

SOCIAL BEHAVIORAL INSTRUCTIONS AND TEMPLATE

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Instructions and Notes:

- Depending on the nature of what you are doing, some sections may not be applicable to your research. If so, mark as "NA".
- When you write a protocol, keep an electronic copy. You will need a copy if it is necessary to make changes.

1 Protocol Title

Include the full protocol title: **Ecological Momentary Determinants of Sedentary Behavior**

2 Background and Objectives

Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge.

- Describe the purpose of the study.
- Describe any relevant preliminary data or case studies.
- Describe any past studies that are in conjunction to this study.

The unique attributes of sedentary behavior (SB) (e.g., ubiquitous, habitual, socially-reinforced) and its link to cardiometabolic health risk have led to several studies aimed at understanding the correlates of SB. However, these studies have primarily focused on "static" correlates (e.g., built environment, income status, educational attainment, etc.) and have largely ignored the complex situational, contextual, and dynamic "in the moment" factors that can influence SB.

The development of smart phone apps and wearable devices (e.g. Fitbit, apple watch, jawbone, etc.) within the technology industry has resulted in an increase in personal notifications to stand or move more during the workday. These prompts may vary in medium (phone, email, watch), delivery (textual, visual, sound, vibration) and content (personalized, generic, short, long, motivational, educational, feedback). However, the extent to which these prompts actually reduce SB is not fully understood.

The *overall objective* of this set of exploratory studies *is to understand the personal, behavioral, environmental, and contextual factors that underpin SB and to systematically test a series of contextual prompt characteristics that may lead to subsequent change in SB.*

The primary aims are:

Aim 1. Using Ecological Momentary Assessment (EMA), we will determine which personal (e.g. fatigue, mood, and stress level), behavioral (e.g. watching TV, working at desk, and eating meals), environmental (e.g. being at home or work, time of the day, and weather) and contextual factors are associated with SB. We will identify the combination of factors most likely to precede and proceed short (<30 min) and long (≥30 min) bouts of SB.

Aim 2. Using a micro-randomized screening experiment, we will identify efficacious behavioral strategies to produce an acute (within 5 min of receiving the prompt) reduction in SB based on three factors: (a) behavioral target (sit-to-stand vs. sit-to-light physical activities (LPA)); (b) social effects (group vs. individual); and (c) content (Target set vs. No target set). Our primary outcome will be a change from a sitting behavior to a standing behavior within 5 minutes of receiving the prompts. Furthermore, we will look at overall stand time (minutes), steps.

3 Data Use

Describe how the data will be used. Examples include:

- Dissertation, Thesis, Undergraduate honors project
- Publication/journal article, conferences/presentations
- Results released to agency or organization
- Results released to participants/parents
- Results released to employer or school
- Other (describe)

Data will be used for publications and conference presentations.

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4 Inclusion and Exclusion Criteria

Describe the criteria that define who will be included or excluded in your final study sample. If you are conducting data analysis only describe what is included in the dataset you propose to use.

Indicate specifically whether you will target or exclude each of the following special populations:

- Minors (individuals who are under the age of 18)
- Adults who are unable to consent
- Pregnant women
- Prisoners
- Native Americans
- Undocumented individuals

Inclusion criteria:

Full-time employees, males or females, ages 18-65, with sedentary working habits (as indicated by >7 hrs/day of sedentary time at work in the Sedentary Behavior Questionnaire), and are willing to engage in the study assessment and intervention for 10 weeks.

Exclusion criteria:

Non-ambulatory, pregnant, non-English speaking, diagnosis of psychiatric problems or taking psychiatric medications, and a medical history that prohibits prolonged standing.

5 Number of Participants

Indicate the total number of participants to be recruited and enrolled: 20

6 Recruitment Methods

- Describe who will be doing the recruitment of participants.
- Describe when, where, and how potential participants will be identified and recruited.
- Describe and attach materials that will be used to recruit participants (attach documents or recruitment script with the application).

Participants will be employees of the Parking and Transit Services (PTS) at ASU, recruited in person by members of the research team. We have already established contact with PTS and they have expressed their support to this project (see supplemental document for letter of support).

7 Procedures Involved

Describe all research procedures being performed, who will facilitate the procedures, and when they will be performed. Describe procedures including:

- The duration of time participants will spend in each research activity.
- The period or span of time for the collection of data, and any long term follow up.
- Surveys or questionnaires that will be administered (Attach all surveys, interview questions, scripts, data collection forms, and instructions for participants to the online application).
- Interventions and sessions (Attach supplemental materials to the online application).
- Lab procedures and tests and related instructions to participants.
- Video or audio recordings of participants.
- Previously collected data sets that that will be analyzed and identify the data source (Attach data use agreement(s) to the online application).

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This 10-week study has 2 main parts: (A) an EMA study and (B) a Screening experiment. Twenty participants will be recruited for the study.

Prior to the start of the study, participants will first have to complete an initial online screening survey to determine eligibility. All eligible participants will be requested to complete an online consent and depending on their smartphone operating system, will be sent instructions (see appendix D, E, F, and G) on how to download the smartphone apps that will be used in the study:

| Smartphone App | OS | Description |
|----------------|----------------|--|
| PACO | Android or iOS | An open-source app designed that will be used to deliver EMA questions randomly throughout a participant's workday. |
| Daynamica | Android | An app designed to collect user activity and travel data using raw smartphone accelerometer and GOS data. |
| Prox | iOS | An iOS app designed to capture real-time indoor (office) location through proximity sensors deployed around the workplace. |

Eligible and consented participants will be invited to a one-hour orientation session where they will be given detailed information about the study, along with answering any questions or concerns they may have. During this visit, proximity sensors will also be deployed to various key areas in the workplace (i.e., participant's desk, lobby, kitchen, and conference rooms).

Timeline:

| | Week | | | | | | | | | |
|-------------|--------|---|---|---|--------|---|---|---|---|----|
| | Part A | | | | Part B | | | | | |
| Measures | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| Main Survey | X | | | | | | X | | | X |
| Daily logs | X | X | X | X | | | X | X | X | X |
| EMA | X | X | X | X | | | | | | |
| Prompts | | | | | | | X | X | X | X |
| ActivPAL | X | X | X | X | | | X | X | X | X |

Throughout Parts A and B (weeks 1-10):

All participants in both part A and B will be asked to complete daily logs that will ask them of the time they went to work and got off of work the previous day, sleep time of the previous night and the time they woke up, and any work-related meetings that they had the previous day. In addition, they will be asked to complete a battery of assessment (see appendix A for list of questionnaires) at three time points in the study: at week 1, 7, and 10. Participants will also be asked to wear the activPAL device on their thigh as an objective measure of sedentary and physical activities. They will be asked to wear the device continuously throughout the study except for the interview weeks (week 5 and 6). The activPAL will be dropped off every Monday morning and picked up every Friday of the same week.

Part A (Weeks 1-4):

For part one, all eligible participants will be asked to download a mobile app, pre-programmed to collect ecological constructs. Proper instructions on how to use this app and what to expect in the following weeks will be given and any questions from the participants will be addressed (15 mins).

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Participants will receive 3 random EMAs (Appendix B) per day throughout the 4-week study. EMAs will only be sent during work hours (9AM-5PM). A total of 1200 EMA observations (3x/day x 20 work days x 20 participants) will be collected.

Part B (weeks 5-9):

Participants will be randomized to either receive or not to receive prompts every work hour (8 per day) via email, for 4 weeks. A total of 80 prompts will be sent to participants over a 4-week period during their work hours (9AM-5PM) on workdays.

8 Compensation or Credit

- Describe the amount and timing of any compensation or credit to participants.
- Identify the source of the funds to compensate participants
- Justify that the amount given to participants is reasonable.
- If participants are receiving course credit for participating in research, alternative assignments need to be put in place to avoid coercion.

For part A of the study, participants who complete the entire 4-week will receive a \$20 gift card as compensation for their time and effort. In addition, participants will receive an additional \$10 for completing at least 80% of the EMA questionnaires for that 2-week period (24 out of 30 EMAs), for up to \$20 of additional compensation for the entire 4 weeks of part A. For part B of the study, all participants who complete part B will be compensated with a \$20 gift card. Furthermore, participants will also receive feedback on their physical activity behaviors gleaned from the activPAL device.

9 Risk to Participants

List the reasonably foreseeable risks, discomforts, or inconveniences related to participation in the research. Consider physical, psychological, social, legal, and economic risks.

The proposed study presents no major risk for physical injury and does not involve any invasive procedures. However, minor complications could still potentially arise:

- Potential risks to participants include possible physical discomfort that may occur due to participation in a program focused specifically on increasing walking/reducing sitting time at the workplace, although standing/walking behaviors are totally voluntary.
- Participation in the study may cause some participant burden from the assessment questionnaires and prompts designed to reduce sedentary activity that they will be receiving multiple times per day (3/day). As these text messages will be sent randomly throughout the study period, it can cause disruption in the normal daily activities of the participants. However, these questionnaires are designed to be short (<1 min to complete) and easy to answer.
- Any collected data (demographic information, answers to questionnaires, etc.) will be at risk for divulgation. Each participant will be assigned a participant ID number immediately after enrollment. All collected data will be stored a secure ASU storage drive, which is only accessible to the researcher.

10 Potential Benefits to Participants

Realistically describe the potential benefits that individual participants may experience from taking part in the research. Indicate if there is no direct benefit. Do **not** include benefits to society or others.

While no benefits to the participants in the study can be guaranteed, it is possible that participating in the study will help the individuals to be aware of their physical activity behavior and develop strategies to decrease their sedentary behavior at the workplace.

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11 Privacy and Confidentiality

Describe the steps that will be taken to protect subjects' privacy interests. "Privacy interest" refers to a person's desire to place limits on with whom they interact or to whom they provide personal information. Click here for additional guidance on [ASU Data Storage Guidelines](#).

Describe the following measures to ensure the confidentiality of data:

- Who will have access to the data?
- Where and how data will be stored (e.g. ASU secure server, ASU cloud storage, filing cabinets, etc.)?
- How long the data will be stored?
- Describe the steps that will be taken to secure the data during storage, use, and transmission. (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data, etc.).
- If applicable, how will audio or video recordings will be managed and secured. Add the duration of time these recordings will be kept.
- If applicable, how will the consent, assent, and/or parental permission forms be secured. These forms should separate from the rest of the study data. Add the duration of time these forms will be kept.
- If applicable, describe how data will be linked or tracked (e.g. masterlist, contact list, reproducible participant ID, randomized ID, etc.).

If your study has previously collected data sets, describe who will be responsible for data security and monitoring.

All staff will have taken the required online human subjects course on this topic. In addition, this topic will be regularly addressed during weekly staff meetings where staff will be encouraged to ask questions pertaining to this issue. All participants will receive a randomly assigned research ID number. A "key" will be maintained which links the participants to the previous identification. The key will be maintained electronically (with regularly scheduled data backups), using data encryption procedures and stored on University maintained servers with electronic firewall protection. "Strong" computer passwords will be required to gain access to the key; passwords will be changed routinely. The PI and other senior level staff will have access to the key (maintained electronically). These data will be password protected.

The local smartphone data will be stored in an SQLite database, which is an industry-standard data management strategy that encrypts data and is not accessible to others.

The master list will be destroyed immediately after data are linked. The data will be de-identified. Data will be retained up to a five years after the final publication from this work and any paper files will be shredded prior to disposal. Electronic files will be deleted from all storage sites including back-up drives.

12 Consent Process

Describe the process and procedures process you will use to obtain consent. Include a description of:

- Who will be responsible for consenting participants?
- Where will the consent process take place?
- How will consent be obtained?
- If participants who do not speak English will be enrolled, describe the process to ensure that the oral and/or written information provided to those participants will be in that language. Indicate the language that will be used by those obtaining consent. Translated consent forms should be submitted after the English is approved.

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A short consent will be obtained before the individual completes the initial screening form online (see attachment) to determine eligibility for the study. Any identifying information obtained during this time will be retained only if the participant is eligible. If participant is eligible and interested, consent for further study participation will be obtained virtually through the use of Qualtrics.

During this consent process, individuals will specifically be asked to consent to allow the research team to gather location data as it is a particularly personal type of data being collected. Participants will also be asked if they have jailbroken their phone and to acknowledge, in writing that their phone is not jailbroken. If it is, participants will be informed of the added data security risks and asked to initial their consent to participate, knowing this added data security risk. Rooting or Jailbreaking involves allowing the user of the smartphone added privileges to the phone, similar to running programs as administrators in Windows. With a rooted (or jailbroken) phone you can run apps that require access to certain system settings. Note, rooting/jailbreaking a phone is a fairly lengthy process and thus, if the participant purchased the phone from a normal channel, such as from a cell phone company, and did not actively root/jailbreak their phone, then it is highly unlikely that the phone is rooted/jailbroken. Participants will also be told that they have the right to revoke access to these data any time during the research process.

13 Training

Provide the date(s) the members of the research team have completed the CITI training for human participants. This training must be taken within the last 4 years. Additional information can be found at: [Training](#).

CITI Training:

- Matthew Buman completed on 09/25/13
- Meynard John Toledo completed on 07/26/13
- Sarah Mullane completed on 04/09/13
- Eric Hekler completed on 09/29/2011
- Sayali Phatak completed on 50/27/2014
- Elizabeth Korinek completed on 04/17/2015
- Kirti Das completed on 02/24/15