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: Just in Time Adaptive mHealth Intervention -Trial

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.

Smartphones and wearable/ubiquitous sensors, such as physical activity monitors, have the potential to help individuals improve their lives through behavior change by monitoring a person and then using that information to provide the most appropriate customized interventions exactly when and where it would be most beneficial for that person. While these mHealth technologies have this capacity in theory, in practice the models and decision rules required to determine exactly when, where, and how to intervene do not exist. *The goal of this project is to create a mathematical model that will provide the insights for making decisions about when, where, and how a "just in time" adaptive mHealth physical activity intervention (JITAI) should intervene.*

Creating this dynamical behavioral model is a challenging problem that requires insights from different disciplines, behavioral science and control systems engineering in particular. Behavioral science provides insights regarding what to measure, and behavioral intervention strategies that could be used dynamically; however, current behavioral theories fail to provide any real insights on when, where, and how to intervene at the opportune moment. Control systems engineering provides a methodology for creating dynamic mathematical models and decision-making, but this methodology has only sparsely been applied in a human behavioral context. A key first step for developing a dynamical behavioral model is to gather "informative" empirical data to estimate the model. During this project, we will conduct a system identification "informative" experiment within a human context that builds on lessons from behavioral science about experimental designs and that takes full advantage of the temporally rich data available from mHealth technologies. We will use these data to develop a fundamental yet empirically-supported dynamical behavioral model for understanding steps per day as our target behavior based on our previous experience with physical activity for mHealth interventions,(Adams et al., 2013; Buman et al., 2011; Hekler, Castro, Buman, & King, 2012; King, Castro, et al., 2013; King, Hekler, Castro, et al., 2013; King, Hekler, Grieco, et al., 2013; McMahon, Vankipuram, Hekler, & Fleury, 2013, Online First) dynamical simulation models,(Martin et al., 2014; Riley et al., 2013) and system identification (ID) analyses.(Hekler et al., 2013) This work will support the next step in model development, namely, the design of an optimized experiment that could experimentally evaluate if the "decision rules" generated in the informative experiment are actually useful. If they do prove useful, this would provide a solid empirical foundation for an optimized JITAI.

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) - exclude
- Adults who are unable to consent - exclude
- Pregnant women - exclude
- Prisoners - exclude
- Native Americans - exclude
- Undocumented individuals - exclude

Inclusion criteria will be:

1. Inactive (engaging in less than 1000 metabolic equivalent of task (MET)-minutes/week reported on the International Physical Activity

Questionnaire);
2. Aged 40 -65 years
3. Own an Android smartphone that can connect to a Fitbit Zip via Bluetooth 4.0
4. Willing to engage with the mHealth intervention for 12 weeks.

Exclusion Criteria:
1. Not proficient in English, pregnant
2. If they indicate medical problems that preclude physical active based on the Physical Activity Readiness Questionnaire (PAR-Q),
3. Have a BMI above 45
4. Currently participating in a commercial or research-related diet or exercise program

4 Number of Participant

I 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 the general public who will be recruited through community advertising techniques (e.g., emails to student listservs, word-of-mouth, social media advertisements).

6 Procedures Involved

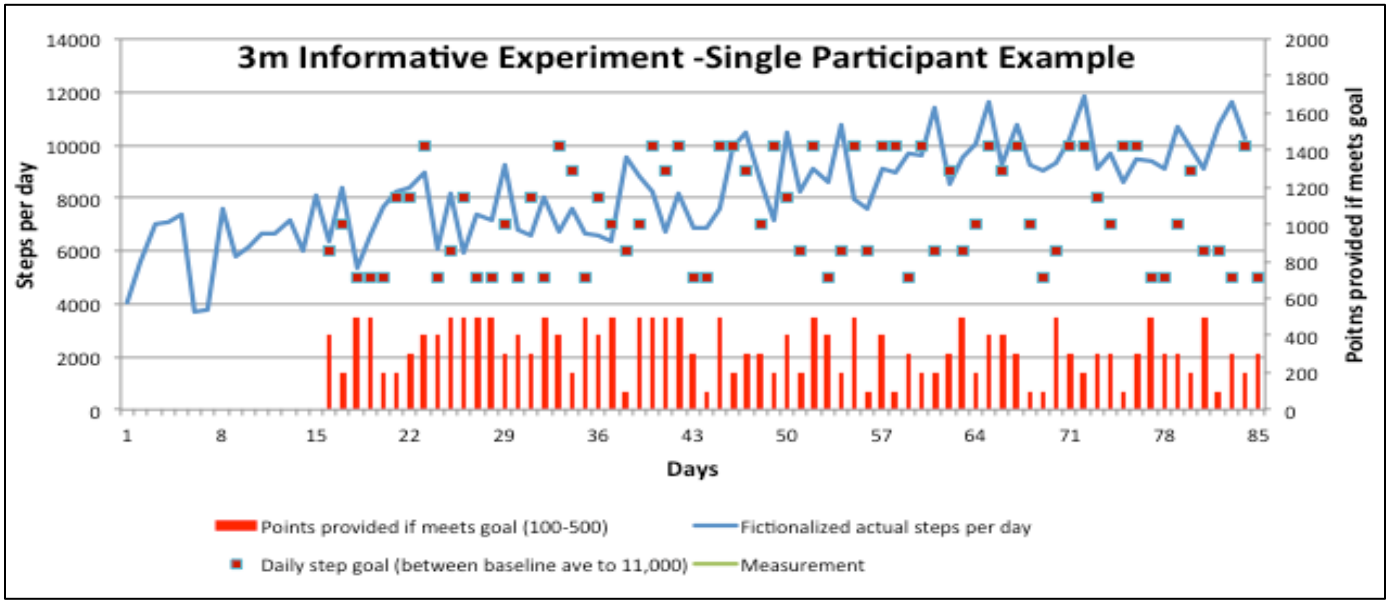
Describe all research procedures being performed and when they are performed. Describe procedures including:

- 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.

Experimental Design:

As we are interested in delineating decision rules on when, where, and how to intervene, our experimental design will use a within-person/idiographic randomization strategy. An illustrative example of what this type of study might look like, including fictional data on a hypothesized response of a participant is presented in Figure 1. On any given day, we will randomly assign a feasible step goal (i.e., between each person's baseline median steps to a max of double a person's baseline median steps) and different points (i.e., between 100 to 500 points). As this is an idiographic study design, each individual will receive a different experimental design based on control systems methods of pseudo-randomization to support orthogonal (i.e., statistically independent) delivery of intervention components and to allow for control of ordering effects across participants. To further provide an estimate of the unique impact of step goals without reinforcement, we will stagger the introduction of reinforcement by one week. As our final design will require the use of previous data to create step goals, we will have a 2-week baseline phase of measurement only.

Figure 1. 3m Informative Experiment – Illustrative Example of Single Participant



Since this is a first-generation study, it is difficult to determine how many observations will be required to create a good dynamical behavioral model. Indeed, establishing some strategies for determining the appropriate number of observations (i.e., number participants X number of observations to be anticipated per participant) could be explored in more detail via simulation studies, after a dynamical behavioral model based on an informative experiment is created. Since we do not have a dynamical behavioral model based on an informative experiment, we must rely on previous work to provide an estimate. We know of only two empirically-supported health behavior-focused system ID studies utilizing secondary data analyses, both conducted by our team. In one study, we achieved a relatively steady dynamical model for physical activity among a group of only 10 with daily measurement followed for 4 months (i.e., 1,120 potential observations)(Hekler et al., 2013) and in a second we found stable patterns in a sample of 100 followed for only 6 weeks, measured weekly (i.e., 600 potential observations).(Rivera et al., 2011) As both of these utilized secondary data that was not originally designed to support system ID and based on our interest in having individuals utilize the system for 14 weeks with daily measurement, a sample of up to 100 participants (i.e., 9,800 potential observations) should be more than sufficient to generate a preliminary dynamical behavioral model.

The two intervention strategies to be used will now be described in more detail. Goal-setting is a pivotal behavioral strategy that is utilized in many research- and non-research-based behavioral interventions. Based on the central role of goal-setting, a pivotal first decision a JITAI would likely need to make is to determine what an "appropriate" goal should be. To examine this, we will randomize the recommended daily step goal each day pulling from a reasonable range for each person (i.e., baseline median of steps to double the baseline median of steps). Based on our previous work,(Adams et al., 2013) a simple intervention that provides only adaptive step goals and positive reinforcement can influence steps.

The second intervention we would like to better understand is the amount of points to give after achieving a step goal. We will build on our previous work(Adams et al., 2013; King, Hekler, Grieco, et al., 2013) and general research on token economies(Fisher, Piazza, & Roane, 2011) (e.g., the mechanism whereby tokens/points are traded in for rewards such as gift cards) as the reinforcement mechanism. We will utilize points as a reinforcer that could be delivered contingent upon reaching the daily step goal that can then be traded in for self-chosen rewards (e.g., gift cards or donations). Much previous research suggests the importance of using a continuous-reinforcement schedule (i.e., contingently providing a reinforcer [points] when a behavioral goal is met) when initiating a behavior.(Ferster, 2002; Hanley & Tiger, 2011) As such, we will use continuous reinforcement in this small pilot only. Related to the reward gift cards, all individuals will be eligible to receive up to $100 worth of gift cards but these rewards will be delivered contingent upon meeting the step goal for that day.

Data to be collected:

Data from the Fitbit Zip – steps. The Fitbit Zip is a clip-on physical activity-monitoring device that tracks the number of steps taken. This activity monitor can provide data wirelessly to a phone via Bluetooth technology. Steps, as determined by the Fitbit Zip, will be the primary outcome measure for the study.

Phone-sensor based data- Geo-tagged location data based on phone GPS, number of phone calls (note, content will not be recorded only number of calls and length of calls), text messages (time and number of messages only), meeting schedule (i.e., busy or not) from shared calendar and smartphone application usage (i.e., documentation of time and duration of use of key apps, including the research apps and the use of the Fitbit app). These data are being gathered to support the development of a robust dynamical behavioral model. It is feasible that location, social interactions (as measured via number of phone calls, text messages, and length of calls, and social media discussed next), busyness (as measured via the calendar), and the use of other smartphone apps (particularly other health-related apps including the Fitbit app itself), might all impact a person's walking throughout the day to some degree. For example, a person may be more open to receiving a message about walking when at home compared to at work. A person's steps might also be impacted by interactions with others because these others may provide improved social support for walking via phone calls, text messages, or social media (discussed next), thus reducing the need for the smartphone app to intervene. Finally, it is plausible that other smartphone apps, particularly the use of other health-related apps such as the Fitbit app (which is required to be downloaded as it connects with the Fitbit Zip for gathering data), may impact daily walking. Based on the possibility of these factors influencing walking, in this early-stage study, the goal is to gather the data now to explore if these variables significantly contribute to an improved model for determining exactly when, where, and how to intervene at the opportune moment.

Survey Data: Daily and weekly surveys delivered on the phone (see attachment); baseline psychosocial battery of questions (see attachment); and a pre-study online screening survey (see attachment); and a follow-up survey questionnaire including a semi-structured interview about response to the study (see attachment).

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.

Potential risks to participants include possible physical discomfort that may occur due to participation in a program focused specifically on increasing steps. This could include the possibility of physical injury due to increased activity. This risk will be mitigated by having all participants fill out the physical activity readiness questionnaire as an initial screening devise. If individuals fail the readiness questionnaire, they will not be eligible for this study. Beyond this, the other major potential risks are possible breaches of privacy and confidentiality based on some of the personal data being collected within this study. Strategies to mitigate these risks are described in greater detail below but, in brief, encrypting all data, storing highly personal data such as location information in a separate file from all other data in a separate server location with higher firewall protection, and full disclosure and right to refuse the continued collection of these data.

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.

While not benefits to individuals participating in the study can be guaranteed, it is possible that participating in this study will help individuals to increase their overall level of steps per day. This could result in improved health via increased physical activity.

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.)

None.

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 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. Any electronic transmission of data, if required, will be encrypted through the use of 256-bit SSL or other industry acceptable methods. Wireless communication will be encrypted using Wi-Fi Protected Access (WPA), VPN, or 256-bit SSL.

More specifically, since this study utilizes a smartphone as the intervention and to gather data, data will reside on the smartphone, remotely on our central host system, and in flight in the communication between them. Specific methods used to protect data for each location are listed separately below.

Smartphone
1. 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 unless the phone has been "rooted", which is a strategy whereby all aspects of a smartphone are opened and unlocked for a more customizable experience. Rooting is a highly technical task that the vast majority of smartphone users do not do, thus it is unlikely that our participants will have "rooted" phones. All participants will be asked if their phone is rooted and if they do, during the consent process, individuals will be warned of the potential data compromise that this rooting presents and be asked to explicitly acknowledge that they are OK with this added data risk.
2. A second strategy whereby an individual's data can be compromised from a smartphone occurs when a smartphone app includes a local export function. This function allows for external entities to potentially utilize that function to glean protected data. To ensure this does not happen, no export function will be included in our system.
3. The smartphone app has functions that display participant data as part of the intervention such as progress, status and history displays, and screenshots could potentially create copies of this data that would be readily accessible. To protect these data, during the orientation process, all participants will be asked to establish a lock (dot pattern, facial recognition, password or other) be activated on their phone, which will ensure the data cannot be gleaned this way either.

Central Server System
1. The central server system is managed by Servers On Demand, who ensure that the servers are secure by applying patches and managing edge routing, thus ensuring continuous, industry-standard data protection standards are being applied as needed.
2. The central server system is a two-tiered system comprised of a web tier and an application tier. Data is stored on the application tier server in a MySQL database. The servers are fire-walled such that external access to the database is limited to the web servers in the web tier. This separated strategy adds a further layer of data protection as gaining access to the system would require breaching two separate firewalls with separate encryption and password protections.
3. Remote access to the servers is controlled by the ASURITE domain control system, and the list of authorized users is limited to UTO personnel and Kevin Hollingshead, the School of Nutrition and Health Promotion programming core lead programmer.
4. All personal identifying information will be stored as a separate, password-protected and encrypted file that can only be linked via the participant ID to the rest of the research data. This personal identifying information will also include all location data gathered via GPS from the smartphone. This removal of the location data from the rest of the research data ensures a high degree of safety and control over this highly personal identifying information and also allows a higher degree of control over these data as it can be separately deleted if required (e.g., if a person does not allow for location data to be gathered).

In Flight
1. When data is uploaded to the host it is sent via SSL using 256-bit encryption (TBC).
2. When data is downloaded, automatic authentication will be performed to ensure that the requestor is a valid participant in the study.

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.

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.

Consent will be obtained virtually using an online survey tool (Qualtrics, see attachment). Consent will be obtained after a person fills out an initial screening form online (see attachment) only to determine initial eligibility. The online pre-screening survey will not require the same level of consent as other parts of the research as it will be used inly to determine if individual is eligible. Identifying information will only be gathered during the pre-screening survey if a person is found to be eligible and will only be used to contact the individual for the informed consent process. Prior to the informed consent process, further details of the study will be given to the individuals through a telephone conversation, where the pros and cons of participating in the study will also be described. The online consent form will also include detailed information about the study, timeline, and review of the participant rights and resources for consent. In the consent process, participants will be asked to individually consent to allow the research team to gather location data and calendar data, as they are a particularly personal type of data being collected. Participants will also be asked if they have rooted their phone and to acknowledge, in writing that their phone is not rooted. If it is rooted, participants will be informed of the added data security risks and asked to initial their consent to participate, knowing this added data security risk. Participants will also be told that they have the right to revoke access to these data any time during the research process.

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