This study will help to optimize the development of HeartSteps — a mobile health application for helping heart disease patients maintain physical activity after graduating from Phase II cardiac rehabilitation programs.

Micro-randomized Trial Protocols for Intervention Components in HeartSteps 2.0

Xiaolei Wang1; Shawna N. Smith, PhD2; Susan A. Murphy, PhD1,3; Predrag Klasnja, PhD2

1University of Michigan Department of Statistics, 2UM School of Information, 3UM Institute of Social Research

Background for the HeartSteps Study

- Heart disease leads to more than 600,000 deaths in the US annually1.
- Phase II cardiac rehabilitation (CR) programs are beneficial for patients recovering from a heart attack or heart surgery. However, fewer than half of patients maintain CR behavior changes after graduation.
- Mobile health applications offer an accessible platform to deliver sophisticated physical activity interventions to CR graduates. However, few interventions are optimized to adapt to individuals’ needs and circumstances, especially in the longer term.

Micro-randomized trials (MRTs), which randomize participants at multiple decision points to either receive treatment or not, provide one avenue for evaluating the effectiveness of individual intervention components.

HeartSteps 2.0 Overview and Objective

- A 12-week trial which will enroll 60 participants in their last 4 weeks of CR.
- Participants will wear a FitBit Charge 2 activity tracker to record step count and use the HeartSteps app on iPhone to receive intervention suggestions.
- Qualitative and survey data will be collected both at the beginning and at the end of the trial.

Micro-randomized Intervention Components

<table>
<thead>
<tr>
<th>Intervention Components</th>
<th>Intra-daily Intervention Components</th>
<th>Daily Intervention Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Activity Suggestions</td>
<td>Anti-sedentary Suggestions</td>
</tr>
<tr>
<td>Content</td>
<td>• Lock screen messages that suggest 5-15 minute walks.</td>
<td>• Lock screen messages that suggest standing, stretching or a short walk.</td>
</tr>
<tr>
<td>Decision Points &amp; Randomization</td>
<td>• 5 user-specified 30-minute windows per day.</td>
<td>• Every 5 minutes, sedentary individuals will be randomized to either receive a suggestion or not.</td>
</tr>
<tr>
<td>Proximal Outcome(s)</td>
<td>• Step count in the 30 minutes immediately following a decision point.</td>
<td>• The longitudinal pattern of steps over the 30 minutes following a decision point.</td>
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</table>

Significance

This study will help to optimize the development of HeartSteps — a mobile health application for helping heart disease patients maintain physical activity after graduating from Phase II cardiac rehabilitation programs.

Next Steps

After the 12-week trial, we will conduct a year-long study with CR graduates to investigate:
- The ability of study-team developed online learning algorithms to further improve and personalize intervention delivery;
- The long-term effectiveness of HeartSteps on cardiovascular outcomes.

Contact:
Xiaolei Wang
University of Michigan
Email: wxiaolei@umich.edu
Phone: 734-893-7158

Reference: