- 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

Study Protocol & Statistical Analysis Plan

1. RESEARCH DESIGN AND METHODS

Overview

This study is a 270-day, system identification experiment with two key facets. Building on our prior work, including our previously developed mobile health app, HeartSteps, we will conduct a system identification experiment designed to rigorously test a JITAI with two key components: 1) notifications delivered up to 4 time per day designed to increase a person's steps within the next 3 hours via either increased awareness of the urge to walk or via bout planning; and 2) adaptive daily step goal suggestions. Notifications prompting planning of short walks within the next 3 hours will be experimentally provided or not across variations of need (i.e., whether daily step goals were previously met), opportunity (i.e., the next three hours is a time window when a person previously walked), and receptivity (i.e., person received fewer than 6 messages in the last 72 hours and walked after receiving a notification). In addition, suggested daily step goals will also be provided and systematically varied using system identification techniques between a person's baseline steps/day (e.g., 4,000 steps) towards meeting clinically meaningful targets (e.g., averaging 8,000 steps/day on average each week). N=60 sedentary participants aged 25+ with no health conditions that preclude them from walking will be recruited. Participants will wear a Fitbit Versa 3 and use the study app for 270 days (10 day baseline period + 260 system ID experiment). We will recruit 60 English-speaking adults aged 25+ who are physically inactive and own a smartphone. All participants will receive support, but the support will be systematically varied using pseudo-random signal designs, which is common practice in system identification experiments (see prior work for more details [1]). Our prior system identification experiment and other system identification experiments illustrate the acceptability of this experimental approach among humans. [7-10] All participants will be monitored continuously for 270 days using a Fitbit Versa 3 (steps, min/week MVPA, and heart rate) and asked to fill out brief surveys on the phone, called ecological momentary assessments (EMA).

Process Overview (participant's perspective)

1. Study website is exposed through online advertisements (e.g., Facebook Ad) or word of mouth that points groups to study pages hosted on cwphs.ucsd.edu (note page will go live after IRB approval).
2. Read brief explanation about the study and inclusion criteria
3. Fill up the "I am interested to join" online form
4. Enrollment meeting (10-15 minutes max): One-on-one virtual meeting with staff
    a. more information about study will be given, ask any questionsSign the enrollment consent
    b. Respond to enrollment forms (online GPAQ and PAR-Q, demographics)
    c. Provide information to receive Fitbit Versa 3
5. Fitbit Versa 3 is delivered
6. Pre-Intervention meeting (30-60 minutes): One-on-one virtual meeting with staff
    a. how-to-use information about Fitbit and HeartSteps app

   b. information about the 10-day baseline
   c. what will happen after the baseline period
7. Baseline (10 days - ≤5 minutes/day interaction with app = 50 minutes total across 10 days)
8. Intervention (260 days, ≤10 minutes/day interaction with app = 2,600 minutes total across 260 days)
9. Participants can always ask staff to ask any questions or intention to drop from the study via call, email, or one-on-one virtual interview
10. Post-Intervention meeting (20 minutes): One-on-one virtual meetings with staff
    a. Participants will be invited to opt out of allowing the team to continue to monitor their Fitbit activity data and their natural use of the Fitbit data. As noted in consent, participants would be asked to allow the team to monitor their Fitbit data for a maximum of 1 year post intervention.
    b. Participants will receive, if consented, individualized analysis results
    c. Total time engaging with the study = 15+60+50+2,600+20≅2,745 minutes across 270+ days, including pre-enrollment activities.

Description of the Processes

Study Website

Participants will be recruited through word-of-mouth, social media posts on Facebook, Twitter, Instagram, and TikTok, and via Facebook Ads. All entry points will direct participants to the study page, which will be hosted at cwphs.ucsd.edu/just-walk (note, website will go live after IRB approval). See recruitment materials for language to use on the social media points. A Facebook Ad will be created under the name "Just Walk." It will be noted that this study is conducted under certification of the UCSD IRB. It will contain brief information about the study (i.e., what the participant will experience, what the inclusion and exclusion criteria are, what compensation they will attain, and what the risks are in the study). It also will lead the potential participants to the "I am interested to join" online form.

Fill out the **"I am interested"** online form

Participants will be directed from the study home page to complete a brief Qualtrics survey, which will include a pre-screening survey to determine eligibility. Specifically, participants will be asked to complete an initial waiver of consent to enable the team to determine eligibility. If they agree, then they will be asked to report their age, physical activity levels (as reported using the GPAQ) and Physical activity readiness Questionnaire (PAR-Q). If a person is determined to be above the age of 25, inactive (engaging in less than 60 minutes of moderate intensity activity per week), and does not have any issues that would preclude them from engaging in an exercise program, as determined by the PAR-Q), then they will be asked to provide their contact information (i.e., first name, phone number, and email address).

Enrollment meeting: One-on-one virtual meeting with staff

With the information provided through the "I am interested to join" form, the staff will reach out to the potential participant. Zoom will be used unless the participant specifically requests otherwise. The interview will occur within 2 weeks after the form is completed.

During the meeting, the potential participant will be provided a full description of the study, which will include a summary of the pros and cons to participating in the study and invitation to come up with additional pros and cons to participate. As part of this, they will be invited to ask any questions to clarify the purpose, goals, and their involvement in the study. In addition, the study personnel will also review the participant's answers to the pre-screening questionnaire to confirm eligibility. Using the pros and cons list that both the team and the individual develops, participants will be asked to decide if they would be interested in participating or not. If they are, they will then be asked to review and sign the online study consent form. Staff will answer any questions that arise as the participant reviews the consent form, which will include having participants fill out an online form via DocuSign that enables a person to electronically sign to confirm enrollment. For participants that review and decide not to consent, they will be thanked and the call will end.

For participants that provide consent, participants will the nbe asked to complete an baseline survey that includes more detailed demographics, such as Age, sex, ethnicity, race, household income, tobacco and alcohol use, medical history, self-reported weight and height, and a range of psychosocial measures drawn from prior validated questionnaires. No questions will be included, such as questions about suicidality, that would establish a potential risk for the participants or researchers in terms of liability.

Last, participants will be informed of the next steps, which includes mailing them a Fitbit Versa 3 and setting up a follow-up meeting to set up the Fitbit and the Study app on the phone. After the next meeting is scheduled with sufficient time factored in for the participant to receive their Fitbit Versa, the meeting will be completed. and to arrange a Pre-Intervention meeting.

Interviews will be audio-recorded then transcribed without any identifying information. After transcription, the audio recording will be destroyed.

Fitbit Versa 3 Delivery

Fitbit Versa 3 will be delivered to their designated address. For the ease of logistics, the instructions about how to use it for the study will be sent separately through email. If the delivery tracking information is noted as "delivered," staff will call them and confirm the Pre-Intervention meeting, as scheduled in the previous meeting.

Pre-Intervention meeting: One-on-one virtual meeting with staff

During the Pre-Intervention meeting, participants will be instructed on the following topics:

- Information on the installation and use of both the Fitbit and study app.
- information about the 10-day baseline
- what will happen after the baseline period

Central to this, study staff will help participants get fully set up and prepared walking them through each step of the process of installing and setting up their Fitbits, installing and setting up the study app, and getting started with the study. As part of this, participants will be provided with tips and other instructions on how to use and maintain the Fitbit (e.g., strategies for remembering to keep it charged and clean so as to reduce potential skin reactions).

Interviews will be audio-recorded then transcribed without any identifying information. After transcription, the audio recording will be destroyed.

Baseline (10 days)
During the Baseline period, participants will be asked to engage in their normal level of steps/physical activity and to wear the Fitbit at all times, except while showering and charging. Participants will also be asked to complete a few minimal ecological momentary assessment (EMA) questions that will be asked via the study app. During the baseline period, no interventions/support will be provided to the participants.

Beginning of Intervention
After the baseline, the intervention will automatically start. All of the intervention features of the app, such as the two intervention components described earlier (notifications to increase awareness of the urge to walk, and planning bouts of walking within the next 3 hours, and adaptive suggested step goals) and also other parts of the HeartSteps app, such as activity history and planning support will be made available to the participant. Participants will be asked to interact with the app whenever it sends notifications and also informed that they can open the app at any time if they would like further support. Total interaction time with the app will not exceed 10 minutes each day, with the option to use more features of the app, if they so choose. The interactions will occur in response to three types of notifications: 1) intervention notifications; 2) prompts to complete daily EMA battery; and 3) experience sampling prompts to complete EMA items throughout the day and in relation to the notifications to either increase the urge to walk or plan.

Intervention notifications: They will also receive an app notification such as "Can you squeeze 10-min walk in the next three hours?" throughout the study period. The notification might be sent up to four times a day, starting at user-defined "start of day" in the morning (i.e., 6 am, 7 am, or even 10 am), which will be gathered during the baseline survey. Starting from the participants' self-described "start of day", the decision points will then occur every 3 hours afterwards (e.g., if their day starts at 8a, the next decision point will be 11a, followed by 2p and finally 5p). The system identification procedures for determining if a notification will be sent or not will account for previous participant data, algorithmic settings, and experimentation parameters all towards systematically studying different ways of operationalizing just-in-time states. For example, the decision to send a notification or not will sometimes be chosen fully randomly or sometimes accounting for a variation of: 1) need, defined as a person did not meet their step goal yesterday; 2) opportunity, defined in terms of the person engaging in steps within the 3-hour targeted window based on their step data; and 3) receptivity, defined in terms of the number of notifications a person has been sent and, if a person responded favorably in the past from notifications). If the calculation results suggest the participant should get a notification, the app sends an app notification with a vibration. Otherwise, the participant will not get a notification. A second type of intervention notification will be sent whenever a person meets their daily step goal. These types of interactions are designed to be brief and require no more than 30 seconds of total time to engage with for each notification (2 minutes total as a possibility from these types of notifications)

Daily EMA: Participants will be prompted to answer a few daily EMA questions related to psychological constructs that are theorized to be informative for predicting a person's need for support, such as measures of self-efficacy, behavioral outcomes, perceived urge to engage in PA, and contextual barriers and facilitators of walking. During these daily EMA surveys, participants will also be provided their daily targeted step goal, which will be generated using previously published system ID strategies. [1] Whenever participants achieve their daily step goal, they will be notified of this achievement as an intervention notification, which will also include a visual summary of their history of meeting their goals across time. The EMA battery takes less than 3 minutes to complete in total.

Experience Sampling Prompts: Last, participants will be asked to complete brief (a question) experience sampling questions meant to further test the proximal impact, or lack thereof, of the intervention prompts over the 4 timepoints. To minimize burden and total interactions, these experience sampling prompts will be sent randomly across the 4 possible time windows throughout the day, both during times when a notification is sent and when it is not sent, with no more than 2 of these sent on any given day. Completing an experience sampling EMA survey will take no more than 1-2 minutes each time, thus a max amount of time would be 4 minutes per day if two are sent on a given day.

Study Mobile App: A pre-developed mobile app, HeartSteps [11], is slightly modified for this study. One of the study staff, Junghwan Park is responsible for the modification. There are a few more contributing developers, but they do not have access to server or identifiable data from this study. There are three levels of users in the system: Superstaff (i.e., Junghwan Park), staff (i.e., research personnel who finished the training on the research protocol), and participants. Participants do not have any access to any data. Staff are allowed to see the data and make limited changes to studies that they have an approval to take part in. Superstaff have access to all projects and they can grant permissions to other users. For this study, a separate secure server will be created and no other study will be in the server. All staff will be assigned as "staff".

Measures

Baseline survey We will ask a variety of baseline questionnaires about a person's context and support. The questionnaire includes a) personal characteristics related to the study (i.e., phone use, familiarity to smart watches), b) self-perception (i.e., personality, mood), and c) life habits and physical activity.

Continuous steps/day and min/week MVPA will be measured using the Fitbit Versa, a wrist-worn, consumer-level activity tracker that uses triaxial accelerometry to measure movement. See the next subsection for the details.

Daily intervention engagement: Among participants, quantitative markers of engagement will include usage of the apps including interactions with all intervention support, morning survey in the form of Environmental Momentary Assessment (EMA) tool, app usage (i.e., visualizations of current progress).

Psychological constructs and other key process variables: A variety of self-reported measures will be asked daily via EMA, to enable measurement of key psychological constructs for inclusion in our targeted dynamical models. The EMA items will include concepts like: 1) Behavioral Outcomes (i.e., sleep, mood, physical fitness, physical appearance); 2) Busy; 3) Stress; 4) Typicalness of day; 5) Internalized cue to action; 6) Commitment to goal; 7) Self Efficacy for meeting daily goal; 8) Outcome Expectancies (i.e., sleep, physical appearance, mood, concentration, physical fitness). We will also gather weather data (current weather, weather forecasts) only and location data, but with location data being coded automatically only as home, office, or other, based on baseline reports of their home and office addresses. Thus, no actual location GPS data will be stored. Weather will be gathered daily based on a person's self-reported zip code information.

Measurement of Physical Activity

Physical activity (PA) will be measured in two ways:

a) **Objective Measurement**: For the entire intervention period, the Fitbit Versa 3 which provide data on PA (i.e., intensity, energy expenditure, steps, distance traveled, and flights of stairs) and sleep (i.e., total sleep time, sleep onset latency, wake after sleep onset, and number of awakenings after sleep onset) at 1-minute epochs, and heart rate at variable epochs.

b) **Manual Input**: As Fitbit's automatic recognition of physical activity is not perfect, if the participant wants, they can share some of the details of what they physical activity have conducted. Also, if the participant forgets to wear, or recharge the Fitbit during the time of activity, the activity will not be automatically recorded. In this case, the user can input their activity through either Fitbit App or the study app.

Post-Intervention Interview

After 260-day intervention, the participant will be arranged with the post-intervention interview with staff. They will be given the choice of stopping using the app or not. Similar questionnaire will be provided as the pre-intervention interview. Interviews will be audio-recorded then transcribed without any identifying information. After transcription, the audio recording will be destroyed.

After the data has been analyzed, the produced individualized results will be explained, if the participant would like, as well as how their results compare to other participants.

mHealth App Usability Interview

At the end of study, participants will be interviewed using a semi-structured interview to examine their reactions and understand any usability issues with the apps (e.g., ease-of-use; see attachment for example protocol). Interviews will be audio-recorded then transcribed without any identifying information. After transcription, the audio recording will be destroyed.

Table 1. List of measures and assessment timepoints

Measures	**Assessment Timepoint**	
	pre-intervention	**post-intervention**

Demographic information	X	
Recent health history	X	X
Self-reported height and weight	X	X
App Usability Interview		X

Data Analyses

A series of system identification modeling approaches will be used to analyze the data and obtain control-oriented dynamical models of the system. General data analysis will start with examining the cross correlation of the data to verify the hypothesized structure of the system of interest in terms of the influence between the constructs included. Nonparametric estimation methods such as correlational analysis (CRA) and spectral analysis (SPA) will be used to obtain preliminary information about the responses of each individual (i.e. time constants, gains, order). The knowledge gained from the nonparametric estimation methods will be utilized to obtain ideographic models through prediction-error modeling approaches such as AutoRegressive with eXternal input (ARX) and output error (OE) estimation, and more elaborate greybox methods utilizing problem structure. Additionally, Model-on-Demand (MoD) estimation will be used to estimate more flexible models that address nonlinearities in the system. The estimated models from all approaches will be contrasted with one another, and the advantages/disadvantages of each will be assessed in order to inform future efforts.

Collected Information and Justification

Participant home, work, or other address will be collected to provide the weather forecast report and timezone information. Phone numbers and Email addresses will be collected for further contact if technical or study issues arise (e.g., low adherence, tech support). Device ID and serial numbers are required to send the in-app notifications. All of this information will be collected at baseline timepoint.

Fitbit Data Gathering

This research team has a privilege to fetch users' Fitbit data via Web API from the Fitbit server. The privilege is approved by Fitbit Inc.

2. HUMAN SUBJECTS

Inclusion criteria:

- inactive: engaging in less than 60 min/week of self-reported moderate intensity PA,
- adults: aged 21 or older, and
- own a smartphone that can run HeartSteps (iOS or Android)

Exclusion criteria:

- not proficient in English, or
- indicate medical problems that preclude PA

3. RECRUITMENT AND PROCEDURES PREPARATORY TO RESEARCH

Recruitment

N=60 sedentary participants aged 25+ with no health conditions that preclude them from walking will be recruited. Participants will wear a Fitbit Versa 3 and use the study app for 270 days (10 day baseline period + 260 system ID experiment). We will recruit 60 English-speaking adults aged 25+ who are physically inactive and own a smartphone. All participants will receive support, but the support will be systematically varied using pseudo-random signal designs, which is common practice in system identification experiments. Our prior system identification experiment and other system identification experiments illustrate the acceptability of this experimental approach among humans. All participants will be monitored continuously for 270 days using a Fitbit Versa 3 (steps, min/week MVPA, and heart rate).

Process Overview (participant's perspective)

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d) **Enrollment meeting**: One-on-one virtual meeting with staff
    i) more information about study will be given, ask any questions
    ii) Sign the enrollment consent
    iii) Respond to enrollment forms (online GPAQ and PAR-Q, demographics)
    iv) Provide information to receive Fitbit Versa 3
e) Fitbit Versa 3 is delivered
f) **Pre-Intervention meeting**: One-on-one virtual meeting with staff
    i) how-to-use information about Fitbit and HeartSteps app
    ii) information about the 10-day baseline
    iii) what will happen after the baseline period
g) Baseline (10 days)
h) Intervention (260 days)
    i) Participants can always ask staff to ask any questions or intention to drop from the study via call, email, or one-on-one virtual interview
i) **Post-Intervention meeting**: One-on-one virtual meetings with staff
    i) Participants can decide whether they keep using the app

4. INFORMED CONSENT

Informed Consent

Digital informed consent will be obtained through virtual enrollment interviews prior to completing the baseline measures. However, there are several steps, as described in section 1. The study staff will obtain written informed consent through DocuSign prior during the enrollment interviews, and it will be kept separately from all other research data.

5. COMPENSATION FOR PARTICIPATION

Participants will receive the following incentives: 1) Fitbit Versa 3 (received at study enrollment, $229 value); and 2) $25 gift cards provided to them up to 3 times ($75 total), provided that they complete at least 80% of EMA items within each 3-month period.