduce SB. This new technique is a potentially low-cost and sustainable strategy to deliver SB reduction interventions. Because there is no SB reduction program specifically focusing on sedentary breaks in T2D patients, we propose to develop and conduct a pilot study to test a wearable technology-based SB reduction intervention in T2D patient The 8-week intervention includes: 1) one instructional and goal setting session; 2) the use of a wearable device (Fitbit) that provides stand/walk prompts and self-monitoring; 3) a smart water bottle (HidrateSpark) that syncs with the Fitbit, and 4) weekly tailored text messages for behavior reinforcement and weekly goal monitoring. Since text messages and wearable device-based intervention requires a complex and multiple iterative process to customize research participants' needs and refine the contents and frequency of the text messages. To find the most suitable frequency and contents of text messages, we will use an iterative design process. Outcomes will be measured at baseline and post-intervention. Specifically, we aim to: **Aim 1**: Determine the feasibility and acceptability of the SB reduction intervention in T2D patients by evaluating reach, retention, satisfaction, and compliance with the

intervention.
Aim 2: Evaluate the preliminary efficacy of the SB reduction intervention on changes in total SB time and numbers of prolonged SB bouts.
Aim 3 (Exploratory Aim): Explore preliminary effects of the SB reduction intervention on light physical activity (total standing and stepping times), cardiometabolic markers (24-hour glycemic control, BMI, waist circumference, blood pressure) and patient-centered outcomes (confidence in reducing SB, habit strength for SB, and quality of life).

3. Inclusion/Exclusion Criteria

Inclusion criteria: 1) ages 18 and above, 2) diagnosed with type 2 diabetes, 3) self-reported HbA1C<13, 4) self-report of sitting ≥ 8hr/day, 5) ability to stand and walk, 6) ownership of a smartphone.
Exclusion criteria: 1) currently using an activity tracker; 2) currently participating in exercise or other research programs; 3) use of insulin; 4) non-English speaking; 5) patients who are classified as unstable (e.g., heart failure, uncontrolled arrhythmia) or have kidney disease that limits daily water intake, or any other conditions contradictory to standing or walking[19,20]; and 6) random blood glucose > 300, and 7) currently pregnant.

4.0 Enrollment

Recruitment

We will use five recruitment strategies:

1) **Self-referrals**
   Recruitment flyers and brochures will be posted in Primary care clinics at Vanderbilt for self-referrals. The flyer and brochure are attached to this application. If the subject is interested, they will call the number on the recruitment flyers. During the phone call, the trained research staff will answer any questions from the potential participants and ask about their eligibility. Any of the data regarding their eligibility will not be recorded or stored. If subjects are interested in participating and meet all the eligibility criteria, an in-person baseline visit will be scheduled. The detailed procedure regarding pre-screening prospective participants is described below

2) **Research Notification Distribution List**
   Email distribution list allows researchers to email IRB-approved participant recruitment announcements to the Vanderbilt community. Members of the distribution list have the option to subscribe/unsubscribe with each email. The potential participants will click the pre-screening consent. The detailed procedure regarding pre-screening prospective participants is described below

3) **ResearchMatch.**
   ResearchMatch is a national electronic, web-based recruitment tool that was created through the Clinical and Translational Science Awards Consortium in 2009 and is maintained at Vanderbilt University as an IRB-approved data repository (see IRB #090207). The detailed procedure regarding pre-screening prospective participants is described below.

   After advertisement, there will be two approaches to identify eligible participants. For online recruitment (using Email distribution list and ResearchMatch) placed via email, there will be a link directing the potential participants to the prescreening e-consent via REDCap. They will have an

option to download the e-consent for prescreening activities. After they sign on the prescreening e-consent, they will answer several questions about their eligibility (e.g. sitting hours > 8 hours a day). These pre-screening data will be saved into REDCap. Once they meet all the inclusion criteria, the trained research staff will call them to confirm their eligibility and schedule an in-person baseline visit.

4) **Reporting Workbench**
Reporting Workbench Reports are available/viewable in eStar. These reports are developed using real-time data and can be customized to meet study-specific inclusion/exclusion criteria that are computable in the EHR. The reports often include additional variables to facilitate study team outreach, such as Research OK to Contact status, MHAV account status, contact information, next upcoming appointment in a specific clinic. While the report displays certain variables/data, it provides easy access to a patient's record for additional screening and confirmation of eligibility. Research team members with appropriate eStar access can view/run the reports as frequently as needed.

We plan to use the results from our custom Reporting Workbench report to facilitate outreach in the following way: To send My Health at Vanderbilt (MHAV) recruitment requests, as detailed below in recruiting strategy 5. KSP do not have an existing provider relationship with the patients being approached about study participation. Results will be restricted to those marked as 'OK to Contact'. We will not be reaching out to employees or persons of interest.

5) **My Health at Vanderbilt (MHAV) Recruitment Requests**
Participants will be recruited through My Health at Vanderbilt. My Health at Vanderbilt (MHAV) is VUMC's patient portal where the patient may sign up and participate in managing his/her health care. MHAV can also be used for sending recruitment requests to a predefined cohort of patients who meet certain study-specific inclusion/exclusion criteria, have an activated MHAV account and are marked as OK to Contact in eStar. The recruitment requests are sent by a central VICTR team on behalf of the study team. The notification preferences for the recruitment requests can be managed by the patients in MHAV. The system default is an email notification like clinical notifications (see attached MHAV Recruitment Request messaging). If the patient has turned off notifications, the study will just be listed on their research studies page in MHAV.

Once the Recruitment Requests are sent, the patients' enrollment status is automatically updated to (IT Use Only) Identified - RWB Recruitment Message or Auto DL. If the patient clicks '**No Thank You'**, the patient's enrollment status in eStar is automatically updated to **(IT Use Only) Not Interested - Pt. answered in MHAV**. The study team does not get a notification in Epic In Basket or in REDCap.

If the patient clicks '**I'm Interested**', the designated KSP (with eStar access) receive an In Basket message in eStar indicating the patient is interested

The patient's enrollment status is automatically updated to **(IT Use Only) Interested - Pt. answered in MHAV**. The REDCap Participant Updater Module looks for the patient's MRN in the study specific database. If a matching MRN is not found, the Participant Updater Module creates a record in the study-specific database with the following information from eStar:

(1) Patient's MRN

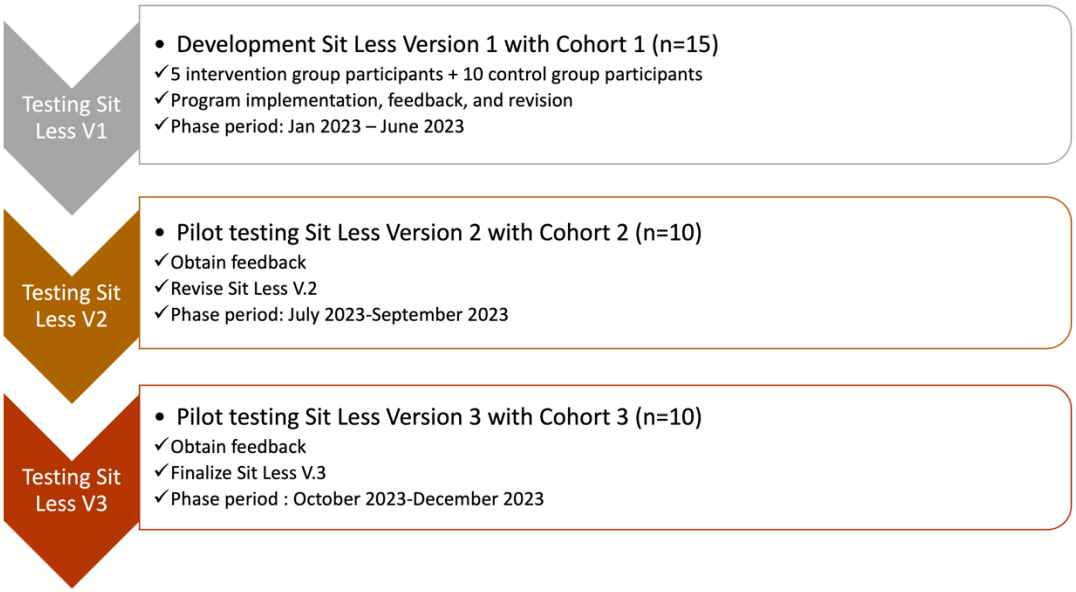
(2) Patient's enrollment status - (IT Use Only) Interested - Pt. answered in MHAV
(3) Study ID (IRB#)

REDCap CDIS is then triggered to pull in the patient email address from eStar if available for all patients who click I'm Interested. This will trigger an email from REDCap to the patient which contains a link to the IRB approved pre-screening and eConsent surveys on REDCap.

If the patient responds to the email from REDCap or completes a pre-screening survey or eConsent, the study team will update the patient's enrollment status accordingly in eStar or REDCap. Once the patient's enrollment status has been updated in the study specific record in REDCap, the Participant Updater Module will automatically update the enrollment status in eStar. The study team will contact the interested patient by telephone call or email to confirm their eligibility and schedule an in-person baseline visit

5.0 Study Procedures

This iterative design process requires multiple cohorts until reaching the general agreement in terms of participants' satisfaction and feedback on the intervention. Below is the steps to iterative process of developing Sit Less Program.
As of today (May 15, 2023), we are currently undergoing the first phase, testing Sit Less V1 and will collect participants' feedback in June 2023. We also collected user's feedback from a sibling study " Reducing sedentary time in patients with cardiovascular disease: A pilot randomized controlled trial (Sit Less Study)" IRB # 220416. This sibling study has the same intervention components and is now undergoing qualitative analysis based on intervention group participants' feedback. 35



Below is a detailed study process over time for all of cohort participants.

5.1. Baseline visit 1: Initial contact, screening, and consent

Interested respondents will be screened by a trained research staff over the phone or in-

person, depending on the recruitment methods. For this research, no aspect of the participant's diabetes treatment regimen will be modified.

Those who are eligible for the study will be invited to the in-person visit. The first visit (i.e. Baseline visit 1) will be conducted at VUSN (Vanderbilt School of Nursing)'s lab at Wesley building.

At the Baseline visit 1, the trained research staff will ask the individual what their most recent blood glucose level was. If their reported glucose levels are between 80-300, they will complete the informed consent with assistance from the trained research staff. Those who are consented will participate in 1) completing survey questionnaires (30minutes), 2) biometric assessments 3) brief instruction regarding the wear of activPAL and continuous glucose monitoring (CGM) devices (30 minutes), and 4) start to wear two devices for 7 days. The activPAL3 device (PAL Technologies Ltd., Scotland, UK) will be worn on the thigh and a CGM (Abbott FreeStyle Libre) will be attached to the upper arm. The research staff will provide 1) a copy of the informed consent form; 2) instructions with photos and 5 waterproof dressings (Tegaderm) for attaching the activPAL on the thigh; 3) information about the CGM; and 4) daily sleep diary and wear log for 7 days. Participants will receive $25 for baseline visit 1.

1. **Questionnaires**
   Participants will be given an iPad to answer questions about their demographics, socioeconomic characteristics, and a series of questionnaires detailed below. All responses will be recorded in REDCap.
   a) **Demographics**: demographics and socio-economic status will be self-reported by the patients.
   b) **Health behavior**: Questions about their tobacco use, alcohol intake, physical

activity (measured using the 16-item Global physical activity questionnaire[21]), sedentary behavior (measured using 11-item Weekly sitting inventory[22]), and diet (measured using the 16-item Rapid Eating and Activity Assessment for Participants Short Version (REAP-S)[23], sleep quality (measured using the 10-item Pittsburgh sleep quality index[24]) will be answered with the assistance of the study team member.

c) **Confidence in reducing SB and increasing PA**: Confidence in reducing SB and increasing physical activity will be measured using 12 items from the Self-

Efficacy Questionnaire for Physical Activity and Sedentary Behavior (Cronbach's alpha = 0.79). [25]

d) **Habit strength for SB**: Habit strength for SB will be assessed by using a validated measure, Self-Report Habit Index (Cronbach's alpha = 0.91). [26] This 7-item index was adapted to sedentary breaks (standing/walking) to assess the degree to which sedentary breaks become habitual.
e) **Quality of life**: Quality of life will be measured by using the 12-item Short Form Health Survey (SF-12). The SF-12 is well-validated in T2D patients[27] and provides physical and mental health scores.[28]
f) **Medical history and current medication**: Medical history and current medication will be self-reported by the patients.
g) **Depressive symptoms**: Depressive symptoms will be measured by using Patients Health Questionnaire 9 (PHQ-9)[29].
h) **Diabetes self-management**: Self-efficacy of diabetes self-management will be measured by the Perceived Diabetes Self-Management Scale[30].

2. Biometric assessments

Participants will undergo a basic physical examination (e.g., height, weight, blood pressure, hip circumference, waist circumference).

a) **Anthropometrics:** Height, weight, and waist and hip circumferences will be measured using a validated stadiometer, digital scale, and flexible tape measure, respectively. All measurements will be recorded to the nearest 0.1 cm and 0.1 kg.
b) **Blood pressure:** Blood pressure will be measured using an automated and validated BP monitor. In a private room, participants will be seated comfortably for 5 minutes with feet flat on the ground prior to measurements.[32] The device will take three readings at 2-minute intervals and the mean of three BP readings will be recorded.[32]
c) **Random glucose via finger prick**: The trained research staff will conduct a finger prick and one drop of blood will be obtained on a glucometer. The glucometer will be used to test their random glucose. Participants will NOT be required to fast overnight prior to the study visit. If the random glucose >300, the PI will be immediately informed and the participant will be withdrawn per the protocol (see section 7).

3. ActivPAL

The activPAL is a non-invasive method of monitoring activity and rest cycles through an inclinometer. The device will be worn on the anterior upper thigh of the dominant leg and kept in place by an adhesive pad (Tegaderm). If the participants have hair on the upper thigh, shaving an area of the thigh will be considered; we will provide a disposable shaving razor and foam as well as a private room with a sink. The participant will apply the device by themselves in a private room. The participants will wear the activPAL 24hours over a 7-day period. There is no need to charge the device. The activPAL monitor has been validated against direct observation and is the most sensitive device to detect sitting-to-standing transitions.[31]At a follow-up visit (Baseline visit 2), the activPAL data will be downloaded to the secured PI's computer and summary reports will be reviewed by the study team member and the participants.

4. Continuous Glucose Monitor (CGM)

The device (FreeStyle Libre Pro™; Abbott Diabetes Care, Witney, Oxon, UK) will be worn on the back of the upper arm to measure their 24-hours glucose levels for 7

days. The CGM has one sensor applicator, one sensor, and one reader. Skin will be prepared using an alcohol wipe and the sensor applicator will be placed over the application site. The research staff will press firmly, hold for a few seconds, and gently pull the sensor applicator away from the site. A sensor applicator has an introducer needle which will be retracted after application. Only a thin, flexible filament will remain under the skin and the sensor is held in place by an adhesive. The sensor applicator serves as a container for disposal. The water-proof sensor, worn on the upper arm, is factory calibrated. The reader is retained by the PI and data are not visible to participants during sensor wear. The sensor automatically captures and stores glucose data every 15 min (96 glucose readings/day).

5. **Sleep diary and wear log**
   The participants will be asked to complete a daily sleep diary each morning while they are wearing the monitor, which takes about 2 minutes. The participant will also complete a daily wear log each evening. The information about sleep onset and offset and wear time will be used to validate the activPAL wearing protocol.

Once they complete the 7 days of activPAL and CGM monitoring, they will be scheduled for the in-person visit (Baseline visit 2) and will return the devices and log to the study team at the visit.

5.2. Baseline visit 2

5.2.1. Device removal

The in-person baseline visit 2 will take place at the VUSN Clinic in the Wesley building. Participants will return the activPAL and the continuous glucose monitoring devices at Baseline visit 2. The trained research staff will assist the participant in removing the two devices as needed, and then download the data from the activPAL and CGM devices. Baseline visit 2 will last approximately 1 hour and 30 minutes. Participants will receive $25 for baseline visit 2.

1. **ActivPAL data download**

   The 7 days of activPAL data will be downloaded and stored in the secured PI's computer. The variables of interest from the activPAL data are listed below:

   a) **Sedentary behavior**: SB will be objectively measured as time spent sedentary (sitting or lying, minutes/day) and number of prolonged sedentary bouts (>30 minutes and >60 minutes) using the activPAL3. ActivPAL data will be downloaded and processed using activPAL software.

   b) **Physical activity**: Time spent standing and walking (stepping), number of sitting-to-standing transitions, and daily step counts will be measured using the activPAL.

2. **Continuous glucose monitoring data download**

   The 7 days of CGM data will be downloaded via Libreview and stored in the PI's computer. The variables of interest from the CGM data are listed below:

   a) The 24-hour glucose control: the 24-hour glucose control will be evaluated by mean 24-hour glucose levels and numbers of events and time in hypoglycaemia (glucose < 3.9 mmol/l), euglycaemia (glucose 3.9–7.8 mmol/l), hyperglycaemia (glucose > 7.8 mmol/l) and above target (glucose > 9 mmol/l).

5.3. Intervention

The 8-week intervention will consist of four components. All study subjects will be assigned to intervention group. After the intervention, the study subjects will keep their Fitbit and the HidrateSpark smart water bottle.

5.3.1. Instructional/goal setting session

The study team member will provide an orientation at the baseline visit 2. The study team member will review the activPAL data and identify targetable prolonged SB bouts. The study team member and the participant will set two goals: 1) a SB reduction goal will be set as reducing daily sedentary time gradually until they reach the goal of ≥ 120 minutes SB reduction; and 2) a sedentary break goal will be set as 3 minutes of standing/walking every 1 hour and then increasing its duration to 5 minutes and its frequency to every 30 minutes. These goals were feasible in stroke patients and T2D patients.[16,33] The participant will enter the goal into the Fitbit for self-monitoring and fill out the first worksheet in the Ten Top Tips (TTT). The TTT is a booklet developed from the Habit Formation Theory and includes 10 tips to add SB breaks into their daily routine.[34] The ten tips are modified to eight in our study. See Appendix for the TTT and worksheet. This goal session will last 1 hour.

5.3.2. Fitbit

We will provide Fitbit (Inspire 3) that can alert participants with a vibration when they have been sitting for 60 minutes. Participants can select the days and the time ranges to receive the move alerts. Patients will be encouraged to review their daily summary before they go to bed.

The Fitbit is not intended to be used as a medical device. All participants will have the ability to monitor physical activity, sleep, and heart rate with the Fitbit. All data from the Fitbit will be continuously, streamed to the secured Fitbit servers. The study team member will assist participants in downloading the app and creating an account and will instruct them on how to use the device, with the official Fitbit user manual. When we create Fitbit accounts for research subjects, we do not use their real name or email address and default their account settings to the most privacy-protective option available.

Fitbit accounts require a unique email address for each user. To ensure participants' anonymity and privacy when creating Fitbit accounts, we will (1) set up anonymous Gmail accounts and (2) set up deidentified Fitbit accounts for the purpose of the study. This individualized email address will then be linked to a Fitbit account in which personal identifiers should not be used. Importantly, research staff and participants will be advised that the email and Fitbit accounts should be used strictly for the study's purpose. Moreover, account information will be stored in protected PI's computer within encrypted documents. Once the intervention is concluded, Fitbit data will not be collected. Also, Fitbit and Fitbit app will be reset for the participant to keep using the Fitbit after study completion.

5.3.3. Smart Water Bottle

We will provide a HidrateSpark water bottle, and the study team member will assist participants in downloading the app and creating an account. The study team member

will instruct participants on how to use the bottle, with the official user manual. The device alerts participants with a color change and message on the Fitbit to keep them hydrated. The device provides the daily water intake summary in the Fitbit app. We will advise participants to drink 4.5 – 6 bottles (500ml/bottle) of water per day based on current recommendations by the U.S. National Academies of Medicine.[35]
The HidrateSpark accounts require a unique email address for each user and the same email which is used to Fitbit account will be used to the HidrateSpark app. The same rules will be applied to the HidrateSpark account, and the account information will be stored in protected PI's computer within encrypted documents.
Once the intervention is concluded, HidrateSpark data will not be collected. Also, HidrateSpark bottle and the app will be reset for the participant to keep using the bottle.

5.3.4. Weekly Text Message

Text messages will be provided to support and enhance the habit formation process. Text messaging has shown effectiveness in many exercise studies.[36-38] There are three default text messages which will be sent and depending on study subject's preference, they will receive the text message up to one text message per day (a maximum of 10 text message a week). The first default text message will be sent on Thursday to provide feedback on their progress for the week. The second default text messages will be sent on Saturday morning to encourage them to sync their Fitbit to the Fitbit app. The third text messages will be sent on Monday morning to provide a weekly Fitbit summary and set next week's goal on reducing sedentary time. This Monday message will be structured by 1) positive reinforcement, 2) a weekly summary of sedentary time, steps counts and a suggestion for extra sitting breaks (data retrieved from Fitbit), 3) one tip from the TTT booklet, and 3) setting of next week's goal.
Participants will text back with a new goal. Examples of text messages are included in the appendix. Depending on the subject's preference, they will receive additional text messages which include positive reinforcement and encouragement. In addition to the weekly text messages, they will receive two monthly progress check up messages at the end of week 4 and week 8. These monthly text messages include their monthly sitting hours followed by restatement of overall goal. They will also get an introductory video explaining Fitbit app navigation and filling out the weekly goal sheet.

Below is the process of developing and providing text messages.

1. Creation of weekly text message template: Dr. Mulvaney (Co-I), an expert in effective health communication, and the PI co-created the weekly message template with Dr. Mulvaney.
2. Fitbit data transfer: We will transfer the Fitbit data from the participants' Fitbit accounts to REDCap by developing our own data collection interface using Fitbit's Web Application Programming Interface (API). This platform provides secure data acquisition and management tools that facilitate remote data collection from Fitbit without the need for study participants to return the devices to researchers for data extraction.
3. Integration of Fitbit data into the text message template. The collected Fitbit data in the Redcap will be integrated into our weekly text message template.
4. Send text messages by using Twilio and Redcap. The customized text message will be sent using the Twilio plug-in for REDCap. Twilio module enables our study to make and receive SMS text messages, both to and from study participants. A REDCap and Twilio account are linked together. When a user indicates that an SMS (text) or a call should be sent to a cell phone, REDCap requests that action through Twilio. When a user responds, Twilio relays that information back to

REDCap. The data is stored in the REDCap database. Twilio does not store any data, nor does it keep a log of its actions.

5. Ask next week's goals via text message. This study uses survey function via SMS conversation to set a next week's sedentary hour and step counts goal. When participants take an SMS survey, questions are asked one at a time as an SMS text message conversation/thread. We will ask three questions (three SMS text messages). Participants may respond with any kind of alpha-numeric text for SMS survey. Only REDCap administrators are allowed to enable the Twilio option to initiate a survey as an SMS conversation. All messages and Fitbit data will be managed in REDCap.

5.4. Post-intervention visit

After 8 weeks, all participants will be invited to an in-person visit (post-intervention visit). During the visit, all the above parameters will be re-measured by the same trained research staff. The visit will take approximately 1 hour including completion of a series of questionnaires (which may be completed by the participants beforehand) and biometric assessments. All participants will wear the activPAL3 and the CGM for 7 days to examine their post-intervention activity and glycemic control. They will return the devices via pre-paid mail. All participants will receive $50 for the post intervention visit, and an additional $50 for mailing back the devices to the study team.
Therefore, total compensation would be $150 for each participant. Also, all participants will be informed of their 24-hour glucose results, and activity patterns retrieved from the ActivPAL device. A subsample of participants from the intervention group will be invited to participate in a separate qualitative exit interview. The one-on-one exit interview will be conducted by the trained study team member during the visit. The interview will last 30 minutes, and each participant will be compensated with $30 for completing this interview.

1. **Questionnaires**

Participants will answer the same questions about their demographics, socioeconomic characteristics, medical history and current medication, health behaviors, and patient-centered outcomes (e.g., fear of movement, confidence in reducing SB and increasing PA, habit strength for SB, quality of life, and depressive symptoms). Participants will have a choice to complete these questionnaires during the post-intervention visit in person or to receive paper copies of the questionnaires by mail. Printed copies will be identified by the participant's REDCap record ID number; there will be no additional identifying information on the printed questionnaires. If a participant chooses to receive the questionnaires by mail, he or she will be asked to complete them using a blue or black ink pen no sooner than 2 days prior to their scheduled post-intervention visit and will bring the completed surveys to their post-intervention visit. After the post-intervention visit is completed, the study team will enter their responses manually into REDCap and upload a scanned PDF version of the paper questionnaires to their REDCap record. Paper copies of the surveys will be kept in a locked cabinet in the study team's office at the Vanderbilt School of Nursing. In addition, participants will answer questions (Table 2) about feasibility and acceptability of the intervention. Level of satisfaction with the intervention will be assessed by using 23 items from the questionnaire developed by Lyons, Swartz, Lewis, Martinez and Jennings [39] and Burner, Zhang, Terp, Bench, Lee, Lam, Torres, Menchine and Arora [40]. We will also use the 10-item of System Usability Scale[55] to assess usability. The scale is considered as "industry standard"

and provides a global measure of satisfaction [56].

Table 2. Feasibility and Acceptability Assessment

Variables	Measures
Reach	(participants enrolled/participants screened and eligible) × 100
Retention	(participants completing post-intervention assessment/participants enrolled) × 100
Satisfaction	23 items from Lyons and Burner's questionnaires, System usability scale, Exit interviews (n=20)
Compliance	Number of days the Fitbit device was worn by week Number of days the Fitbit app was logged in by week

Number of text messages replied about the next week's goal

2. **Biometric assessment**
   Participants will undergo the same physical examination (e.g., height, weight, blood pressure, hip circumference, waist circumference). The same protocol and instruments will be used.
3. **activPAL data download**
   The 7 days of activPAL data will be downloaded and stored in the PI's computer.
4. **Exit interview**
   A one-on-one interview will be conducted by the trained study team member during the post-intervention visit. The exit interview will be structured to capture feedback on the acceptability and satisfaction of the intervention, barriers and facilitators to SB reduction, and perceived health impacts of SB reduction. A semi-structured interview guide is attached in the appendix. The exit interview will be audio recorded by using a secure iPad and transcribed verbatim. The transcripts will be saved on the secure computer. The interview will take approximately 30 minutes.
   1. To generate initial speech-to-text transcription of the mp4 audio file of the exit interview, trained study team members will utilize the transcription tool on a Microsoft Teams meeting. Alternatively, the Microsoft Word for OneDrive transcription tool will be used for recorded audio files. The mp4 file will be uploaded from the iPad to the Microsoft OneDrive Word application to begin transcription. These transcription methods have been approved and recommended by the VUMC Center for Technology Transfer and Commercialization. The transcript will be saved on the secured online VUSN server and only the study team will have access to the transcripts and audio recording files. De-identified audio files will be coded with four-digit numbers (ex. 0001) at the time of entry into the research study so that no direct identifiers appear on any samples or questionnaires. Audio files will be stored on a secure computer at Vanderbilt School of Nursing and password-protected, only accessible by the PI and/or her staff. No identifiable information will be stored on any mobile devices (laptops, USB keys, CDs, DVDs, etc.). The voice recording files that are saved under VUSN server will be permanently disposed 5 years after the study has been completed.

Table 3. Overview of Study Visits

	Screening	Baseline assessment 1	Baseline assessment 2	Intervention (Week 1 to Week 8)	Post-intervention assessment (after Week 8)	Exit interview (after Week 8)
Related personnel	Research staff	Research staff	Research staff	Research staff or PI	Study staff member	Research staff
Delivery methods	Phone or in-person	In-person	In-person	In-person for only initial session	In-person	In-person
Activity	Screening eligibility	Consenting, Support for completing questionnaires, distributing activPAL device and CGM	Biometric assessment, activPAL and CGM data download	Initial goal setting session, Activity tracker distribution, weekly text message	Support for completing questionnaires, Biometric assessment, Distributing activPAL and CGM	Structured one-on-one interview

Length of time needed	10 minutes	1hour	40minutes	Initial session: 1hour Weekly text message: 5-10minutes	1hour	30minutes

6.0 Reporting of Adverse Events or Unanticipated Problems involving Risk to Participants or Others

Consent
For the pre-screening activity, potential participants recruited from the email distribution list or ResearchMatch will sign an e-consent in REDCap. Participants will be given information about what questions we will ask. There are no benefits or side effects related to this prescreening activity. Once they meet all the eligibility criteria, they will be invited for the in-person baseline visit. At the visit, participants are given as much time as they would like to consider participation from the initial invitation to participate until they sign the "main" consent form. Participants are encouraged to ask as many questions as possible and reminded that participation is completely voluntary and will not affect their medical rights. They are also told that they have the option to discontinue participation at any time for any reason.

Finger Prick Blood Test
Risks associated with the finger prick include: temporary discomfort from the needle prick, bruising, and rarely (<1%) infection. These risks will be minimized by using a sterile technique and applying sustained pressure to the site.

ActivPAL
The activPAL activity tracker is a safe, non-invasive method to capture information about activity cycles. Participation in this study requires that participants wear an activPAL tracker taped (using Tegaderm adhesive dressing) to the front of the right thigh during waking hours for a minimum of 7 consecutive days (baseline and follow-up). The Tegaderm adhesive dressing used to apply the activPAL devices are hypoallergenic and consist of a dual layer hydrogel that does not pull at the skin or hair. There are few risks associated with wearing the activPAL device and include slight discomfort, such as light pressure from the activPAL or irritation from the waterproof dressing.

Continuous Glucose Monitor
The FreeStyle Libre Pro Flash Glucose Monitoring System is an FDA-approved, professional continuous glucose monitoring device indicated for detecting trends and tracking patterns in persons (age 18 and older) with diabetes. After application of the sensor, only a thin, flexible filament will remain under the skin and the sensor is held in place by an adhesive. The following are possible adverse effects of inserting a sensor and wearing the adhesive patch: local erythema (redness), local infection, inflammation, pain or discomfort, bleeding at the glucose sensor insertion site, bruising, itching, scarring or skin discoloration, and adhesive irritation. There is a remote risk of sensor or needle fracture during insertion, wear or removal, with fragments retained under the skin.

Fitbit

Participants will wear an additional wrist-worn activity tracker for 8 weeks during waking

hours. There are few risks associated with wearing the device and include slight discomfort, such as light pressure from the wristband or irritation from wearing a damp band after showering or swimming. There is a possible risk of confidentiality loss. To reduce the risk, we will create an anonymous email account for the Fitbit app. All identifiable data will be kept on password-protected computer systems in a locked office.

Smart Water bottle
Participants will use the smart water bottle to increase the frequency of standing and moving by frequently going to the restroom and kitchen for refills. There is no risk associated with using the smart water bottle. To reduce the possible risk of confidentiality loss, we will create an anonymous email account for the HidraSpark app. All identifiable data will be kept on password-protected computer systems in a locked office.

8-Week Sedentary Behavior Intervention
Participants will gradually decrease their sedentary behavior and replace the sedentary behavior with a short period of light intensity physical activity such as 2 to 3 minutes of standing or walking over 8 weeks. The risk of falling or injury is the same as would be associated with day-to-day activity. Study staff members will instruct participants to make sure there are no hazards within the walking path and surrounding area.

Suicidal ideation or severe distress
Research has confirmed that simply asking a participant about whether they have thoughts of suicide is not a likely trigger of such an event[41]. It is usually only when the person reports ideation as well as an intent, plan, and/or means to commit suicide that risk for immediate suicide is considered to be more acute.

If a participant reports severe distress or suicidal ideation during the survey administration (Baseline visit 2 or Post-intervention visit), the research staff will immediately notify the PI. The PI will provide the participant with help to get treatment. This may include:

- working with the participant to contact his/her doctor,
- contact a trusted family member, or a therapist to discuss his/herthoughts,
- or work with the participant on a plan that may include getting him/her to a hospital for safety.

7.0 Study Withdrawal/Discontinuation

Taking part in this study is voluntary, and the participant has the right to refuse to take part in the study. The participant can withdraw from the study at any period and should notify the PI or a study staff member. The decision to withdraw will not affect the participant's ability to get healthcare at the institution, or their enrollment in any health plans or benefits. The investigator may decide to discontinue a participant's participation without permission because she may decide that staying in the study will be harmful for the participant, or the sponsor may stop the study. A participant's decision to withdraw from this study will not be retroactive. For example, if a participant provides consent and completes the baseline visit but then decides to withdraw from the study at the post-intervention visit, the data collected from the baseline visit, which was collected in good faith, will not be destroyed.

Criteria for Discontinuation of Individual Participants

Subjects can decide to discontinue entirely from the study at any time for any reason. Subjects can also be discontinued from the study or discontinued from the study treatment due to Investigator decision as detailed below.

1. Withdrawal of consent.
2. At the Investigator's discretion in certain situations such as lack of compliance or serious adverse event.
3. One DKA event or one episode of hyperglycemic, hyperosmolar nonketotic syndrome (HHNS)
4. Dangerous hypoglycemia (glucose <54mg/dl after three treatments or unable to function due to low blood glucose during study visits)
5. Continuous hyperglycemia (random blood glucose >300mg/dl two times in a row during study visits)

Protocol for hypoglycemia

During any study visits, if the study participant develops any of the symptoms below, the study team member will check glucose levels immediately. The symptoms are

- Weakness and tiredness
- Sweating
- Fast breathing
- Shakiness, nervousness, and or anxiety
- Nausea
- Confusion and problems communicating
- Light-headedness, dizziness

If the glucose level is below 70mg/dl, one of the following options will be administered.

1. 2 oz (60ml) juice
2. 15mg of glucose tables

After 15 minutes, the study team member will re-check glucose level. If the glucose level is still below 70mg/dl, the treatment will be repeated up to 2 times.

If the participant's glucose level is still below 70mg/dl after three treatments, the study team member will notify the PI and ask participants to call healthcare provider. If the participant's glucose level is still below 54mg/dl or the participant is unable to function because of mental or physical changes due to low blood glucose, call 911 immediately and notify the PI.

Protocol for hyperglycemia

During first visit, the finger prick random glucose level of potential participants is 300 mg/dl or higher two times in a row, the RA will notify PI immediately. The potential participants will be informed of their glucose levels and asked to contact their healthcare provider immediately. The PI will withdraw the study participant to prevent severe hyperglycemic events and/or DKA.

Adverse events (AEs) will be reported according to IRB policies. Any adverse event requiring reporting will be reported no later than 10 working days to the IRB using the IRB form "Report of Unanticipated Problem Involving Risk to Participants or Others" (IRB Form #1105). Reporting will depend on adverse event severity:

<u>Grading of Severity</u>

0: No AE or within normal limits.
1: Mild AE.

2: Moderate AE.
3: Severe AE resulting in inpatient hospitalization, or a persistent or significant disability/incapacity.
4: Life-threatening or disabling AE.
5: Fatal AE.

8.0 Statistical Considerations

Sample Size Calculation

Because this is a novel intervention, we cannot use an exact effect size from the literature. As of today (May 22), we have recruited 16 participants; 3 have withdrawn, 5 randomized into intervention group, 8 assigned to control group. For the remaining iterative process, each cohort will have 10 participants. It will give us enough power to be saturated in terms of qualitative findings. Assuming a 15% attrition rate, we plan to enroll 24 more participants, for a total of 40 participants.

Analysis Strategies

Aim 1: Feasibility and acceptability outcomes will be reported as percentages or averages. For the exit interview, we will collaborate with the Vanderbilt Qualitative Research Core in developing a semi-structured interview guide and thematic analysis. To enhance credibility, we will follow the consolidated criteria for reporting qualitative research (COREQ) guidelines.[44]

Aims 2 & 3: Descriptive analyses are planned to characterize the study sample on all measures including baseline demographics and covariates. For this pilot study, exploratory linear mixed modeling will be used to provide descriptive statistics relative to treatment effects, both within- and between-groups effects on the primary and secondary outcomes over time. We will also estimate effect sizes for those outcomes.

Exit Interview

We will develop a semi-structured interview guide and thematic analysis. The exit interview will be audio recorded, transcribed verbatim, and analyzed using a thematic approach to guide refinements to future SB reduction interventions as well as identify barriers and facilitators to SB reduction. To enhance credibility, we will ensure methodological triangulation (audio recording, surveys, and field notes), audit trail and peer-debriefing process.[45]

9.0 Privacy/Confidentiality Issues

All Personal Health Information (PHI) and Personal Identifying Information (PII) will be kept confidential, unless release is required by law. Release of PHI/PII information will only be allowed if it is legally required by law. The PI and staff have been trained in confidentiality and HIPAA requirements and will conduct the study using Good Clinical Practice guidelines.

Upon study enrollment, participants will be assigned a unique study ID number and anonymous email account that will be used to label all research data including Fitbit data, CGM data, questionnaires, activPAL data, and interview recording files. The study ID and the anonymous email will serve as the only identifier used on all study-related documents. Informed consent will occur at the time of recruitment once verification of

eligibility has been completed. The participant identifiers will be stored in the Master List, which will include full name and contact information (e.g., phone number, email address) and will be used for administrative purposes only.
The Master List will be maintained by study staff and stored in a file separate from the coded study dataset on a password-protected computer. Only individuals directly involved with the study (e.g., PI or her staff) will have access to this file.

This individualized email address will then be linked to a Fitbit account in which personal identifiers should not be used. Importantly, research staff and participants will be advised that the email and Fitbit accounts should be used strictly for the study's purpose. Moreover, account information will be stored in protected PI's computer within encrypted documents.

All of the Fitbit data will be extracted from the Fitbit account to Redcap by using the Fitbit web API developed by VU School of Nursing IT team. Fitbit data will be stored on a secure computer at University School of Nursing server and password-protected, only accessible by the PI and/or the IT team. The Fitbit data will be uploaded into REDCap.
To send weekly text messages from REDCap, we will utilize the third-party service Twilio.com which means that all voice calls and SMS messages will be routed through Twilio's servers. However, REDCap goes to great lengths to ensure that voice call records and SMS transcriptions do not stay in Twilio's logs but are removed shortly after being completed. This is done for security and privacy concerns (e.g., HIPAA), in which our survey participants' phone numbers and their survey responses do not get permanently logged on Twilio's servers but instead remain securely and separately in REDCap. Twilio uses two-factor authentication to access the application administratively. The integrated module can only be turned on by a REDCap Administrator. Twilio configuration is managed by a REDCap administrator. The integration requires 'inspectors' be turned off at the Twilio level to ensure no logging data is retained.
However, this method is limited to have two-way interaction, which means that Twilio and REDCap system do not allow research participants to text back to the study team. To facilitate two-way communications, we will have a wireless cell phone and answer any questions if the participants have any.
All hard copy documents (e.g., sleep diary or wear log) will be stored in a locked filing cabinet and office. All electronic records, including the Master List and voice recordings, will be stored on a secure computer at Vanderbilt University School of Nursing and password-protected, only accessible by the PI and/or her staff. No identifiable information will be stored on any mobile devices (laptops, USB keys, CDs, DVDs, etc.). Research files will be kept for a period of 7 years after the study has been completed. Data entry will be completed in REDCap by the PI and/or her staff and will be imported to SPSS file format for analysis. Only de-identified data will be used for analysis.

10.0 Follow-up and Record Retention

Raw hard copy research data will be kept in locked file cabinets in a locked office. All electronic records, including the Master List and voice recordings, will be stored on a secure internal Vanderbilt University School of Nursing server and password-protected, only accessible by the PI and/or her staff. After a period of seven years from the end date of the study, all identifying information, including signed consent forms and the Master List, will be destroyed. Anonymous raw data and electronic data will be maintained indefinitely.

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