- The official title of the study: The JustWalk JITAI Study: A System Identification Experiment to Understand Just-in-Time States of Physical Activity
- The NCT number: NCT05273437
- The date of approval from the UCSD IRB: January 12, 2022

University of California, San Diego
Consent to Act as a Research Subject

"Just Walk"
-A research study to create and test a smartphone app intervention that provides the right support at the right time

Introduction

Dr. Eric Hekler and associates are conducting this research and asking for your consent to participate. This section provides a summary of important information about the study. The rest of the form provides additional details.

- Research is voluntary - whether or not you join is your decision. You can discuss your decision with others (such as family, or friends).
- You can say yes but change your mind later.
- If you say no, we will not hold your decision against you.
- Your decision will not affect any other benefits you may be entitled to.
- Please ask questions or mention concerns before, during, or after the research.

It is common for smartphone apps that try to help someone change their behavior to send a lot of notifications. The problem is these notifications can become overwhelming, particularly when they are not sent when they would be most helpful. This study is the first step to develop a smart mobile app to nudge people to walk more with alerts only sent when they will be beneficial. The study compares a variety of different ways to figuring out when to send messages, such as reducing the total number sent during the day, or only sending them if a person is not meeting their goals. The data collected through this study will help us to understand strategies that can be used to make sure behavioral support is only provided when it would actually be useful. If successful, the strategy will be shared with the public, thus providing guidance to digital health companies on how to provide the right support at the right time, minimizing unhelpful alerts on your phone from a fitness app.

You will first undergo an interview with one of our staff to determine if you are eligible for the study. If you are eligible, you will receive a wearable device ("Fitbit") and install our mobile app on your phone. The study will be about 9 months long (270 days total). During that time, you will be guided to actively use the app and answer a few questions on the app, which will require 5-10 minutes of your attention each day. In addition, there will be three interviews: Enrollment, Pre-Study, and Post-Study. Each interview will last 1-2 hours. For your participation, you will be given a Fitbit Versa 3 to keep after study completion ($229 value). In addition, you will be provided $25 for each 3-month period of participation if you complete the interview and at least

80% of phone surveys (takes less than 1.5 hours in total to complete the surveys over 3 months) during the 3-month window. If you miss one period, you are still eligible for the $25 from the next time window.

This app only nudges you to walk occasionally. The level of risk is low and is similar to the same risks you experience from walking every day. As with any exercise, it is possible you might trip or fall while walking or you might experience mild lightheadedness or some other soreness or discomfort. Although it is highly unlikely for you to experience any severe health risks during this study, please share your concerns during the enrollment interview.

Additional, detailed information about this research is provided below. Please feel free to ask questions before signing this consent.

Why have you been asked to participate, how you were selected, and what is the approximate number of participants in the study?

You have been asked to participate in this study because you own a smartphone, you reported engaging in less than 60 minutes per week of exercise, you are interested in starting to walk more, you are at least 25 years old, and you are healthy enough to participate in the study. There will be approximately 60 participants.

What will happen to you in this study?

In addition to the information at the beginning of this form, here are some additional details about what will happen if you agree to be in this study,

You will take part in the following activities:

- A 15-minute consent and enrollment virtual meeting (this meeting)
- A Pre-intervention virtual interview and survey (30-60 minutes). During this interview we will discuss baseline survey, how to use the study app, the details of the intervention and the way to get tech support (if needed).
- The first 10 days are called “the baseline phase”. During this time, you will be asked to go about your normal everyday activities while wearing the Fitbit, day and night. You will also be prompted each day to complete a short (less than 5 minute) survey through the app (10 days, ≤5 minutes/day interaction with app = 50 minutes in total across 10 days).
- After the first 10 days, “the study phase” will start and will last for 260 days, or just over 8 months. During this time, you will wear the Fitbit, day and night, and the app will provide suggestions and support to help you increase your steps per day. Every day, you will be prompted to interact with the app for between 5-10 minutes (≤10 minutes/day interaction with app = 2,600 minutes (approx. 43.3 hours) across 260 days).

- A 20 minute post-intervention virtual interview whereby we will ask you about your experiences with using the app. At the end of this interview, we will ask if we can continue to monitor your natural use of Fitbit for up to 1-year post intervention.
    - If you opt in, there will be no expectations upon you to use the app, use the intervention, or even to continue to use the Fitbit. We would monitor what you naturally do with a Fitbit.
    - If you opt out, we will disconnect monitoring your Fitbit.

All meetings' audio will be temporarily recorded, then transcribed without personal information. After transcription, all audio files will be deleted.

You will be asked to wear the Fitbit, day and night, for 270 days (just over 8 months).

While taking part in the study, you will receive:

- A Fitbit activity tracker;
- a suggested step goal each day that will strive to challenge you but still be doable for you, based on the number steps per day measured earlier in the study;
- notifications meant to help you find ways to plan short walks in the next 3 hours, sent sometime between 0 to 4 times per day
- a daily survey which consists of approximately half a dozen multi-choice questions and takes less than one minute to complete,
- a quick reflection survey after your activity which consists of approximately half a dozen multi-choice questions and takes less than one minute to complete, and
- a weekly reflection survey, which consists of about one dozen multi-choice questions and takes approximately two to three minutes to complete, at your preferred time.

How much time will each study procedure take and how long will the study last?
This study consists of two phases: the baseline and the study phase.

1. **The baseline phase** will last 10 days. You will not receive any notifications focused on increasing your steps during this period. The app will gather data about your usual level of physical activity and ask you questions. The data gathered in this phase will be used to adjust initial support to your personal needs.
2. **The study phase** will last 260 days (approximately 9 months). As explained in the last section, you will use the app to measure your physical activity and answer a few daily questions. These questions are about how you are feeling today in general, and specifically about physical activity. These questions are asked to help us improve our capacities and providing support only during times that would actually be beneficial for someone.

What risks are associated with this study?

Participation in this study may involve some added risks or discomforts. In addition to the risks described at the beginning of this form, there are a few additional risks.

1. During the enrollment interview, subjects may feel anxiety and/or embarrassment when answering personal questions on medical and lifestyle history and completing the questionnaires, including possible feelings of inadequacy if they cannot meet their criteria.
2. Walking, even if it is a voluntary activity, may produce light-headedness, fatigue, nausea, chest discomfort, or delayed-onset muscle soreness, especially under severe weather.
3. Subjects may feel
    a. feelings of inadequacy or embarrassment if unable to succeed at the steps goal,
    b. concern for privacy related to divulging personal information and security of providing personal information through the Fitbit app,
    c. injury during physical activity,
    d. the rare occurrence of a cardiovascular event during physical activity, and
    e. physical discomfort related to wearing the Fitbit Versa.
4. Participating in the study might involve a level of effort or burden (likely in the realm of 2-3 minutes per day), especially since the mobile applications will be designed to help participants think about their health and health behaviors more frequently.
5. Some participants might worry about the security of their data on study servers and on their mobile phones. During the study, even with our best effort, there is a risk to lose confidentiality of your data.

The risks involved in this study are no more than minimal and are reasonable in relation to the potential knowledge that may result from this study.

Because this is a research study, there may be some unknown risks that are currently unforeseeable. You will be informed of any significant new findings.

Are there risks to the reproductive system or a developing fetus?

A moderate level of walking is safe for pregnancy unless there are specific medical reasons. This study does not push you to vigorous exercise which could be potentially harmful to a developing fetus under certain circumstances. However, if there is a concern about being unable to meet your will to exercise due to ongoing reproductive procedures or pregnancy, please share this information during the enrollment interview.

Participation in this study does not create risks for the reproductive system.

What benefits can be reasonably expected?
In addition to the benefits listed at the beginning of this form, the investigators may also learn more about the ways in which people react to app notifications, or not, depending on the circumstances. This knowledge will help researchers to create a better app that reduces unnecessary notifications and, hopefully maximizes benefits.

Further, it also gives us the knowledge to help people to prevent chronic diseases such as diabetes or heart problems. Since this study introduces a new engineering concept called control systems engineering into the mobile health sector, it will develop health science in general. The tools for this project will be published as open-source to be used freely by other researchers.

What happens if you change your mind about participating?
If you decide that you no longer wish to continue in this study, you will be requested to notify the study team and respond to a "reasons to terminate" survey. It will only take less than 5 minutes. You may retain the provided Fitbit device.

You will be told if any important new information is found during the course of this study that may affect your wanting to continue.

Can you be withdrawn from the study without your consent?
You may be withdrawn from the study for the following reasons:

1. In the view of the PI, participating in the study poses a risk to your health or welfare.
2. Stop responding to study staffs' contact regarding things like not recharging your smartwatch, not using the app, and not responding to survey questions.

You may also be withdrawn from the study if you do not follow the instructions given to you by the study personnel. You may retain the provided Fitbit device even if you have withdrawn.

Will you be compensated for participating in this study?
For your participation, you will be given a Fitbit Versa 3 to keep after study completion ($229 value). In addition, you will be provided $25 for each 3-month period of participation if you complete the interview and at least 80% of phone surveys during the 3-month window, potentially $75. If you miss one period, you are still eligible for the $25 from the next time window.

Are there any costs associated with participating in this study?
There will be no cost to you for participating in this study. The download size of the apps for this study is approximately 200MB and it constantly connects to the internet. It will download less than a few megabytes even with extensive use of the app. However, depending on your mobile contract, this amount of data transfer can cost you. This cost will not be reimbursed. If available,

it is recommended that you download the apps when you can access cost-free internet such as wi-fi.

Along with the study app, you will also be requested to install the Fitbit app which includes paid premium services. You may purchase this service, however it is not required for this study. If you do choose to purchase this service, you will NOT be reimbursed for it.

What about your confidentiality?
The following data will be collected:

- Interview audio (temporary, deleted after transcription) and transcript
- Survey responses
    - Gathered from the meetings
    - Daily inputted online survey
- Activity data
    - Number of steps
    - Heartrates
    - Activity intensity: light, moderate, or vigorous
    - Estimated Calories used by physical activities
    - Distances of walking, running, or participant inputted activities
    - Number of floors you climb
    - Sleep hours
- Study App usage data
    - When and what page of our app is opened by participant

Research records will be kept confidential to the extent allowed by law.
All measurements will be de-identified (i.e., processed or partially deleted to make it hard to know whose data it is) and treated confidentially. Written consent forms will be kept in separate locked files cabinets separate from participant data on the study's secure database so that individuals are not easily connected to the study results. All data from the Fitbit Versa will be continuously, passively, and securely streamed to the Fitbit website. It will then be retrieved using software developed by Fitbit Inc (https://www.fitbit.com) and stored securely on their servers. All data that is subsequently downloaded from Fitbit Inc. servers for analytic purposes will remain de-identified and will be stored on secure, password-protected UCSD servers.

Research records may be reviewed by the UCSD Institutional Review Board and Dr. Hekler's associates at the University of Michigan (Dr. Predrag Klasnja) and Arizona State University (Dr. Daniel E. Rivera).

After this study is over, information and data from this study will be de-identified (i.e., delete all personal identifying information) and maintained indefinitely. It could be used in future research studies or distributed to another investigator without your additional consent. If this were to occur, it will be remained unidentifiable status. For example, step totals from this study could be shared with another investigator but there wouldn't be any way to tie those step totals back to a specific person. The investigator will not be given your personal information including name, or your contact.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Will you receive any results from participating in this study?

Study staff will use the results of this study to present our findings via presentation(s) at scientific meetings or in scientific publications. When results are made public, your identity will not be shared. Additionally, after the data is collected and we have had time to analyze the data, we will share your personal results with you, if you'd like. We will be in touch after study completion to offer you the opportunity to learn more about your personal results. This will include the option for you to retain your personal data, if you so choose, as well as any personalized results developed about and for you. You may opt-out from this communication. Once the study is completed and we have had the chance to offer all participants personalized results, we will produce a final de-identified dataset that will be retained. We will then permanently delete all identifying information and capacities to link the study data with individuals, including yourself.

Who can you call if you have questions?

This study has been explained to you and your questions have been answered by the signing witnesses. If you have other questions or research-related problems, you may reach Eric Hekler at (858) 429-9370. Or, send an email to us (justwalk@ucsd.edu).

You may call the Human Research Protections Program Office at 858-246-HRPP (858-246-4777) to inquire about your rights as a research subject or to report research-related problems.

Your Signature and Consent

You have received a copy of this consent document to keep.

You agree to participate.

_____	_____	_____
Full name of the subject (print)	Signature	Date

_____	_____	_____
Full name of the person conducting the informed consent discussion (print)	Signature	Date

The research team may contact you following the study to ask additional questions and/or regarding potential participation in other research. Please mark whether you agree to be recontacted following the conclusion of the study.

Yes, you agree to be recontacted.

No, you do not agree to be recontacted

_____	_____
Subject's signature	Date