HeartSteps: A Case Study in Trial Design and Evaluation of Mobile Health Interventions

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Abstract

The use and development of mobile interventions are experiencing rapid growth. In just-in-time adaptive interventions (JITAIs), interventions are provided via a mobile device and are intended to help an individual make healthy decisions in the moment. A micro-randomized trial is a trial design which can be used to evaluate the effectiveness of mobile interventions. Due to a mobile device's ability to collect data in real time, the data provided from a micro-randomized trial are typically large and complex. In this poster, we provide an overview of HeartSteps, one of the first micro-randomized trials ever to be implemented. In the HeartSteps trial, the goal of the mobile intervention is to increase physical activity of adults throughout the day. We describe the aims of the trial, the trial design, and the data collection process. We also describe the analysis of this complex data and summarize the interesting results found from the trial.

An Overview of HeartSteps

Description of the HeartSteps application

The HeartSteps application is composed of two time-varying interventions. First, the evening planning intervention: every evening, each user may be prompted to develop a plan for the following day's physical activity. The second intervention consists of in-the-moment activity suggestions tailored to the person's current context. The app can deliver these suggestions at any of five time intervals during the day, which correspond roughly to morning commute, mid-day, mid-afternoon, evening commute, and post-dinner times. When a suggestion is delivered, the user's phone plays a notification sound, vibrates and lights up, and the suggestion is displayed on the lock screen of the phone. These suggestions encourage physical activity in the current context and are intended to have an effect (getting a person to walk) within the next 30 minutes.

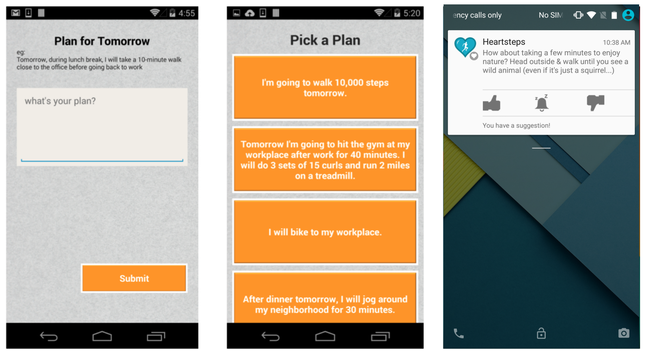

Figure 1: Examples of HeartSteps displays

Micro-randomized Trials

To evaluate the effectiveness of the application and understand which situations are best for intervention delivery, we ran a micro-randomized trial. In a micro-randomized trial, interventions are sequentially randomized throughout the conduct of the study, with the result that each participant may be randomized at hundreds or thousands of decision points. At any decision point, intervention options may correspond to whether or not an intervention is provided; for example in HeartSteps, whether or not the individual is provided a tailored activity suggestion.

This repeated randomization of interventions under investigation in a micro-randomized trial enables causal modeling of each intervention's time-varying proximal effect as well as modeling of time-varying effect moderation. Thus, the micro-randomized trial can be seen as a first experimental step in the development of effective mobile interventions that are composed of sequences of interventions.

Data collection within the HeartSteps Trial To pilot the interventions in HeartSteps, a 42-day micro-randomized trial was conducted with 37 participants. At five occasions per day, each participant received an activity suggestion with probability 0.6. Suggestion messages were not delivered if the participant's phone indicated they were currently driving, walking, or without network connectivity. Every evening, participants were also randomized, with probability 0.5, to receive a planning intervention.

Data were collected via sensors and participant self report. Each participant was provided a Jawbone wristband which collects daily step count. Furthermore sensors on the phone also collected contextual information at each decision point, including the participant's location, weather, and currently used phone application. Each evening, participants answered questions regarding the usefulness of the momentary suggestions and how hectic/stressful their day was. Figure 2 displays the daily step count for three of the participants. When a participant was sedentary the Jawbone step count is missing; we set these missing values to zero for the analyses.

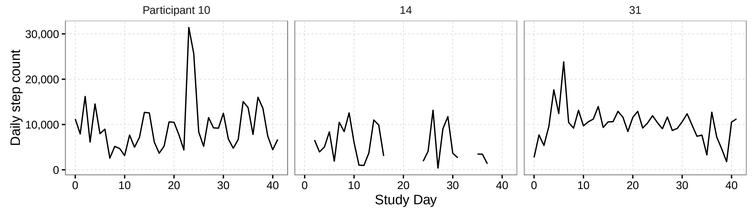

Figure 2: Daily step counts for three participants in HeartSteps.

Initial Analysis of HeartSteps

The primary analysis concerned the effect of an activity suggestion message on the participant's step count during the next 30 minutes. All analyses excluded decision points when the participant was unavailable (driving, walking, or without network connectivity), and step counts were transformed to a logarithmic scale. Controlling only for the prior 30-minute log step count, the estimate for the marginal effect of the activity message on the log step count was 0.13 (SE $= 0.067$, $P = 0.06$). This corresponds to an increase of about 33 steps in the next 30 minutes. Changes in this effect over time were explored using an interaction term between the suggestion message and the study day (see Figure 3).

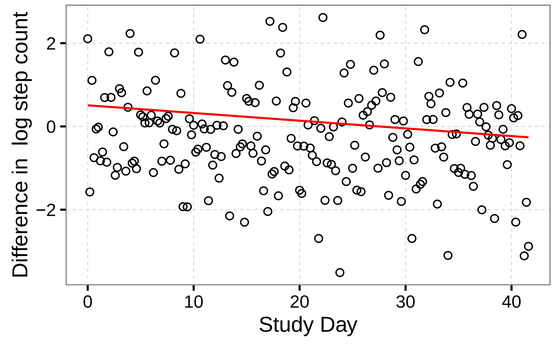

Figure 3: Sample mean difference in log step count at each decision point between participants who received an activity message and participants who did not. The line represents the estimated effect of the activity message moderated by a linear effect of the study day. The estimated intercept and slope for this moderated treatment effect are 0.507 (SE $= 0.151$, $P = 0.002$) and -0.018 (SE $= 0.006$, $P = 0.004$), respectively. Putting this in context, for the first day in the study, providing a suggestion increases the step count about 170 steps in the next 30 minutes. However, for the 20th day in the study, providing a suggestion increases the step count about 40 steps.

User Context and Suggestion Effectiveness

We wish to see if a participant's context (e.g. location, time of day) changes the efficacy of an activity suggestion. Participant location was determined using GPS coordinates and was classified as either Home, Work, or Other. The time of day variable has five levels (Morning, Lunch, Afternoon, Evening, and Dinner) corresponding to the five decisions times each day. The data did not provide evidence that the participant's location altered the effectiveness of a suggestion message. In addition, there is no significant difference in step counts depending on the time of day we sent the suggestion messages.

Participant Engagement

Each time participants were provided an activity suggestion, they had the opportunity to rate the suggestion. The participant could either rate the suggestion with a thumbs up, a thumbs down, snooze the suggestion, or do nothing (see panel 3 of Figure 1). We analyze the relationship between next 30-minute log step count and participant suggestion rating, controlling for prior 30-minute step count. The results are:

Suggestion Response	Thumbs Up	Thumbs Down	No Response
Average Next 30-minute Log Step Count	3.29	2.72	2.33

We see that the average number of steps is largest following a thumbs up response. We also see that the number of steps following a thumbs down response is still larger, on average, than the number of steps following a non-response. The analyses excluded decision point where the response to a suggestion was missing (22% of responses) or snoozed (1% of responses). Also, note these relationships are correlational (i.e. non-causal).

Analysis of Daily Planning Intervention

Every evening, with a randomization probability of 0.5, each participant may be asked to make an activity plan for the next day. The question asks the participant either to choose among several activity options (structured planning) or to freely type in the plan (unstructured planning) for the following day.

We drew several interesting results regarding the daily planning intervention. The data indicates that there is a causal effect of planning the next day's activity on the following day's step count. This effect is mostly due to the unstructured planning interventions. The estimated treatment effect of an unstructured planning intervention on the next day's square root transformed step count is 3.1 (SE $= 1.6$, $P = 0.07$). In addition, the step count increase occurs primarily on weekdays. On average, during a weekday, an unstructured planning intervention increases the subsequent day's step count by approximately 780 steps.

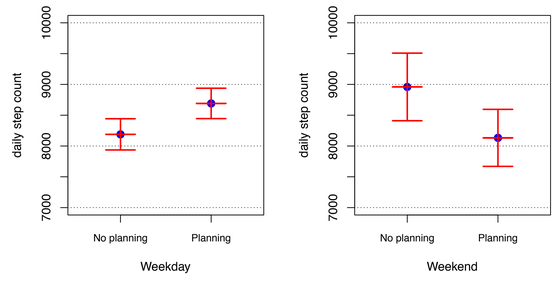

Figure 4: The figure shows the average daily step count values (plus/minus one standard error) of participants who received the planning message the previous day and those who did not. The left plot is the average over weekdays and the right plot is over weekend days.

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References: Liao, P., Klasnja, P., Tewari, A., and Murphy, S. A. (2016) Sample size calculations for micro-randomized trials in mHealth. Statist. Med., 35: 1944 1971. doi: 10.1002/sim.6847.