Official Title: Using Real-Time Data Capture to Examine Affective Mechanisms as Mediators of Physical Activity Adherence in Interventions: Formative Study

NCT #: NCT06125964

Document: Informed Consent Form

Date: 01.23.24

University of Southern California
Department of Population and Public Health Sciences, 1845 N. Soto St., Los Angeles, CA 90032

INFORMED CONSENT FOR RESEARCH

Study Title: eMOTION Study

Principal Investigator: Genevieve Dunton, PhD, MPH

Department: Department of Population and Public Health Sciences

24-Hour Voicemail: 323-419-1849

INTRODUCTION

We invite you to take part in a research study. Please take as much time as you need to read the consent form. You may want to discuss it with your family, friends, or your personal doctor. If you find any of the language difficult to understand, please ask questions. If you decide to participate, you will be asked to sign this form. A copy of the signed form will be provided to you for your records.

KEY INFORMATION

The following is a short summary of this study to help you decide whether you should participate. More detailed information is listed later in this form.

1. Being in this research study is voluntary–it is your choice.

2. You are being asked to take part in this study because you are an adult (at least 18 years of age), have a body mass index (BMI) of at least 25, and currently engage in less than 60 minutes of physical activity per week.

3. The purpose of this study is to test a physical activity program delivered through an app and smartwatch. Your participation in this study will last around three weeks. You will be given a physical activity prescription and daily physical activity goals to follow. Other procedures will include remotely attending video orientation sessions, wearing a Fitbit Versa smartwatch on your wrist, answering short surveys several times per day on the Fitbit Versa smartwatch and on your smartphone, completing online questionnaires, and completing an exit interview.

4. There are risks from participating in this study. The most common risks are feeling sore after engaging in physical activity and feeling burdened by the number of surveys on the Fitbit Versa smartwatch and your smartphone. More detailed information about the risks of this study can be found under the “Risks and Discomforts” section.

5. There are no direct benefits to you from taking part in this study. However, your participation in this study may help us learn how to promote physical activity in adults at risk for preventable cancers.

6. If you decide not to participate in this research, you will not have alternative choices (i.e., your only choices are either to participate or to not participate).

DETAILED INFORMATION

PURPOSE

The purpose of this study is to test a physical activity program delivered through an app and a smartwatch. Feedback from this study will help us to make changes to improve the program. You are invited as a possible participant because you are at least 18 years old, have a BMI of at least 25, and engage in less than 60 minutes of physical activity per week. This research is being funded by the National Cancer Institute.

PROCEDURES

If you decide to take part, this is what will happen.

All study activities will be remote, so you won't have to attend any in-person visits. After reviewing and signing this document with a study team member, you will officially be considered a participant in the study and will go through the following steps.

Start-Up Period. First, you will receive an email with a link to an online survey that will ask questions about your health, physical activity, and other behaviors. This survey will take about 45 minutes to complete. Then, over the next three days, you may receive two brief surveys per day to complete on your smartphone: one in the morning and one in the evening. You will also provide your mailing address. Next, study staff will mail you a Fitbit Versa smartwatch to wear for the duration of the study. When you receive the Fitbit, we'll ask you to charge it and download the Fitbit app.

Orientation Session. You will then be asked to attend a 60-minute video orientation session. At this remote meeting, a researcher will show you how to connect your Fitbit Versa smartwatch to our study platform. You will also learn how to complete morning and evening physical activity goal sessions and respond to short surveys on your Fitbit Versa smartwatch.

Physical Activity Program. The study will last around three weeks. You will be asked to do the activities described below.

1. **Daily Physical Activity Goal Sessions on Your Smartphone.** Every Sunday, you will receive a text message through your personal smartphone with a link to an online form. This form will ask you to select the days in the upcoming week that you are planning to do physical activity. It will allow us to schedule your

morning and evening physical activity goal sessions for the week. On days you plan to do physical activity, you will receive text messages through your personal smartphone in the morning and evening with a link to an online form to complete about your physical activity goals that day. The morning goal session will give you a physical activity goal for that day, help you to plan how to reach your goal, and solve problems that might keep you from reaching it. You will also answer questions about how you feel. During the study, you will be assigned to receive one of two types of physical activity goals. The different types of morning goal sessions look very similar to each other but use different wording and strategies for achieving physical activity goals. The evening goal review session will ask you about any physical activity you did that day.

2. **Fitbit Versa Smartwatch.** You will be loaned a Fitbit Versa smartwatch for the study and asked to wear it all the time when you are awake and sleeping, except for when you need to charge it. A study team member will teach you how to use the Fitbit Versa smartwatch during the orientation session at the beginning of the study. The Fitbit Versa smartwatch has sensors that track your physical activity, count your steps, and measure your heart rate. The Fitbit Versa smartwatch will be paired to your personal smartphone using Bluetooth, so that study data can be sent to your phone. Data will then be safely sent through the Internet to the researchers throughout the study period. You will not be held responsible if the device is stolen, lost, or damaged.

3. **Brief Smartwatch Surveys.** Brief surveys will be sent to your Fitbit Versa smartwatch several times per day when you are awake. Each question can be answered by tapping on the Fitbit Versa smartwatch screen. The Fitbit Versa smartwatch will vibrate to notify you of a new survey to complete. If you do not respond, the Fitbit Versa smartwatch will send up to one more reminder signal. Please ignore any survey notifications that occur during activities where it would be unsafe to respond, like driving a car. Some questions will be prompted when the Fitbit Versa smartwatch senses you are doing physical activity. Other questions will be prompted at random times throughout the day.

During the first week of the study, you will start by wearing the Fitbit and answering questions on the Fitbit Versa smartwatch, to make sure that you understand how to do each of them. Then, in the second and third weeks, we will ask you to also participate in morning and evening physical activity goal sessions on your smartphone.

Post-Study Questionnaire and Exit Interview. You will be asked to respond to a 30-minute online survey at the end of the study. It will have questions about your opinion of the study and how your participation went. A 45-minute exit interview will occur on Zoom where we will also ask some more questions that will help us improve the study for future participants.

RISKS AND DISCOMFORTS

Possible risks and discomforts you could experience during this study include the following:

Questionnaires & Daily Goal Sessions: Some of the questions may make you feel uneasy or embarrassed, and some questionnaires may ask you to disclose illegal behaviors (i.e., smoking or using alcohol for individuals younger than 21). You can choose to skip or stop answering any questions you don't want to.

Fitbit Versa Smartwatch: The Fitbit Versa smartwatch may feel slightly uncomfortable on your wrist as you adjust to it, especially during sleep. Wearing the Fitbit Versa smartwatch may cause mild skin irritation, especially if soap or lotion becomes trapped under the band. As with any watch, after a week or two, wearing the watch is likely to feel completely natural.

Brief Smartwatch Surveys: Possible risks and discomforts that you could experience during this study include feeling burdened by the number of surveys per day or that your privacy is invaded by being asked to report your current activities. Also, there is a small risk associated with answering surveys during physical activity. To protect against injury, we ask you to safely pause your activity and check your surroundings before answering Fitbit Versa smartwatch surveys.

Other: You might feel sore after doing physical activity. The physical activity program is designed to start relatively easy (based on your age-predicted heart rate max) and progress slowly. Carefully increasing physical activity difficulty over time will help your body adapt and minimize soreness. There is also a small risk that you will injure yourself while doing physical activity. We will teach you how to do warm-up and cool-down activities to minimize this risk. We also encourage you to listen to your body and stop immediately if you feel pain.

Breach of Confidentiality: There is a small risk that people not connected with the study will learn your personal information or identity; however, steps will be taken to minimize this. Data will be stored in a secure server.

BENEFITS

There are no direct benefits to you from taking part in this study. However, your participation in this study may help us learn how to improve a physical activity program for people at risk for preventable cancers.

PRIVACY/CONFIDENTIALITY

We will keep your records for this study confidential as far as permitted by law. However, if we are required to do so by law, we will disclose confidential information about you. Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who are required

to review this information. We may publish the information from this study in journals or present it at meetings. If we do, we will not use your name.

The University of Southern California's Institutional Review Board (IRB) and Human Subject's Protections Program (HSPP) may review your records. A description of this clinical trial will be available on http://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 website at any time.

Your responses to the screening survey will be kept and stored with the rest of the study data (which includes your responses to questionnaires, daily goal sessions, interviews, and smartwatch surveys and physical activity data). Also, the exit interview will be recorded and stored in Zoom's password-protected cloud. Only people on the study team will have access to the recording. Recording and storage will allow for post-interview transcription. Recordings will be deleted immediately after they are transcribed or after 5 years, whichever comes first. Your data will be labeled with a code that the research team can link to personal identifying information and stored on a secure database that is password protected. Databases with your information will be in password protected files and be de-identified and stored on secure, firewalled servers that only approved study staff will have access to. A temporary Fitbit account will be created for you to use during the study. After the study is over, this account will be deleted and the research team will no longer be able to collect data using it. Fitbit Versa smartwatches will be reset to factory settings when they are returned to the research team, with none of your information remaining on it. Also, you have the right to delete any data that can still be associated with you. This includes data from a particular day or period of time.

Your data collected as part of this research may be used or distributed for future research studies without your additional informed consent. Any information that identifies you (such as your name) will be removed from the data before being shared with others or used in future research studies. At any stage in the study, you agree to be contacted by the study team to participate in future research studies.

ALTERNATIVES

An alternative would be to not participate in this study.

PAYMENTS / COMPENSATION

Overall, you may receive up to $75 for participating in this study. Payment will be given when the Fitbit Versa smartwatch is returned to study staff, and following examination of Fitbit Versa smartwatch wear and survey completion data. Payments are as follows:

1. If you have worn the Fitbit Versa smartwatch all day and night (with no more than 1 hour that it is not worn per day) per day, you will receive $35.
2. If you have responded to all Fitbit Versa smartwatch surveys (with no more than one missed per day), you will receive $35.

3. If you have completed the post-study questionnaire and 45-minute remote exit interview, you will receive $5.

COST

There are no costs related to participation.

INJURY

If you think you have been hurt by taking part in this study, call the study voicemail immediately. All messages will be returned within 24 hours. If you require treatment because you were injured from participating in this study, you will need to go to your primary care physician or local emergency room. The study sponsor will not pay for this treatment.

There are no plans to offer any type of payment for injury. However, by signing this form you have not given up any of your legal rights.

VOLUNTARY PARTICIPATION

It is your choice whether to participate. If you choose to participate, you may change your mind and leave the study at any time. If you decide not to participate, or choose to end your participation in this study, you will not be penalized or lose any benefits that you are otherwise entitled to. If withdrawal must be gradual for safety reasons, the study investigator will tell you. If you stop being in the research, already collected data may not be removed from the study database.

If you decide to withdraw during the study, you will be given a number to call to return the Fitbit Versa smartwatch.

PARTICIPANT TERMINATION

You may be removed from this study at any point without your consent for any of the following reasons: you do not follow the study investigator's instructions, at the discretion of the study investigator or the sponsor, your ability to perform physical activity changes, or the sponsor closes the study. If this happens, the study investigator will discuss other options with you.

CONTACT INFORMATION

If you have questions, concerns, complaints, or think the research has hurt you, please call the study voicemail (323-419-1849).

This research has been reviewed by the USC Institutional Review Board (IRB). The IRB is a research review board that reviews and monitors research studies to protect the rights and welfare of research participants. Contact the IRB if you have questions

about your rights as a research participant or you have complaints about the research. You may contact the IRB at (323) 442-0114 or by email at irb@usc.edu.

STATEMENT OF CONSENT

I have read (or someone has read to me) the information provided above. I have been given a chance to ask questions. All my questions have been answered. By signing this form, I am agreeing to take part in this study.

Name of Research Participant	Signature	Date Signed (and Time*)

Person Obtaining Consent

I have personally explained the research to the participant using non-technical language. I have answered all the participant's questions. I believe that the participant understands the information described in this informed consent and freely consents to participate.

Name of Person Obtaining Informed Consent	Signature	Date Signed (and Time*)