

**Title:** StandUPTV: A mobile app to reduce sedentary screen time

**Investigators:** Matthew Buman, PhD – Arizona State University and Sarah Keadle, PhD California Polytechnic State University

## The informed consent process

My name is Dr. Sarah Kozey Keadle and I am an associate professor in the Kinesiology and Public Health Department at California Polytechnic State University (Cal Poly). I am working with Dr. Matthew Buman, an associate professor in the College of Health Solutions at Arizona State University (ASU) on this project. You are being asked to take part in a research study. Before you decide to take part, it is important that you know why the research is being done, how the study will be carried out and what you will be expected to do. You should also know any risks or benefits of being in the study. All of this is explained in this document, called the informed consent document.

Please read the form carefully and talk to the researcher about any questions you may have. You can talk about it with family and friends if you wish. Take your time to decide and make sure that you ask the researcher any questions you have about the study before you decide whether you want to be in the study. Then, if you decide to be in the study, please sign and date this electronic form. We will also send you a copy of the signed form to keep. Your signature on this consent form will show that you received all of the information below, and that you were able to discuss any questions and concerns you had with member(s) of the study staff. If you are in any other research study, you must inform the study staff now. This process is called informed consent.

### 1. Purpose of the study & Key Information

The purpose of the StandUPTV study is to develop a smartphone application (or “app”) to reduce recreational sedentary screen time in adults. We define recreational sedentary screen time as time spent sitting or lying down and using a screen, such as television, computers, smartphones, tablets, or inactive video games in your recreational time (not for school or work). This includes watching television, DVDs, streaming online movies or shows on a media device, playing video games, or using social media (e.g., Facebook, Instagram). We are testing different ways of reducing recreational sedentary screen time in order to determine which ones work the best. This research is funded by the National Cancer Institute, which is part of the United States federal government. A total of 240 individuals will participate in this study, with about 120 recruited in California and 120 recruited in Arizona. Each person will be in the study for about 5 months.

You are being asked to take part in this research study because you are an adult between the ages of 23 and 64 years, you report watching more 3 hours of sedentary screen time daily and are not exercising regularly.

### 2. Description of the study, procedures to be used and how long it will last:

This will be a 4-month study period when you will use a StandUPTV “app” to receive feedback on your sedentary screen time and information about how to reduce sedentary screen time. We will also do some screening and measurement of your current screen time before the study starts, so your total time as a participant will be about 5 months. A brief overview of the study is provided here and study visit details are provided in more detail below.

Once you hear about the study, you will be asked to fill out a survey where you will be evaluated for eligibility based on our questions including providing us with your height and weight. Once you qualify

for the study, you will be given a technology kit that you will use to measure your current level of sedentary screen time for a 7-day period. The kit will include an Android tablet (Samsung Galaxy), Wi-Fi smart plugs and a WiFi router, a small computer called a Raspberry Pi, and 3 different wearable devices (one worn on the wrist – a Fitbit, one worn on the thigh – called an activPAL and a sleep tracker on the wrist – called a GENEActiv) which will record your movement, sitting, standing, and heart rate. We ask that you wear these devices both during wake and sleep. We recommend charging the Fitbit and tablet at night while sleeping when needed. The wearable devices are water resistant such that they can be worn in the shower, bath, or when swimming. During your study participation, we will ask you to view all your usual screen time through only your TV or the StandUPTV app on the tablet we provide you, not your smartphone, tablet, computer, etc.

Once you get the device kit, we will walk you through setup of the devices over a video or phone call that will take about 60 minutes. WE ASK THAT YOU DO NOT SET ANYTHING UP UNTIL YOUR REMOTE VISIT WITH STUDY STAFF. All visits will take place by video conference or by telephone. You will also fill out questionnaires about your health behavior, age, and your confidence in your ability to reduce your sedentary screen time. These questionnaires will be done online and will take about 30 minutes to complete. During the 7-day measurement period, we will also ask that you record the times you get in and out of bed each morning, when you take off or put on the wrist worn devices, we will also ask you to fill out an online diary about your activity on 2 different days and you will recall your usual daily dietary intake on 2 days over the phone. These diaries will take about 20 minutes each to complete. We will send short, 1-item questions via the app to ask about your mood, how tired you are, and snacking, not more than 3 per day. We will also ask you to send us a screenshot of your phone app usage to learn about any screen time which may have been used through your smartphone. At three time points (beginning, 8 weeks, and end of study) we will ask you to obtain your weight and body fat percentage using a Tanita scale that will be shipped to you and measure your waist circumference with a tape measure that will be provided to you. We will ask that you send that information to us.

At the end of the 7-day assessment, you will mail us back the small thigh monitor (activPAL) and the sleep tracker (GENEActiv) and keep the rest of the technology kit. At this point, you will be randomized into one of 8 study Groups. Randomization means that you cannot choose the Group that you will be in, rather you have an equal chance of being placed into any one of the 8 Groups, similar to flipping a coin, but with 8 different options. You must be willing to participate in any of the Groups to participate in the study.

Group 1: If you are assigned to Group 1, you will receive the StandUPTV app and a goal to watch 50% less sedentary screen time. The app will give you feedback on your screen time each day and some materials to help you reduce screen time. You will also receive TEXT messages (up to 3/day) to remind you to reduce your sedentary screen time. You will have the opportunity to EARN more screen time if you exercise. You will get summaries of your exercise time and educational materials about exercise in the app. If you go over your weekly limit of screen time you will be LOCKED OUT of further screen time, meaning your TV and tablet will not turn on.

Group 2: If you are assigned to Group 2, you will receive the StandUPTV app and a goal to watch 50% less sedentary screen time. The app will give you feedback on your screen time each day and some materials to help you reduce screen time. You will have the opportunity to EARN more screen time if you exercise. You will get summaries of your exercise time and educational materials about exercise in the app. If you go over your weekly limit of screen time you will be LOCKED OUT of further screen time, meaning your TV and tablet will not turn on.

Group 3: If you are assigned to Group 3, you will receive the StandUPTV app and a goal to watch 50% less sedentary screen time. The app will give you feedback on your screen time each

day and some materials to help you reduce screen time. You will also receive TEXT messages (up to 3/day) to remind you to reduce your sedentary screen time. You will have the opportunity to EARN more screen time if you exercise. You will get summaries of your exercise time and educational materials about exercise in the app. I

Group 4: If you are assigned to Group 4, you will receive the StandUPTV app and a goal to watch 50% less sedentary screen time. The app will give you feedback on your screen time each day and some materials to help you reduce screen time. You will also receive TEXT messages (up to 3/day) to remind you to reduce your sedentary screen time. If you go over your weekly limit of screen time you will be LOCKED OUT of further screen time, meaning your TV and tablet will not turn on.

Group 5: If you are assigned to Group 5, you will receive the StandUPTV app and a goal to watch 50% less sedentary screen time. The app will give you feedback on your screen time each day and some materials to help you reduce screen time. (Replace with: Same as condition 1, plus) If you go over your weekly limit of screen time you will be LOCKED OUT of further screen time, meaning your TV and tablet will not turn on.

Group 6: If you are assigned to Group 6, you will receive the StandUPTV app and a goal to watch 50% less sedentary screen time. The app will give you feedback on your screen time each day and some materials to help you reduce screen time. You will have the opportunity to EARN more screen time if you exercise. You will get summaries of your exercise time and educational materials about exercise in the app.

Group 7: If you are assigned to Group 7, you will receive the StandUPTV app and a goal to watch 50% less sedentary screen time. The app will give you feedback on your screen time each day and some materials to help you reduce screen time. You will also receive TEXT messages (up to 3/day) to remind you to reduce your sedentary screen time.

Group 8: If you are assigned to Group 8, you will receive the StandUPTV app and a goal to watch 50% less sedentary screen time. The app will give you feedback on your screen time each day and some materials to help you reduce screen time.

Group	Lockout	Text	Earn	StandUPTV App
1	Yes	Yes	Yes	Yes
2	Yes	No	Yes	Yes
3	Yes	Yes	No	Yes
4	Yes	No	No	Yes
5	No	Yes	Yes	Yes
6	No	No	Yes	Yes
7	No	Yes	No	Yes
8	No	No	No	Yes

Once you are randomized there are additional study visits that you will complete.

First visit: You will have a video call with a trained study staff member to talk about the group that you were randomized to, your reasons for joining the study and to orient you to the full StandUPTV app.

This visit will take approximately 60 minutes. We also will ask you at this time for a final weight, body fat, and waist circumference measurement.

Check-in calls: We will check in with 1 within a week of your randomization visit to make sure you are able to use the app and devices and answer any questions you may have. Additionally, throughout your study participation, if we notice that you are not using the app or we are not getting data from the technology kit we make a call to check in and ensure the technology is all working correctly.

Mid-study: At week 8 of the study, we will ask you to wear the activity monitors again. We will mail you the thigh monitor (activPAL) and the sleep tracker (GENEActiv) to wear for 7 days and then mail it back to us using a prepaid envelope. We will also ask that you record the times you get in and out of bed each morning and when you take off or put on the wrist worn devices. We will also send you some questionnaires about your motivation and confidence to reduce sedentary screen time and 2 of the daily activity diaries (ACT24) to complete electronically. The questionnaires will take about 45 minutes to complete and the recalls will take 15-20 minutes each. We will send short, 1-item questions via the app to ask about your mood, how tired you are, and snacking, not more than 3 per day. We will also ask you to send us a screenshot of your phone app usage to learn about any screen time which may have been accidentally used through your smartphone. We also will ask you at this time for a weight, body fat, and waist circumference measurement.

End of study: At week 16 of the study, we will ask you to wear the activity monitors again. We will mail you the thigh monitor (activPAL) and the sleep tracker (GENEActiv) to wear for 7 days. We will also send you the questionnaires about your motivation and confidence to reduce sedentary screen time and 2 of the daily activity diaries (ACT24) to complete electronically. You will also complete two daily recalls of your diet over the phone (ASA24). The questionnaires will take about 30 minutes to complete and the recalls will take 15-20 minutes each. We will send short, 1-item questions via the app to ask about your mood, how tired you are, and snacking during this week, not more than 3 per day. We will also ask you to send us a screenshot of your phone app usage to learn about any screen time which may have been accidentally used through your smartphone. We also will ask you at this time for a final weight, body fat, and waist circumference measurement.

At the end of the study, you will pack up the technology kit and study staff will retrieve it from you if it was delivered to you, or you will mail it back to us using a prepaid shipping box. You will keep the Fitbit device but we will ask that you send back the smart plugs, tablet and Raspberry Pi. A researcher will call you to complete a brief survey about your overall experience as a study participant. This call will take about 30 minutes via Zoom video conferencing and may be audio and video recorded to enable study staff to have a transcript of the call.

### **3. Voluntary participation and ability to withdraw.**

Your participation in this study is voluntary. You decide whether or not you want to be in the study. If you decide now to participate, you can change your mind later and quit the study. You do not have to answer any questions you choose not to answer. If the researcher feels it is in your best interest, they may choose to take you out of the study at any time before you complete the study.

If you choose not to participate or to withdraw from the study at any time, there will be no penalty.

### **4. Study Compensation**

You will be compensated for your time as follows:

Complete baseline assessment: \$40

\$10 for setup of devices completed with study staff. \$30 for wearing activity monitors and, completing questionnaires, the ACT24 diaries, the diet diaries, and responding to >75% of the text messages.

Complete 8-week assessment: \$30

\$30 for wearing activity monitors and completing questionnaires, the ACT24 diaries, and responding to >75% of the text messages.

Complete 16-week assessment: \$30 + Fitbit (~\$130 value)

\$30 for wearing activity monitors and completing questionnaires, the ACT24 diaries, the diet diaries, and responding to >75% of the text messages. Participants who complete the study will also be allowed to keep the Fitbit utilized for this study (~\$130 value).

If you complete all assessments the total compensation is \$100, in addition to the earned Fitbit (~\$130 value).

If you do stop the study before completion, we will ask you to mail back the technology kit including the Fitbit and ask if you would be willing to set up a phone call to give us any feedback on using the smartphone app and any ideas about how to make the app more useful.

## 5. Potential benefits

It is unlikely that there will be a direct benefit from participating in this study, however, you may gain insight into your current sedentary behaviors and learn new ways to reduce your screen time.

## 6. Potential discomfort and inconvenience

The time it will take to complete the study assessments and use the Smartphone applications on a daily basis may be inconvenient to you. Answering some of the questions on the interview forms may make you feel uncomfortable at that time. You may find it bothersome to wear the activity monitor and use the study tablet. Getting locked out of your device if you are in one of the LOCKED-OUT Groups may be bothersome.

## 7. Potential risks of participating in the study

There is a minimal risk that a device or devices you will wear may cause discomfort such as minor skin irritation. You are free to remove any device if it causes you discomfort. There is a small risk of psychological discomfort when answering questions of a somewhat personal nature, you may refuse to answer questions at any time. People may also get muscle soreness as they start to increase their physical activity.

Sometimes research results in findings or inventions that have value if they are made or sold. These findings or inventions may be patented or licensed, which could give the company the sole right to make and sell products or offer testing based on the discovery. Some of the profits from this may be paid back to the researchers and the organizations doing this study, but you will not receive any financial benefits.

**8. Financial costs of the study:** There will be no cost to you for being in this study.

**9. COVID-19 Related Information - Device cleaning and disinfecting**

Before any device is sent to you, it will be cleaned and disinfected using EPA approved guidelines. Devices will be handled and packed into the shipping box by study staff who will wear gloves and masks while doing so. These measures are meant to reduce the chance of spreading the COVID-19 virus. We may choose to ask the COVID screening questions a few times over the course of your participation, also to reduce the risk of spreading the virus.

**10. Privacy and confidentiality**

All data gathered through the course of this study will be associated with a study ID number, your identity will not be readily linked to any of this research data. The screening document is the only location where your name and study ID are linked, that document will be kept under lock and key by study staff. The results of this study may be used in aggregate form for reports, presentations, or publications; your name will never be used. Your activity monitor data will be stored on a password protected computer and a password protected portable hard drive (portable hard drive will be stored in a locked file cabinet). After the study analysis is complete, your study data will be stored for 4 years and then confidentially shredded/erased.

This study is funded by the United States Department of Health and Human Services, National Cancer Institute (1R01CA239612).

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.

If you have any questions concerning the research study, please contact the investigator for your site:

Dr. Sarah Kozey Keadle, 805-756-1785 [skeadle@calpoly.edu](mailto:skeadle@calpoly.edu), Cal Poly Site Investigator

Dr. Matthew Buman 602-496-8617 [mbuman@asu.edu](mailto:mbuman@asu.edu), ASU Site Investigator

If you have any questions about your rights as a subject/participant in this research, or if you feel you have been placed at risk, you can contact the Chair of the Human Subjects Institutional Review Board, through the ASU Office of Research Integrity and Assurance, at (480) 965-6788.

**Follow-up for participation in other studies**

*We'd appreciate it if you'd give your permission for us to contact you to invite you to participate in future studies.*

\_\_\_\_ You have my permission to contact me about future research studies.

\_\_\_\_ You do NOT have permission to contact me about future research studies.



## Video Recording

I consent to be audio and video recorded via Zoom video conferencing if applicable.

I DO NOT consent to be audio and video recorded via Zoom video conferencing if applicable.

By signing below, you are agreeing to be part of the study.

Participant Printed Name: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Person obtaining consent (PRINT): \_\_\_\_\_