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: DIY Self-Experimentation Study

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.

Background: The quality of sleep is an essential factor that affects individual's physical vitality, emotional balance, and productivity, and it is affected by various lifestyles including time to go to bed, dietary, physical activity in daytime, and so on. Thus, people who have sleep problems are encouraged to make healthy changes. However, it is often difficult for them to establish new habits or eliminate old bad habits; novel, transdisciplinary, multi-component solutions are likely need to help improve sleep quality.

Purpose: Our research team envisions that people can achieve better result in improving their behavioral issues, with use of technology-augmented solutions, more specifically, sensor-based responsive systems (Appendix E- System Description), created by themselves based on understanding on behavior change theories. The aim of the current protocol is to validate our assumption with a population in need of building good sleep habits for better sleep quality.

Project Aims: To test if a sensor-based responsive system that is augmented with lessons about behavior change can result in significant improvements in sleep compared to either a sleep-tracking control condition or the behavior change teaching strategy. The study compares three conditions:

Condition 1 (Control): Default intervention (Monitoring sleep behavior, Learning about sleep hygiene)
Condition 2: Default intervention + Lessons about behavior change techniques
Condition 3: Default intervention + Lessons about behavior change techniques + Technological solutions.

3 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:
- Men & Women ages 18 years and older
- Able to understand English sufficiently to provide informed consent
- Willing to wear a monitoring device (ie. a Jawbone UP MOVE)
- Currently uses a smartphone (Android or iPhone mobile)
- Willing to allow devices to be placed in their home
- Currently has an Internet connection at home
- Willing to complete all assessments
- Willing to learn basic technology usage skills

Exclusion Criteria:
- Travel plans over the following 7 weeks
- Pregnant women
- Have a diagnosed seizure disorder

- Have an unmanaged sleep disorder other than insomnia, previously diagnosed not currently being treated (nightmares associated with PTSD are deemed acceptable)
-Have unmanaged sleep apnea
-Actively engaged or have plans to engage in a physical activity, sedentary behavior, sleep, or diet behavior change program in the next 7 weeks

4 Number of Participant

Indicate the total number of participants to be recruited and enrolled: 100

5 Recruitment Methods

- Describe when, where, and how potential participants will be identified and recruited.
- Describe materials that will be used to recruit participants. (Attach copies of these documents with the application.)

Participants will be recruited using posted flyers, social media posts (i.e., Twitter, Facebook), social networking sites, and online support groups (i.e., listserv emails), and word of mouth. (Appendix B- Recruitment Text). The survey link included on the flyer will be used to 1) allow participants to sign up for the study online, and 2) assess potential participants for eligibility online. (Appendix C- Screening Questionnaire)

6 Procedures Involved

Describe all research procedures being performed and when they are performed. Describe procedures including:

- Surveys or questionnaires that will be administered. (Attach all surveys, interview questions, scripts, data collection forms, and instructions for participants.)
- What data will be collected including long-term follow-up?
- Lab procedure and tests and related instructions to participants
- The period of time for the collection of data.
- Describe the amount and timing of any compensation or credit to participants.
- If the research involves conducting data analysis only, describe the data that that will be analyzed.

Recruitment: We will post recruitment flyers around the ASU campuses (Tempe, Downtown), and community sites (grocery shops, hospitals, etc.), and distribute via Internet mailing lists to ASU schools/departments, particularly to faculty and staff as our focus is on community members, not necessarily students. Interested participants will be asked to answer an online pre-screening survey that includes questions to check if they eligibility requirements listed above. Recruiting material will refer all interested participants to a website address (i.e., bitly link for a Qualtrics survey) or email and phone number to learn more about the study and determine eligibility.

Assigned to a condition: If deemed eligible, individuals are assigned to one of the three conditions randomly. Full informed consent will be obtained in-person during Session 1.

Study Timeline:

Study participation will last 7 weeks after initial enrollment and consent. The participant will attend 5 individual in-person sessions held on the ASU campuses (Tempe, Downtown) for condition 1 and 2 and with a few sessions held in person at the person's home (condition 3) during the study. Session 1 (Week 0) will last approximately 30 minutes for all conditions. Sessions 2 (week 1), 3 (week 3), and 4 (week 5) will last 15 minutes for condition 1 and 60 minutes for conditions 2 and 3. Session 5 (week 7) will last approximately 30 minutes for all conditions.

Session Process:

Session 1 (Appendix G1- Session1)

- Participants of all conditions will complete a survey (Appendix H1- Session1 Sleep)
- Participants of all conditions will be given specific instructions for use of two sleep-monitoring tools -- a Fitbit activity and sleep monitor and 'PACO', a mobile phone application for self-reporting that is available for both iOS and Android (Appendix D– Self Monitoring Tools). Participants will be provided instructions on how to download and install the Paco App on their phones. All participants will be asked to wear the Fitbit device 24 hours a day, except during showers and when the device needs charging and also asked to record their sleep using the Paco application (once a day, takes less than one minute) starting on day one until the end of the study (Appendix D- Self Monitoring Tools).
- Participants complete the post session survey (Appendix H2- Session 1 post)

Session 2

- Participants of all conditions will complete two surveys (Appendix H3- Session2 Sleep, Appendix H4- Session2 LastWeek).
- Participants of all conditions will be given sleep hygiene information, and complete a quiz to test their understanding on the given information (Appendix F- Sleep Hygiene material). Then, each condition will follow different steps as below.

- Condition 1 participants will be encouraged to practice any recommendations that they may have found useful in the given sleep hygiene information, or they are already aware of, until Session 3 (Appendix G2- Session2 C1 Control).
- Condition 2 participants will be asked to set a specific goal (e.g., "Go to bed 11pm"), learn about four behavior change techniques (e.g., a behavior change technique, "Reward yourself"), and think of ways to apply them to their goal pursuit (e.g., "If I meet the goal during the weekdays, have a piece of chocolate on Friday night"). They will be encouraged to pursue goals they set with ways they will come up with, until Session 3 (Appendix G3- Session2 C2 Design, Appendix J- Behavior Change Techniques).
- Condition 3 participants do all of the activities in condition 2 and also be presented with the technology via the use of system examples. The purpose is to help them generate system ideas, which will then be implemented within their homes by the research staff (see below). Participants will be asked to pursue the goals they set using the systems they designed. (Appendix G4- Session2 C3 Full, Appendix J- Behavior Change Techniques, Appendix I- Video scenes)
- Participants of Condition 2 and 3 complete the post-session survey of each condition (Appendix H5- Session2 post C2, Appendix H6- Session2 post C3).

System installation at participant's home (Condition 3)

- For installation of developed systems, a trained project staff will visit the participants of Condition 3 in their home in two or three days after Session 2. Upon consent we will plug in a laptop, attach sensors with agreement of participants, and plug in routers and speakers. To connect the routers to the laptop, the laptop will be connected to the participants home wifi network. (NOTE: If a passcode is required, it will not be readable to the researcher and will be deleted at the completion of the study).The installation will take approximately an hour. Additional visits will also occur after Session 3 and 4 to re-configure the existing systems according to participants' modification (refer to description on Session 3 and 4 below).

Session 3 and 4

- Participants will complete the pre-session survey of each condition (Appendix H7- Session3 LastWeek C1, Appendix H8- Session3 LastWeek C2C3), and a survey common to all conditions (Appendix H3- Session 2 Sleep).
- Condition 1 participants will be asked to think about their past two-week experience, and to come up with plans for the following two weeks related to sleep without any additional help beyond the sleep hygiene and tracking already provided in session 2.
- Condition 2 participants will be asked to recall the past two-week experience. If they find it necessary, participants will have the option to modify their goals set in the previous session. Participants will also be taught a theoretical model to help provide a strategy to self-diagnosis the nature of the problem that might be impacting their ability to achieve their sleep goals. Based on the participant's self-diagnosis, additional behavior change techniques will be provided that are appropriate for the domain of the problem (e.g., a motivational problem, ability problem, opportunity problem, or trigger problem). After these new techniques are taught, participants will be asked to generate ideas on how to apply them to their situation. Then, participants will revise their plans by merging the newly-generated ideas into the previous plans, and shape their final plans that will be carried out over the next two weeks. (Appendix G5- Session3 C2 Design, Appendix J- Behavior Change Techniques)
- Condition 3 participants will engage in the same tasks as condition 2 but with a focus on creating new iterations of the system. To facilitate modifications to the system, participants will be provided not only the theoretical model but also additional concrete system examples that they could feasibly implement within their homes. Participants will be asked to revise the design of the previous system into a new system that they will perceive as more supportive of their personal goals. (Appendix G6- Session3 C3 Full, Appendix J- Behavior Change Techniques, Appendix K- System Examples)
- Participants of Condition 2 and 3 complete the post-session survey of each condition (Appendix H5- Session2 post C2, Appendix H6- Session2 post C3).

Session 5

- Participants will complete the pre-session survey of each condition (Appendix H7- Session3 LastWeek C1, Appendix H8- Session3 LastWeek C2C3), and a survey common to all conditions (Appendix H3- Session 2 Sleep).

All sessions are video recorded upon participants' consent. The video recording is described in the consent form, asking participants' agreement (Appendix A- Informed Consent)

Compensation: The Fitbit devices used during the study will be given to participants at the end of the study (Session 5).

Data collection:
We collect (1) Video records of participants' performance in sessions, (2) Survey responses, (3) Fitbit activity and sleep data, (4) PACO self-report data. We anticipate data collection to commence early March 2015 and conclude by October 2015. Data analysis will be ongoing during 2016.

7 Risks to Participants

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

There are no foreseeable risks or discomforts to participation in this study.

8 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.

Participants will receive a Fitbit device designed to help them improve their activity, sedentary, and sleep behaviors. As a result, participants may be able to develop strategies from using the device to improve and maintain their physical activity participation and sleep quality. Additionally, the participants will receive informational feedback on their behaviors.

9 Prior Approvals

Describe any approvals – other than the IRB - that will be obtained prior to commencing the research. (e.g., school, external site, or funding agency approval.)

No prior approvals.

10 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.

Describe the following measures to ensure the confidentiality of data:

- Where and how data will be stored?
- How long the data will be stored?
- Who will have access to the data?
- Describe the steps that will be taken to secure the data (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data) during storage, use, and transmission.

All participant data will be collected on password protected computers. Confidentiality will be protected by using study ID numbers instead of participant names. Electronic data will be collected using a password protected computer and data will be stored on an ASU firewall server.

All data will be kept in locked filing cabinets (for paper records) or on password-protected computers in password-protected files in the PI's locked office building. Only authorized research personnel listed on this IRB application with access to the locked filing cabinets, and with permissions to access the password-protected computers and files, will have access to the data. All data captured through the smartphone will be collected in a de-identified manner and sent directly to ASU servers. Electronic data files will be stored on a secured server that is password-protected and regularly backed up by IT services. Only research staff names on this protocol will have access to these data. For those persons who do not meet eligibility criteria, only non-identifiable information is created. The data will be stored until three years after the last publication of the scientific work.

11 Consent Process

Indicate the process you will use to obtain consent. Include a description of:

- Where will the consent process take place
- How will consent be obtained

Non-English Speaking Participants

- Indicate what language(s) other than English are understood by prospective participants or representatives.
- 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.

Waiver or Alteration of Consent Process (written consent will not be obtained, required information will not be disclosed, or the research involves deception)

- Review the "CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)" to ensure you have provided sufficient information for the IRB to make these determinations.

Participants who are minors (individuals who are under 18)

- Describe the criteria that will be used to determine whether a prospective participant has not attained the legal age for consent to treatments or procedures involved in the research under the applicable law of the jurisdiction in which the research will be conducted.

Participants who express interest in the study will be invited to participate in the web-based screener. If eligibility is determined, they will be invited to session one and participate in a full informed consent process. A trained research assistant will verbally explain all the study procedures to the participant. Participants will be informed of their right to refuse to participate and that there will be no negative consequences if they decide not to participate. All participants will receive a written copy of the informed consent. Participants will be given the opportunity to ask questions and receive clarifications about any aspect of the study prior to signing the consent (Appendix A Informed Consent).

12 Process to Document Consent in Writing

If your research presents no more than minimal risk of harm to participants and involves no procedures for which written documentation of consent is normally required outside of the research context, the IRB will consider a waiver of the requirement to obtain written documentation of consent.

(If you will document consent in writing, attach a consent document. If you will obtain consent, but not document consent in writing, attach the short form consent template or describe the procedure for obtaining and documenting consent orally.)

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 3 years. Additional information can be found at: http://researchintegrity.asu.edu/training/humans