Document:

Informed Consent Form

Official Study Title:

A Multiple Technology-Based and Individually Tailored Sit Less Program for patients with Type 2 Diabetes: A randomized controlled trial

NCT06457802

Document Date:

May 23, 2024

Main E-consent

Please complete the survey below.

Thank you!

You may save or print a blank copy of this consent form for your records if you wish. After you submit this form, you will be offered the opportunity to save or print a signed copy of this consent form.

If you don't have a PDF reader installed, please click here to install one for free and access this document (link will open in new tab or window):

Get Adobe Reader

[UPLOAD COPY OF STAMPED CONSENT PDF]

VUMC Institutional Review Board
Informed Consent Document for Research
Principal Investigator: Chorong Park, PhD, RN
Study Title: A Multiple Technology-Based and Individually Tailored Sit Less Program for patients with Type 2 Diabetes: A Randomized Controlled Trial

Institution/Hospital: Vanderbilt University

Revision Date: 05/23/2024
Date of IRB Approval: 04/30/2024
Date of IRB Expiration: 04/29/2025

---

1) Name of Participant:

_____
(First Last)

---

2) Age:

_____

The following information is provided to inform you about the research project and your participation in it. Please read this form carefully and feel free to ask any questions you may have about this study and the information given below. You will be given an opportunity to ask questions, and your questions will be answered. Also, you will be given a copy of this consent form.

Key Information: The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Date of IRB Approval: 06/03/2024
Date of Expiration: 04/29/2025

Institutional Review Board

VANDERBILT

Key information about this study:

Too much sitting may cause heart and metabolic problems, but people with type 2 diabetes tend to sit 11-15 hours a day, which is most of their waking time. Breaking long periods of sitting with only a few minutes of standing and walking throughout the day is simple, easy and may help improve your health outcomes. The purpose of this study is to develop and test a Fitbit-guided sedentary behavior reduction intervention ("Sit Less" program) for patients with type 2 diabetes. The program aims to reduce and break sitting times among this population through Fitbit monitoring, a smart water bottle (to keep you hydrated), behavior goal setting, and weekly tailored text messages. We will test our program to help diabetes patients break up their sitting time, reduce daily sitting time, and move more. We will also study whether the program leads to improvements in glucose control and heart disease risk factors, and whether diabetes patients like the program and can follow it. Once you join the study, you will be asked to do the following:

Three visits for surveys, a physical exam and random finger prick glucose test via glucometer Wear activity and glucose monitors for 7 days at beginning and end of study Compensated a total of $150 after study completion Each visit will take about 1 hour and 30 minutes You will be randomly assigned to the "Sit Less" program or the Control Group All participants will receive a Fitbit. The program group will receive customized alerts from Fitbit, a Smart water bottle, and weekly-tailored text messages The program group will also receive an instructional goal-setting session during baseline visit 2 and a mid-program counseling session conducted virtually via Zoom after 4 weeks in the program After completion of the study, you will be notified about your test results and activity patterns

Detailed Information:The rest of this document includes detailed information about this study (in addition to the information listed above).

You are being asked to take part in this research study because you are over 18 years old and have been diagnosed with type 2 diabetes. We hope to enroll about 80 participants in this study who will participate in the intervention.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study.

Procedures to be followed and approximate duration of the study:

Date of IRB Approval: 06/03/2024
Date of Expiration: 04/29/2025

Institutional Review Board

VANDERBILT

Being in this study is voluntary. Should you choose to take part, your time in the study will be about 8 weeks with three assessment visits (each visit lasts about 1 hour and 30 minutes). The components of the study include the following:

Baseline Visit 1

You will visit the Vanderbilt School of Nursing Clinic at the Wesley The visit will last approximately 1 hour and 30 minutes. You will receive $25 for baseline visit 1.

You will complete a series of questionnaires that ask about your health, your current participation in physical activities, your attitudes and beliefs about reducing sitting time and becoming physically active, and your eating habits. The questions should not make you feel uncomfortable. The questionnaires will take approximately 30 minutes.

The trained research staff will measure your height, weight, waist circumference, and blood pressure. The trained research staff will conduct a finger prick and one drop of blood will be obtained on a glucometer to test your random glucose. If your random glucose is >300, you will be withdrawn from participation per study protocol.

You will start wearing a thigh-worn activity tracker (activPAL) for 7 days. The activPAL will measure your sitting and activity. You will wear it with waterproof dressing on your upper thigh for 7 days, 24 hours each day. If you have hair on the upper thigh, shaving an area of the thigh will be considered. You will place the device on your body by yourself in a private room after the research staff's demonstration. You will also be asked to complete a daily sleep diary and wear log for 7 days. Extra waterproof dressings will be provided along with instructions.

You will start wearing the continuous glucose monitoring device (Freestyle Libre) to measure your 24-hour glucose levels. You will attach it to your upper arm for 7 days, 24 hours each day.

You will be given a Fitbit (Inspire 3). You will be asked to continuously wear a Fitbit wristband accelerometer, a slim device that tracks your activity and sitting. The study team member will assist you in downloading the Fitbit app and creating an account, and will instruct you on how to use the device. You will log into the app once installed to allow for the study team to collect your Fitbit data via the Fitbit web platform (API), for the time that you are actively a participant in the study. The collected data include daily steps total, measured steps per minutes, estimated energy expenditure, distance moved, minutes of vigorous, moderate, light activity, and sedentary time, and sleep length, quality, and movement. The collected data will be updated wirelessly on a computer or mobile device providing you the ability to track your progress. Trained study team members will also be able to access and monitor your daily activity via the Fitbit API and REDcap. The collected data will be de-identified and stored within the HIPAA compliant and secure REDcap. When setting up your Fitbit account, we do not use your real name or email address and will default the account settings to the most private option available. We advise you that the email address and Fitbit account should be used strictly for the study's purpose. Account information will be stored in a protected computer within encrypted documents. Once the intervention is concluded, you can keep the Fitbit and the Fitbit data will no longer be collected Baseline visit 2

After the seventh day, you will return to the VUSN You will be asked to remove the activPAL (thigh-worn device) and the continuous glucose monitoring device during this visit.

You will be randomly chosen to be in the intervention group or the control group, and you will be informed of your assignment at Baseline visit 2. 8-Week Sit Less Program

If you are chosen to be in the intervention group, you will participate in the 8-week Sit Less Program Instructional/Goal-setting Session The research staff will provide an orientation at the Baseline visit 2. The study team member will review your sitting patterns and provide some tips to add sitting breaks into your daily routine using a "Ten Top Tips" booklet. You will set goals on reducing sitting time. Fitbit The study team member will instruct you on how to monitor your active time and sitting time in the Fitbit app. The data will be used to provide a tailored text message. Smart Water Bottle We will provide a HidrateSpark water bottle. The device alerts participants with a color change and message on the Fitbit to keep you hydrated. The device provides the daily water intake summary in the Fitbit app. The study team member will assist you in downloading the HidrateSpark app and creating an account, and will instruct you on how to use the water bottle. The same email address that is used for the Fitbit account will be used for the HidrateSpark app. The same rules will be applied to the HidrateSpark account, and the account information will be stored in the protected PI's computer within encrypted documents. Once the intervention is concluded, you can keep the HidrateSpark bottle and the data will no longer be collected. Text Messages You will receive text messages throughout your participation in the program to support and enhance the habit formation process. Three weekly text messages (one on Thursday, one on Sunday, one on Monday) will be provided to inform your weekly summary of sitting and physical activity patterns. We will access and download the following data gathered from your Fitbit account (see details under "b. Fitbit"). Additionally, the study team will offer weekly personalized feedback on your progress towards goal achievement and helpful tips. You will also receive up

Date of IRB Approval: 06/03/2024
Date of Expiration: 04/29/2025

Institutional Review Board

VANDERBILT

to one text message per day providing a daily tip, which will be tailored to you based on preferred message frequency and activity choices. To send the weekly text messages, we will utilize the third-party service Twilio.com and integrate Twilio into REDCap. All text messages will be routed through Twilio's servers. Due to security and privacy concerns (e.g., HIPAA), your phone numbers and your survey responses will not be permanently stored on Twilio's servers but will instead remain securely and separately in REDCap. Mid-Program Counseling Session After week 4, you will participate in a virtual focused counseling session (via Zoom). During this session, you will work with the study team to re-evaluate and adjust your activity patterns and sedentary break schedules. Before the session, you will be mailed an activPAL to your home address. You will wear the activPAL again for 7 days. You will return the device using a prepaid express mail envelope for overnight shipping. The study team will review your activPAL and Fitbit data with you during the counseling session. Personalized feedback will be provided, and the sedentary break schedules will be adjusted based on the insights from the activPAL data. Goals and expectations for the remainder of the program will be discussed Control Group

If you are chosen to be in the control group, you will receive a Fitbit and the American Heart Association's "Healthy Living" booklet. You will be instructed to follow your usual medical care. You will be informed about your sitting time and glucose patterns for 7 days from the activPAL and the continuous glucose monitoring devices after the post-intervention visit. Post-Intervention visit

After 8 weeks, you will be invited to an in-person visit (Post-intervention visit) at the VUSN Clinic at the Wesley Building. During the visit, all the above measurements will be re-measured by the research You will complete a series of questionnaires that ask about your health, your current participation in physical activities and sitting, your attitudes and beliefs about reducing sitting time and becoming physically active, your eating habits, and your satisfaction with the Sit Less program. The questions should not make you feel uncomfortable. The questionnaires will take approximately 30 minutes. You will be given the option to complete these questionnaires ahead of time if you prefer, to reduce the length of the final If you prefer to complete the questionnaires before the post-intervention visit, the research staff will email the surveys to you to be completed 1-2 days prior to the post-intervention visit. The research staff will measure your height, weight, waist circumference, and blood pressure. This assessment will last approximately 30 minutes You will also wear the activPAL and the continuous glucose monitor for 7 days to examine your post-intervention activity and glycemic control. You will return the devices via a pre-paid mailing envelope. As compensation, you will be provided $50 for the post-intervention Once you mail back the devices to the study team, you will be provided an additional $50. You will keep your Fitbit and HidrateSpark water bottle (equivalent to $170). You will also be informed about your 24-hour glucose results, and activity patterns.

Expected costs:

There is no cost to you for taking part in this study.

Description of the discomforts, inconveniences, and/or risks that can be reasonably expected as a result of participation in this study:

Date of IRB Approval: 06/03/2024
Date of Expiration: 04/29/2025

Institutional Review Board

VANDERBILT

1. Finger Prick

We will obtain blood through a finger prick. 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.

2. 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 24 hours for a minimum of 7 consecutive days (baseline, mid-program, and follow-up for the intervention group; baseline and follow-up for the control group). 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. Please contact the study team if you develop any skin reactions on the thigh while wearing the device. If you develop a serious skin reaction, you need to immediately remove the device and contact your primary healthcare provider to verify that it is safe for you to continue.

3. Continuous glucose monitor(CGM)

The FreeStyle Libre Pro Flash Glucose Monitoring System is a 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. Please contact the study team if you develop any skin reactions on the upper arm while wearing the device. If you develop serious skin reaction, you need to immediately remove the device and contact primary healthcare provider will have to verify that it is safe for you to continue.

4. Fitbit

Participants will wear a Fitbit, a wrist-worn activity tracker, for 8 weeks. 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.

5. HidrateSpark Smart Water Bottle

Participants who are assigned to the intervention group will use the smart water bottle for 8 weeks. There is no risk associated with using the smart water bottle.

6. 8-Week Sedentary Behavior Intervention

Intervention-group 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. While participating in this intervention, there is a potential risk of experiencing physical discomfort or symptoms that may include, but are not limited to, back pain, muscle ache, knee pain, and other discomforts arising from increased activity levels. Additionally, participants may also experience annoyance or inconvenience associated with filling out weekly goal-setting surveys. These symptoms or discomforts may occur during the course of the study, but the study team will take measures to minimize any adverse effects and ensure participants' safety and well-being throughout the research process. The level of risk associated with these symptoms or the risk of falling or injury is similar to the risks associated with day-to-day activity. Trained research staff members will instruct participants to make sure there are no hazards within the walking path and surrounding area.

There is a possible risk of confidentiality loss. However, we will use study codes when identifying your data and questionnaire information. In addition, we will also create an anonymous email account for Fitbit and HidrateSpark apps. All of your data and questionnaire information will be kept on password protected computer systems at a locked office.

Date of IRB Approval: 06/03/2024
Date of Expiration: 04/29/2025

Institutional Review Board

VANDERBILT

Unforeseeable risks:

Because this treatment is investigational, meaning non-FDA approved, there may be unknown or unforeseeable risks associated with participation.

Compensation in case of study-related injury:

If it is determined by Vanderbilt and the Investigator that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided at Vanderbilt to treat the injury.

There are no plans for Vanderbilt to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

Good effects that might result from this study:

a) The benefits to science and humankind that might result from this study:

By taking part in this study, you will provide knowledge to the research and medical community about the effects of reducing sitting time on heart and glucose biomarkers in patients with type 2 diabetes. This knowledge may help develop new physical activity and sedentary behavior guidelines for diabetes patients and provide evidence about developing a Fitbit-based sedentary behavior reduction program for this population.

b) The benefits you might get from being in this study:

You may lose weight, learn new tips about reducing sitting time and moving more, and improve your overall health. You will know your sitting patterns, physical activity patterns, and heart and glucose-related biomarkers.

Study Results:

A description and results of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time. In addition, after the study team has analyzed all data, other researchers may request to review the data. Should this occur data will be accessible through a password-protected site.

Alternative treatments available:

Your alternative is to not participate in the study.

Date of IRB Approval: 06/03/2024
Date of Expiration: 04/29/2025

Institutional Review Board

VANDERBILT

Compensation for participation:

If you agree to take part in this research study, you will receive a total of $150: $25 for Baseline 1 visit, $25 for Baseline 2 visit, $50 for the Post Intervention visit, and $50 for mailing back the devices to the study team. Intervention group participants will keep their Fitbit and HidrateSpark water bottle (equivalent to $170). Control group participants will keep their Fitbit (equivalent to $100). Payment will be received in the form of an electronic gift card (bank deposit for foreign nationals) within 2-4 weeks upon the completion of the necessary payment documentation.

All participants who wish to accept payment for their participation will be required to submit a payment form that requests personal information (e.g., name, address, email, phone, citizenship status, etc.).

Study payments given to VU employees count as taxable income and will be reported to VU by study personnel to be included on Form W-2.

In addition to the payment form, foreign nationals receiving payment will be required to register as a VU supplier and complete a GLACIER record prior to receiving payment as federal and state tax withholdings apply. Payments made to human subjects who are foreign nationals are reported on Form 1042-S. All payments to foreign nationals are subject to 30% federal income tax withholding and sent via direct deposit.

You are not allowed to accept any money for taking part in this study if you are not eligible to receive money from a U.S. person or company or the U.S. government because of U.S. national security and/or foreign policy laws. You can still take part in the study; however, you will not be paid if you are a resident of a country restricted by the U.S. government's comprehensive territorial sanctions or if you are listed on the U.S. Treasury Department's Office of Foreign Assets Control's Specially Designated Nationals (SDN) list of prohibited individuals. You do not have to say why you choose not to be paid.

If you receive $600 or more from the university in a calendar year, VU must report the amount you receive to the Internal Revenue Service (IRS) on the form 1099-MISC. This form tells the IRS that payment was made to you, but it does not say that you were paid for taking part in this research study. You should talk to your tax advisor regarding the proper use of this form 1099-MISC.

Circumstances under which the Principal Investigator may withdraw you from study participation:

The investigator may decide to discontinue your participation without your permission because she may decide that staying in the study will be bad for you.

What happens if you choose to withdraw from study participation?

If you decide to stop being part of the study, you should contact the investigator. Deciding to not be part of the study will not change your regular medical care in any way.

Contact Information.

If you should have any questions about this research study or possible injury, please feel free to contact the study team at (615) 343-6075.

For additional information about giving consent or your rights as a participant in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to contact the Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Confidentiality:

All efforts, within reason, will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed.

However, the only people who will know that you are a research subject are members of the study team. No information about you, or provided by you during this research, will be disclosed to others without your written permission, except if necessary to protect your rights or welfare (e.g., the VUMC Institutional Review Board monitors the research and consent process). Your name and contact information (e.g., phone number, email address) will be stored in the master list and will be used for administrative purposes only. Only individuals directly involved with the study (e.g., PI or research staff) will have access to this file. This master list will be stored on private electronic files on a password-protected computer. The master list will be destroyed at the conclusion of the study.

All questionnaires, data from 7-day monitoring devices, samples, and interview recording files will be stored with a study code (indirect identifier). Your Fitbit and HidrateSpark smart water bottle accounts will use an anonymous email account. Anonymous email account information will be stored in the protected PI's computer within encrypted documents. All Fitbit data will be extracted from the Fitbit account to REDcap. The data extraction will be done via the Fitbit web API developed by the Vanderbilt University School of Nursing IT team. Fitbit data will be stored on a secure internal Vanderbilt 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.

During the research, if we learn you are having thoughts about suicide or hurting yourself or others, the research staff will ask you more questions about your thoughts. Based on your response, the staff may provide you with help to get treatment. This may include:

working with you to contact your doctor, contact a trusted family member, or a therapist to discuss your thoughts, or working with you on a plan that may include getting you to a hospital for safety. The sponsor and/or Vanderbilt may give or sell your health data, without identifiers, to others or use it for other research projects not listed in this form. The sponsor, Vanderbilt University, Dr. Chorong Park and their staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

Additional Note on Medical Records:

Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

Privacy:

Any samples and information about you may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the tests done on your samples. These tests may help us or other researchers learn more about the causes, risks, treatments, or how to prevent this and other health problems.

HIPAA Authorization:

Date of IRB Approval: 06/03/2024
Date of Expiration: 04/29/2025

Institutional Review Board

VANDERBILT

All efforts, within reason, will be made to keep your protected health information (PHI) private. PHI is your health information that is, or has been gathered or kept by Vanderbilt as a result of your healthcare. This includes data gathered for research studies that can be traced back to you. Using or sharing ("disclosure") such data must follow federal privacy rules. By signing the consent for this study, you are agreeing ("authorization") to the uses and likely sharing of your PHI. If you decide to be in this research study, you are also agreeing to let the study team use and share your PHI as described below.

As part of the study, Vanderbilt University Medical Center may share the results of your study and/or non-study linked questionnaires, data from 7-day monitoring devices, samples (dried blood spot cards), and interview recording files, as well as parts of your medical record, to the groups named below. These groups may include people from the Federal Government Office for Human Research Protections, the VUMC Institutional Review Board, Vanderbilt University, National Institutes of Health. Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts, within reason, will be made to keep your PHI private.

The study results will be kept in your research record for at least six years after the study is finished. At that time, the research data that has not been put in your medical record will be kept for an unknown length of time. Any research data that has been put into your medical record will be kept for an unknown length of time.

Unless told otherwise, your consent to use or share your PHI does not expire. If you change your mind, we ask that you contact Dr. Chorong Park in writing and let her know that you withdraw your consent. Her mailing address is 511 Godchaux Hall, 461 21st Avenue South, Nashville, TN 37240. At that time, we will stop getting any more data about you. But, the health data we stored before you withdrew your consent may still be used for reporting and research quality.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO PARTICIPATE IN THIS STUDY

3) I have read this informed consent document and the material contained in it has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to participate.

◯ Yes ◯ No

4) Signature of patient/volunteer:

_____
(Click "Add signature" and use your mouse (or finger on a touchscreen device) to sign.)

5) Date:

_____
(Date of Volunteer Signature)

6) Consent obtained by (please enter full name and title):

_____
(Signature of staff that obtained consent.)

7) Date:

_____
(Date of staff signature.)