Study Protocol Title: StandUPTV: A mobile app to reduce sedentary screen time
More recent IRB approval date: April 11, 2022

Background and Objectives

Sedentary behaviors (i.e., sitting/lying with low energy expenditure while awake) increase risk for cancer, cardiovascular disease, and mortality, particularly among those who do not engage in recommended levels of moderate-vigorous physical activity (MVPA). Sedentary screen time (SST; i.e., television viewing and/or video streaming outside of work and educational pursuits) consumes more than half of available discretionary time and is the single most prevalent use of time for Americans outside of work and sleep. SST poses far greater health risks than other sedentary pursuits, yet just two intervention studies have exclusively focused on reducing SST. Moreover, the amount and context in which SST is accrued has dramatically shifted since these studies were conducted. Adults (23-64 years of age) only spend half of their SST viewing a traditional television - the other half is spent on mobile streaming platforms (e.g., Netflix) that are likely to promote "binge-watching." There is a need for innovative approaches to reduce SST among adults that are responsive to current and emerging technologies.

The goal of this study is to develop an optimized intervention for reducing recreational sedentary screen time (SST) in adults. We will use the multiphase optimization (MOST) framework to conduct a full-factorial experimental study to simultaneously test the main effects for each of our three intervention components (LOCKOUT, TEXT, EARN) and their interactions (e.g., TEXT+EARN; LOCKOUT+EARN+TEXT) over 16 weeks.

Data Use

Data will be used for the following purposes:

- Dissertation, Thesis, Undergraduate honors project
- Publication/journal article, conferences/presentations
- Results released to agency or organization: In aggregated and summary form data will be presented back to the funder of this work, National Institutes of Health, via annual progress reports.
- Results released to participants at the request of the participant: we will provide summary data back to the participant following the completion of the study

Inclusion & Exclusion Criteria

Inclusion criteria: (1) age 23-64.9 years, (2) BMI ≥ 18.5, (3) 3+ hours per day of sedentary screen time, (4) insufficiently active as assessed by the Leisure-Time Categorical Item (see Appendix 4 – Screening survey, Leisure-time Categorical Item) (5) owns an Apple or Android smartphone or tablet, (6) have access to wireless internet at home or unlimited data plan, (7) willing to download StandUPTV smartphone application, (8) able to read/understand English, and (9) willing to be randomized.

Exclusion criteria: (1) current smoker; (2) major illness or pregnant, (3) physical activity contraindicated, (4) occupation requires media use or high amounts of physical activity 5) active drug abuse, (6) serious psychological disorder.

There will be no exclusion by sex. We will include participants without regard to race or ethnicity. Prisoners will not be included in the study because of the limitations on physical activity, access to the internet, television, smartphones/tablets and any other media. Undocumented individuals may or may not be included in the study, but no attempts will be made to verify the working credentials of study subjects, as it is unrelated to the purpose of the proposed study.

All screening questionnaires will be completed using an online screener delivered by REDCap (see Appendix 4 Screening survey) and then confirmed by telephone or video call.]

Study Protocol Title: StandUPTV: A mobile app to reduce sedentary screen time
More recent IRB approval date: April 11, 2022

Number of participants

Approximately two hundred and forty (240) participants will be enrolled, 120 in the San Luis Obispo regional area and 120 in the Phoenix Metro area. We may consider enrolling outside those geographical areas as needed depending on recruitment success.

Recruitment methods

We will include traditional methods of recruitment including flyers on campus and through local community outlets and newspaper advertisements. But we will more heavily utilize Internet-based strategies including ReseachMatch.com, social media (i.e., Facebook, Twitter) and other social networking sites. We may recruit via flyer at primary care clinics. See Appendix 5 StandUPTV Flyers.

ResearchMatch.org is a national electronic, Web-based recruitment tool that was created through the Clinical & Translational Science Awards Consortium in 2009 and is maintained at Vanderbilt University. The Vanderbilt IRB provides oversight for ResearchMatch as a recruitment tool and this has been documented within the ResearchMatch IRB Letter of Understanding (available upon request). After being granted recruitment access, researchers will be able to search for appropriate matches amongst the non-identifiable ResearchMatch volunteer profiles in the system. Researchers may enter study inclusion/exclusion criteria in the ResearchMatch Search Builder, which will yield a list of potential matches to such criteria. Researchers will send out IRB-approved content in the initial recruitment message to these potential matches (ResearchMatch volunteers) through ResearchMatch. This study's recruitment content will be inserted into the standard ResearchMatch electronic notification that informs possible matched volunteers that a researcher has identified them as a potential match for their study. The secure ResearchMatch clearinghouse will route this standard notification that includes this specific study content (see Appendix 6 – ResearchMatch recruitment email template) to each of these potential ResearchMatch volunteer matches and they will have the option of replying yes, no, or not respond through a set of quick links available in this notification. This message will not include the study's direct contact information (e.g., email, phone) as ResearchMatch will measure the response rate through the clearinghouse's quick links made available in this electronic message. These response rate metrics will be made available to researchers through their ResearchMatch dashboard as well as the Institutional Liaison dashboards. By responding yes, the volunteer has authorized ResearchMatch to release their contact information to the researcher(s) responsible for that study. This information will be made available on the researcher's ResearchMatch study dashboard.

Study Procedures

Recruiting material will refer all interested participants to a website address (i.e., link for a REDCap survey) or email and phone number to learn more about the study and determine eligibility. Participants will be asked to complete a demographic and eligibility screening questionnaire which will include informed consent language at the outset (see Appendix 4 – Screening survey, and Appendix 5 StandUPTV flyers).

Screening Visit 1 (SV1): If preliminarily eligible based on the eligibility screener, individuals will be emailed or called, depending on their contact method preference, and study staff will confirm eligibility criteria and, for eligible individuals, schedule a day and time for an intake appointment via Zoom video conference. During this intake appointment (Visit 1 – approximately 60 minutes), the participant will be fully informed about the study and will consent to participate or decline.

Device Setup (SV2):

StandUPTV kit: Participants will be mailed a technology kit that includes several devices for tracking sedentary screen time (see Device Description document) and given instructions on (a) how to download and

use the StandUPTV mobile application; (b) outfit their home with necessary streaming services; and (c) don wearable devices to be worn for seven consecutive days. They will then use this technology to track their screen time for the duration of the study. In order to remotely record the sedentary screen time of the participant and to provide feedback to the participant within the StandUPTV app, we will provide the participant with 1 Wi-Fi plug per television in the home (WeMo Insight Smart Plug), one WiFi router, and one Raspberry Pi (a small computer to record and transmit data). Participants will also be provided a Samsung Galaxy tablet with pre-loaded apps for social media and streaming. Participants will also be provided a Fitbit in this shipment; this device will be used during their study participation and they will keep this device as part of their incentive for participation. Participants will return all devices (except Fitbit) at the end of the study with the pre-paid shipping box provided to them.

Accelerometers: Both the ActivPAL and the GENEActiv will be used at 3 time points throughout the study to assess behavior over the 24-hour cycle. The activPAL™ classifies an individual's free-living activity into periods spent sitting, standing, or walking. This information can be used to estimate daily energy expenditure and changes in the free-living activity profile can be tracked against medication or treatment regimes. The activPAL™ is worn discreetly on the thigh. The GENEActiv device is worn on the non-dominant wrist and automatically tracks behaviors like sleep, physical activity and sedentary behavior. After baseline assessment week, participants will return the ActivPAL and GENEActiv in a pre-paid envelope along with their completed sleep log. Participant will retain the StandUPTV device kit for use in the study (see Appendix 12 Device Cleaning & Disinfecting Protocol).

Body Composition Measurements: Participant kits will also include a Tanita BF-679 scale and a measuring tape. During assessments (baseline, 8 weeks, and 16 weeks), participants will be asked to twice step on the Tanita scale to measure body weight and body fat % and provide values to staff via a REDCap survey that will be sent to them. After, they will be asked to use the measuring tape to measure their waist circumference (twice) and report values to staff. A zoom “clinical visit” will be scheduled in the morning with participants to provide support with body composition measurements.

All study devices will be cleaned and disinfected using the procedures in Appendix 12 – Device Cleaning & Disinfecting Protocol before and after use by participants.

Baseline week: Individuals who choose to participate in the study will be asked to complete the informed consent document, baseline survey and device agreement via REDCap (see Appendix 1 – Informed consent form), Appendix 15 – Baseline survey battery and Appendix 13 Device agreement). When they have completed this battery, they will be sent a StandUPTV device kit (see above) and they will utilize the StandUPTV device kit for all of their discretionary screen time. During this time, they will maintain their normal activity and screen time habits.

After participants have completed the baseline assessment week, they will be randomized using the multiphase optimization (MOST) framework to receive an intervention or combination of interventions according to the table below:

Study Protocol Title: StandUPTV: A mobile app to reduce sedentary screen time
More recent IRB approval date: April 11, 2022

Table C3-1. Experimental conditions for optimization trial.

Exp Condition	n	LOCKOUT	TEXT	EARN
1	30	YES	YES	YES
2	30	YES	NO	YES
3	30	YES	YES	NO
4	30	YES	NO	NO
5	30	NO	YES	YES
6	30	NO	NO	YES
7	30	NO	YES	NO
8	30	NO	NO	NO

Intervention: The StandUPTV app is a basic self-monitoring application where participants can view their daily sedentary screen time habits (minutes of streaming video services such as Netflix, YouTubeTV, and SlingTV; minutes of physical activity and sedentary time). The app also includes three additional components: (a) a sedentary screen time limiting feature (LOCKOUT) which will disable tablet and Wemo plugs once they reach a target of 50% of their baseline sedentary screen time for the week of observation has been reached; (b) app-based prompts (TEXT i.e., prompts generated through StandUPTV) that provide personalized content based upon length of most recent sedentary screen bout and time of day (see Table below for examples); (c) feedback related to physical activity and the ability to earn additional sedentary screen time through physical activity above their 50% limit (EARN), defined as 10 minutes of moderate physical activity earns 20 additional minutes of sedentary screen time, depending on baseline levels of activity. Physical activity will be monitored continuously via Fitbit.

Table C7.2.3-1. Example prompts.

SST bout length	Time of day	Prompt examples
>60 min	PM	*Break up the binge! Try taking a break from the show. You will feel more alert when you return.*
15-60 min	PM	*Let's multi-task! Stay productive with simple chores while you watch your favorite show.*
<15 min	AM	*<no prompt sent>*

Participants will be then be instructed to use the StandUPTV application at their discretion over the next 16 consecutive weeks. They will be provided a telephone/email hotline supported by our study staff to address any technical questions they may encounter during study participation and will have check in calls periodically.

Interim & Final Assessment: Assessments will take place at week 8 (interim) and week 16 (final) to once again record 7 days of accelerometry data with the ActivPAL and GENEactiv devices and to assess via behavioral questionnaires the response to intervention components (see Data Collection/Outcomes table below). Exit interviews & User burden scale will be conducted interview style when possible and will be audio and video recorded via Zoom video conferencing platform (see Appendix 7 Exit Interview & User Burden Scale).

C9-1. Data Collection/outcomes.

			Baseline	Interim	Post
Outcome	**Measure**	**Week**	**0**	**8**	**16**
Primary outcome	Sedentary screen time, min/wk (app+activPAL)		●	●	●
Proximal mediators	Barriers, outcome expectations, and self-efficacy for SST		○	○	○
	MVPA, min/wk (activPAL)		●	●	●
	24h behavioral composition (activPAL, ACT24)		●	●	●

Displacement effects/causal factors	Sleep (GENEActiv)	●	●	●
	Dietary intake (24-hr recall)	○		○
Health risk	Weight, body fat percentage, and waist circumference	●	●	●
User-experience	Application usage	●●●	●●●	●●●
	User burden			○
	Exit interviews			○

○Survey- or interviewer-administered; ⬤Device-based measure; SST = Sedentary screen time

Screen Time Surveys: Participants will be sent a sleep log each day via REDCap and asked to record information about their sleep habits and quality for the 7-day assessment periods (Appendix 8 Sleep log). They will also complete two ACT24 surveys, a mobile previous day recall (Appendix 10 ACT24 Instrument). Participants will be asked to record a screen shot of their screen time use from their phones and upload this at each time point. The purpose of this is to inform the data of any additional screen time that was consumed on their personal phones inadvertently. Each survey is expected to take between 15-30 minutes.

Compensation

Participants who complete the entire study protocol will receive up to $100.00 over the course of the study to compensate for their time and effort completing the assessments. They will get to keep the Fitbit issued to them for use in the study (~$130 value). Gift cards will be issued via the Tango website, this website will allow participants to pick from a number of different retailers. Any payments made to a single individual totaling $600 or more will be reported to the tax unit of Financial Services.

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).

Risk to participants

In-person visits were initially proposed for this study but, due to the COVID-19 pandemic, in-person visits have been eliminated. Investigators will conduct non-contact participant visits to reduce the risk of transmitting COVID-19 between study staff and participants. Devices will be cleaned and disinfected between participants.

There is a very minimal risk that a device or devices the participant is wearing may cause them discomfort such as skin irritation. They are free to remove any device if they feel that it causes them a problem. There is a small risk of psychological discomfort when answering questions of a somewhat personal nature. These risks are minimized by informing subjects that responses are voluntary and that there will be no negative consequences in withholding responses. Participants in the EARN group will be asked to increase their time in

10-minute bouts of exercise. There is some risk of muscle soreness and injury when starting to exercise. The educational materials in this group will include information on starting slowly and building up activity.

Potential direct benefits to participants

There are no direct benefits of this study. Participants may become more aware of their screen viewing habits and their activity levels by participating.

Privacy and confidentiality

The information obtained in this study will be regarded as privileged and confidential. If the results of this study are published in a scientific journal or presented at a scientific meeting, the participants name will not be used. All records, including questionnaire data, activity monitor data, and video data will be identified only with a numerical ID and names will not be used to identify data. We will record participant's name on the phone screening and record the ID number linked with your name on a document. This document will be stored in a locked file cabinet within the principal investigators' office. 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). The monitors record several variables in addition to steps. These data can be used to develop new algorithms to predict steps and we will retain them for that potential use in future studies.

Consent

Only trained individuals (CITI GCP and protocol-specific training) will conduct the informed consent process. No study procedures will start until informed consent has been obtained. The consent process will include a 30-minute introduction of the study procedures and requirements for participation as well as review of participant rights and resources for consent and the voluntary nature of study participation. Participants will be informed of their right to refuse participation at any point, without suffering negative consequences and be provided with the contact information for the study investigator at the respective sites.

This study will use an electronic consent process via REDCap, the same secure database which is being used for data collection. Research assistants will ensure consent form is complete and accurate. A copy of the signed electronic consent form will be sent to each participant for their records.

Sites or locations where the research will be conducted.

Enrollment Sites

Arizona State University and Cal Poly will each serve as recruitment/enrollment sites for the proposed research with the recruitment goal split evenly between both sites. The sites will work together to ensure processes are aligned and project efficiency is maximized. One coordinator and one graduate student (ASU) and one coordinator and one research associate will dedicate time to the recruitment, screening and assessment for StandUPTV, other graduate or undergraduate students may aid in these tasks as needed and will be added to the protocol as needed.

Communication

Meetings will take place between Cal Poly & ASU sites at least weekly to discuss study progress, address questions, troubleshoot problems, and ensure data quality. During the active data collection for this project we use email communications between both sites and the programming core at ASU after each participant to ensure any technical issues are resolved immediately. Research staff will communicate on a regular basis (i.e., daily, or as needed) and manage tasks via web-based and mobile software applications. These applications

include Zoom communications (for video-conferencing), Slack.com (for project management communication), and Monday.com (for timeline management and task distribution). Investigative teams at ASU and Cal Poly will meet at least once per year in-person for the purpose of ensuring standard training of staff at both sites and enhancing communication.

Project Management

Data collection will take place at both sites. All coding of direct observation data will take place at ASU to ensure identical coding procedures are followed. Shared folders will be used to store all study related documents; each site will be sure to have access to the most up-to-date and accurate study materials. REDCap will be used to capture study data and each site will have access to the study. A tracking system will be used to manage the logistics of participant screening, communication, visits, and follow-up.
The tracking system is a server-client system which is maintained at the Cal Poly site. The tracking system is a desktop application which communicates with the server via secure HTTPS. This allows research staff to securely monitor and track research coordination activities. This system requires a login identification and password in order to gain access to the data. Once logged in, staff have access to features that allow them to insert, edit and analyze data. This includes editing or inserting contact and medical information about participants, tracking assessment windows, writing notes from intervention visits, and running data reports