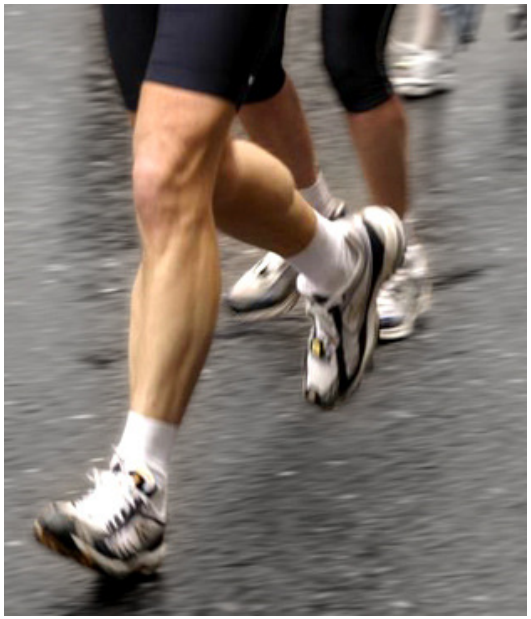
Micro-Randomized Trials in mHealth: A Method for Optimizing Just-in-Time Adaptive Interventions

Pedja Klasnja, Daniel Almirall,
Audrey Boruvka, Peng Liao, & Susan Murphy

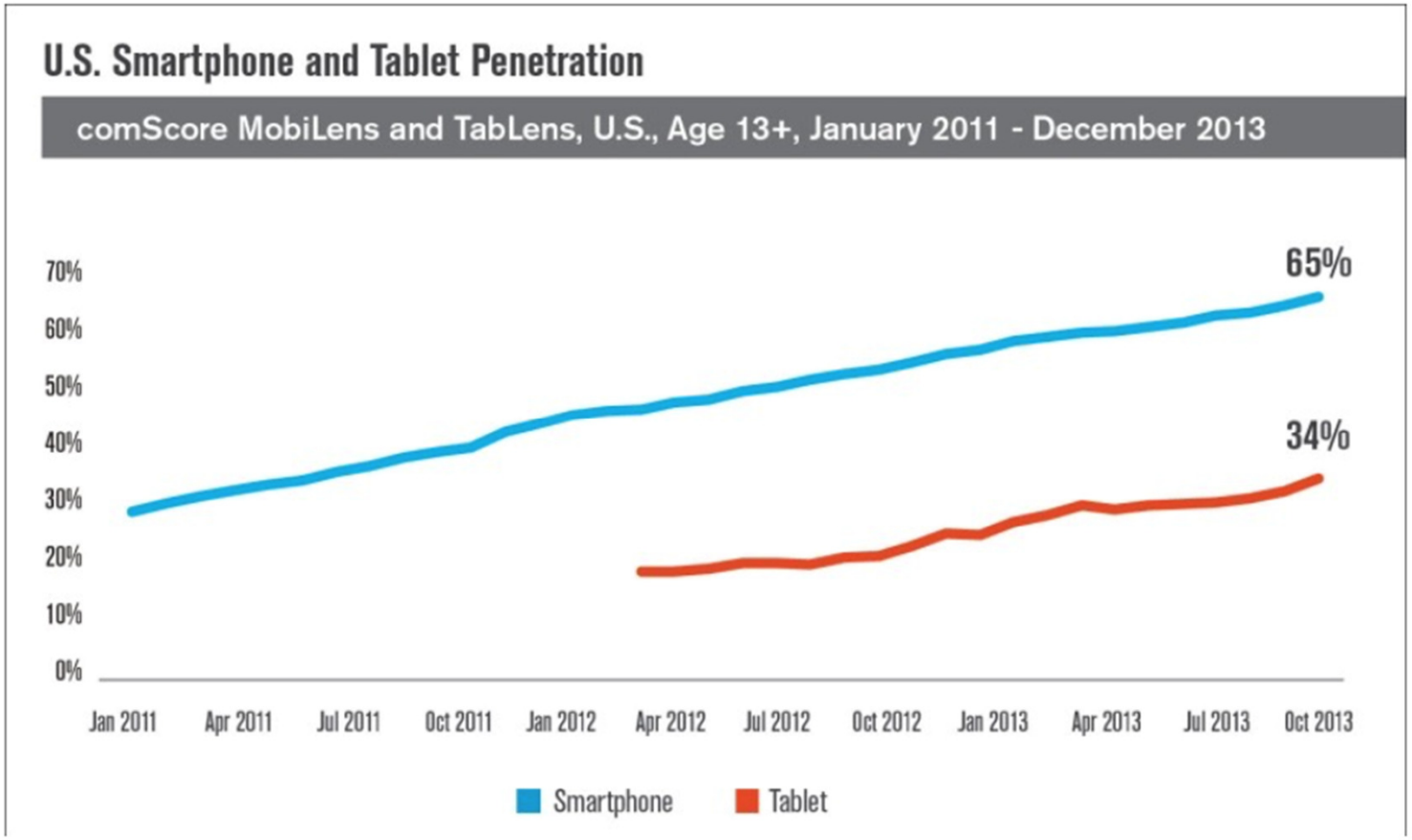
97,000+ mobile apps for health & fitness

$20 billion: mHealth industry size by 2018




You can do it.
We're here to help.

Ubiquity



>**90%** of U.S. adults have mobile phones. **65%** have smartphones

Close at Hand

Dey et al. 2011. *Proc UbiComp* 2011, p. 163–172.

Intimate Connection

Ventä et al. 2008. *Proc UbiComm* 2008, p. 311–317.

Fast, Connected, Aware

Proximity
Wi-Fi
Camera
Microphone
GPS
Compass
Accelerometer
Gyroscope
Light
Bluetooth

Mobile Health

- Highly accessible
- Can sense individuals' context & activities
- Enables sophisticated interventions
- Can provide just-in-time support throughout the day

Evidence So Far

- mHealth effective for smoking cessation and ART adherence
- Evidence for other conditions "promising" but insufficient

Free et al., 2014. *PLOS Medicine*
Holtz & Lauckner, 2012. *Telemedicine Journal & E-Health*

26% downloaded mHealth apps used only once

74% abandoned by the 10th use

Consumer Health Information Corporation, 2011

mHealth Design Challenges

We should aim to develop systems that…

- Can be used long-term
- Adjust to an individual's changing goals and capabilities
- Deliver interventions at the right times and places

Anatomy of an mHealth intervention


PUSH
push pull signs.com © RD


PULL
push pull signs.com © RD

Pull Interventions

Made available to users on the phone but accessed at will

- Graphs and charts for self-monitoring
- Coping strategies, educational materials
- "Help" button to receive coping support

Pull Interventions

- Allow inclusion of many components
- Put user in control of access
- Low burden

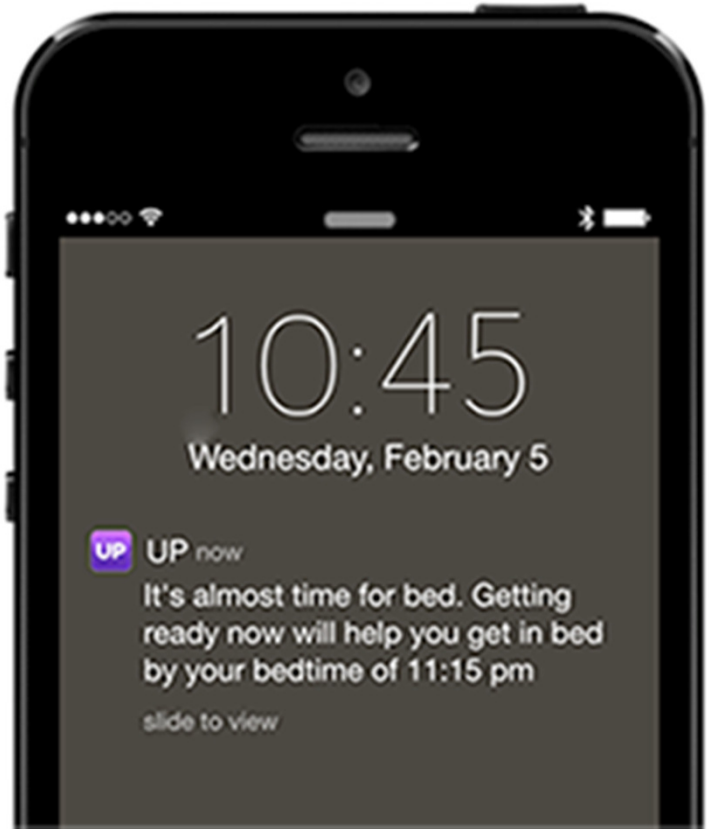
But…

- Depend on users to know when to access them and remember to do it

Push Interventions

Delivered based on time, context, user's state and activities

- Reminders
- Suggestions, tips, motivational messages
- Prompts to set goals, complete EMA…
- Rewards for goal attainment



Push Interventions

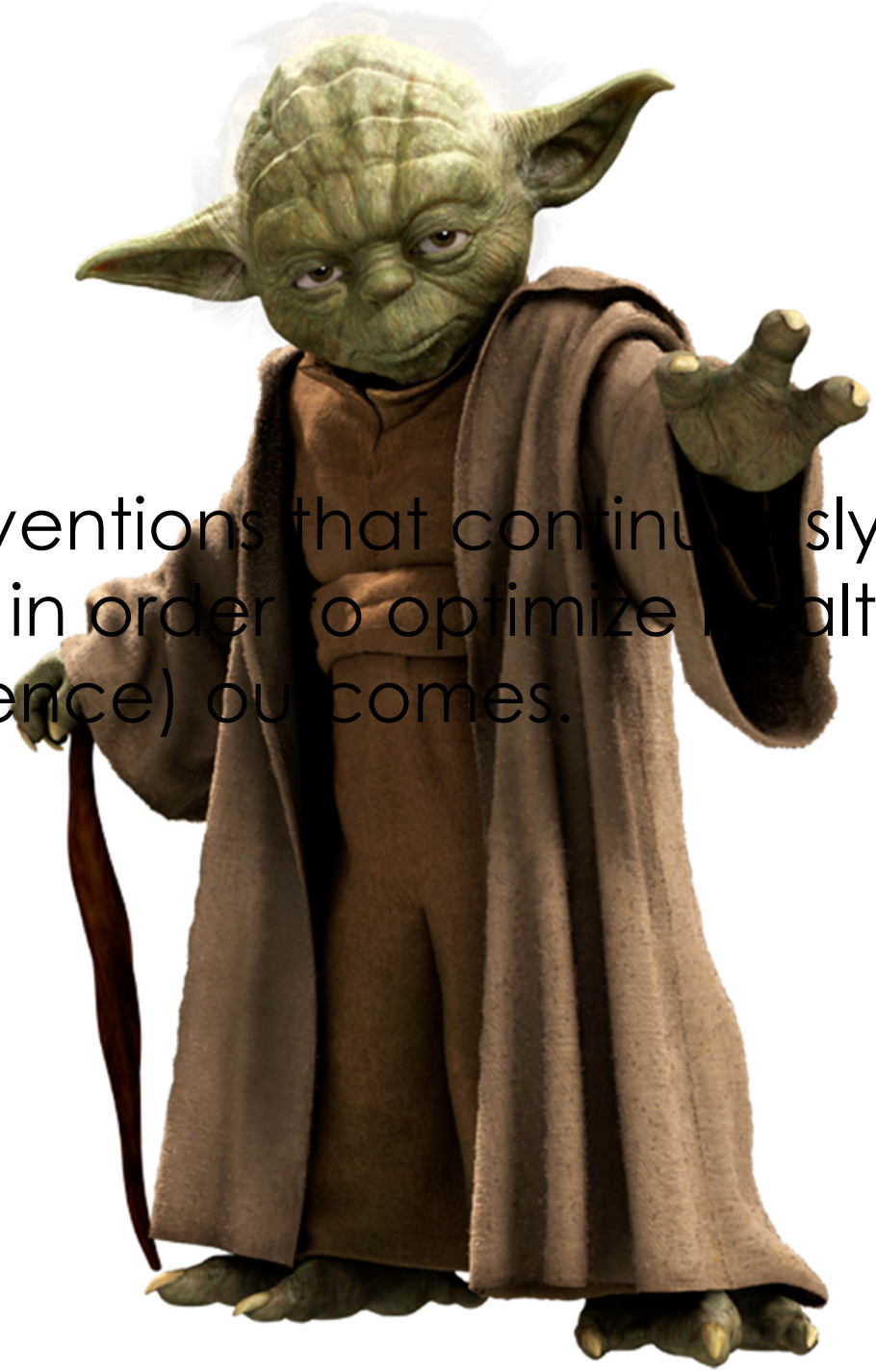
- Can use sensing and user modeling to determine right delivery time
- Don’t rely on user’s awareness of times of need or remembering to access

But…

- High burden

Design Goal

Develop mHealth systems that include the right combination of pull and push components, *delivered at the right times.*



JITAIs: Interventions that continuously adapt their functioning in order to optimize health (and user-experience) outcomes.

JITAIs: Just In Time Adaptive Interventions

- Delivered via mobile devices
- Anytime, anywhere
- When the person is in need and/or vulnerable
- When the person is receptive

Methodological Challenge: We need methods for intervention optimization and evaluation that assess *whether*, *how* and *why* an intervention is working over time

What We Need to Know to Optimize a JITAI

- Do individual components work as intended?
- For whom and in what contexts do they work?
- How does component effectiveness change over time and what factors moderate these changes?
- How do different components in a complex intervention interact?

Micro-randomized trials:
A Method for optimizing JITAIs

Klasnja, Hekler, …, & Murphy (in press). *Health Psychology*.
Liao, Klasnja, Tewari, & Murphy (in press). *Statistics and Medicine*.

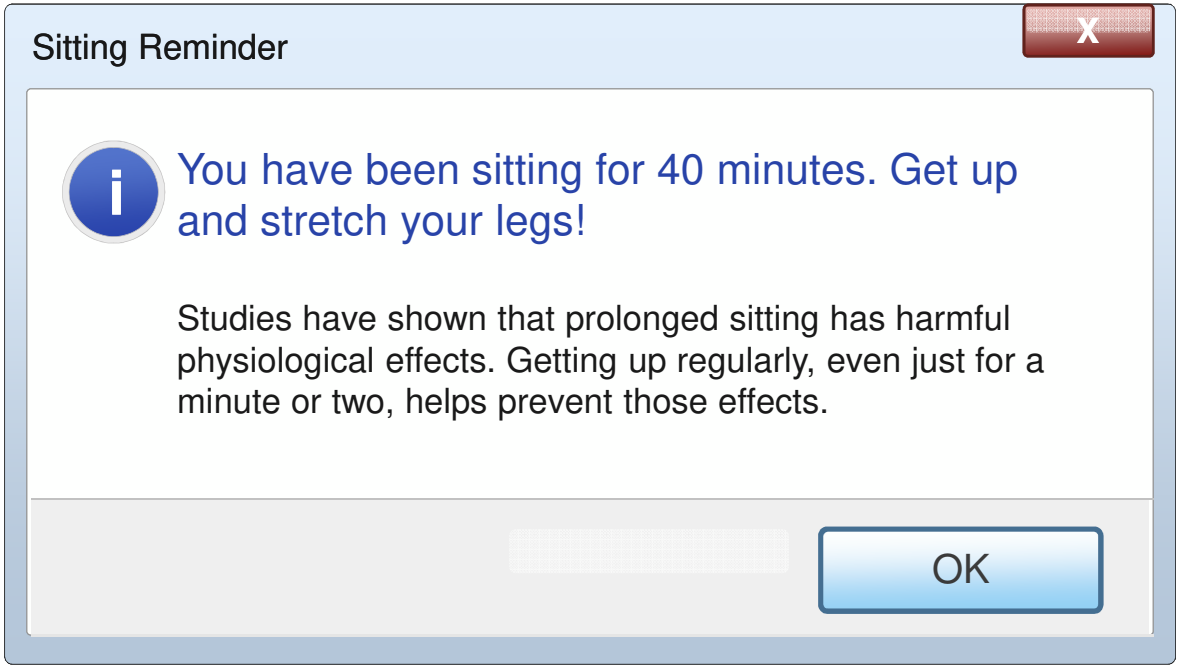
MRTs in a Nutshell

1. Randomize delivery of a push intervention component each time that component *may be* delivered
2. Capture at each randomization…
   - Proximal outcome for randomized component
   - Contextual factors that may influence response
3. Model
   - Component's time-varying causal effects
   - Time-varying contextual moderation of effects

Decision Times

Times when a push intervention component can be delivered, based on…

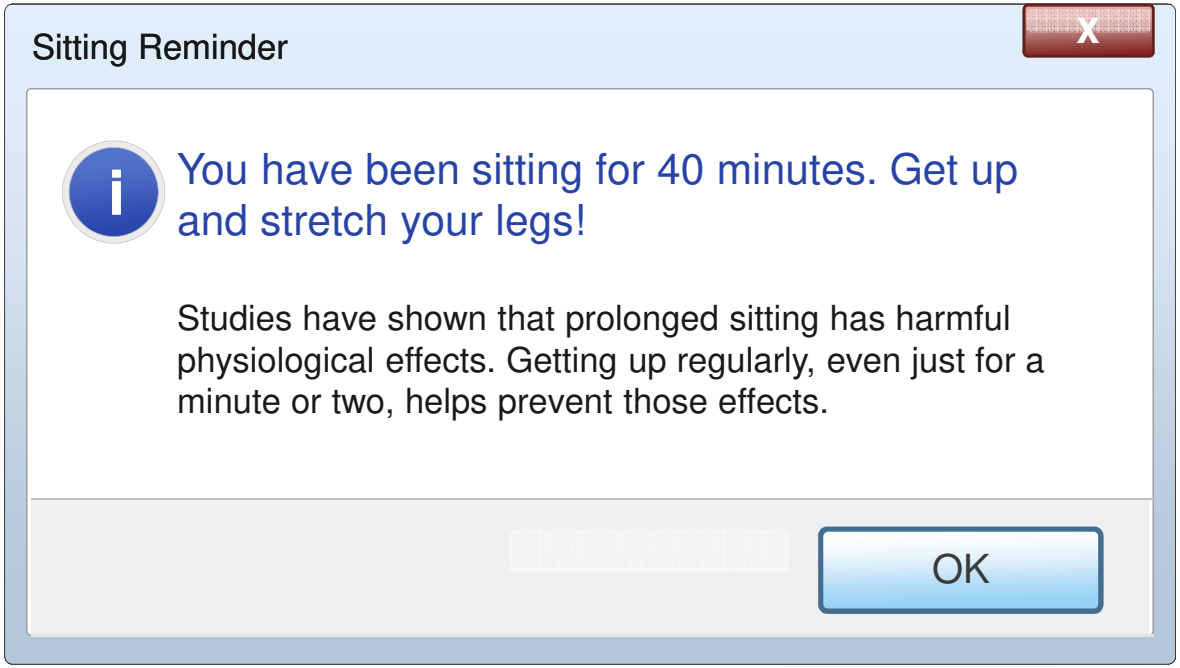
- Theory and prior experience
- User's context
- Level of activity of interest



Decision time: when user has been sitting for 40 minutes

Proximal Outcomes

Most immediate intended outcomes of an intervention component



Proximal outcome: whether the user got up after the reminder

Proximal & Distal Outcomes

- Proximal outcomes are presumed mediators of desired distal outcomes
  - Micro versions of distal outcome
    15-min walk for walking 10,000 steps a day
  - Part of causal pathway to distal outcome
    interactions with abstinence-supporting friends for remaining drug-free
- Different intervention components can target different proximal outcomes

Unintended Outcomes

Intervention components can also have unintended outcomes

- Burden
- Annoyance
- Alert fatigue

Contextual Moderators

Randomization in MRTs

- A component is randomized at each decision point for each participant

- What can be randomized:
  - Whether component is delivered or not
  - What type of component is delivered
  - Combination of the two
    50% No intervention, 25% Type A, 25% Type B

- Multiple components can be randomized concurrently
- During a study, each person randomized 100s or 1000s of times
- MRTs are sequential, full factorial designs

Availability & Randomization

Delivery is randomized only if the person is available to receive the intervention

- It makes sense to deliver the intervention
- It is safe to deliver the intervention

Availability taken into account in effect estimations

Data Captured at Randomization

- Relevant outcomes:
  - Intended proximal outcomes
  - Likely unintended outcomes
- Potentially relevant contextual moderators

What We Learn From MRTs

- Does a component have a proximal main effect and how that effect changes over time?
- Does a component have unintended effects and how they change over time?
- How is a component's effect moderated by time-varying contextual factors (e.g., location, weather, level of busyness)?
- Does a component have a lagged effect?

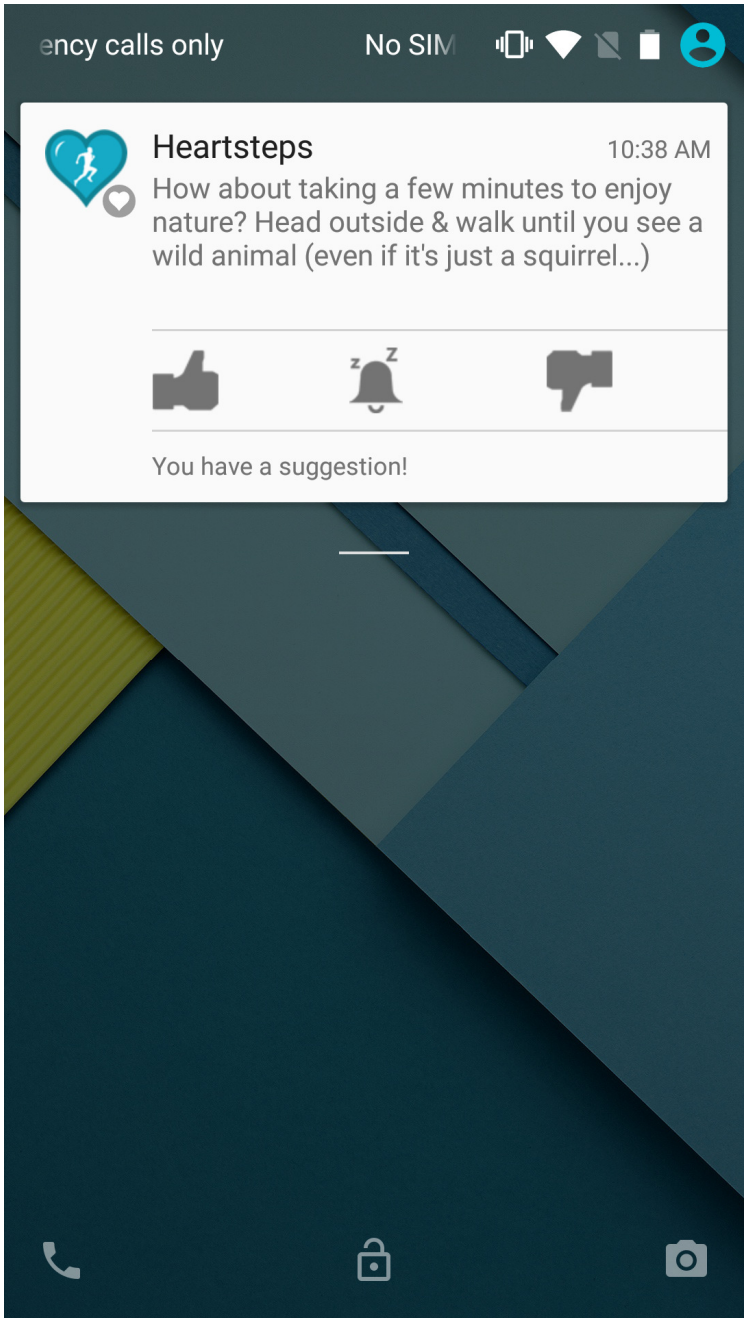
Heartsteps

HeartSteps: An mHealth Tool for Regular Walking

Intervention components:

- Actionable, contextually-relevant suggestions for physical activity
- Planning of when, how, and where one will be active the next day

Intended outcome: steps



Suggestions

Suggestions tailored on:

- time of day
- weekday vs. weekend
- location (work, home, other)
- weather

Two types of suggestions:

- to walk
- to interrupt sitting

Proximal outcome:

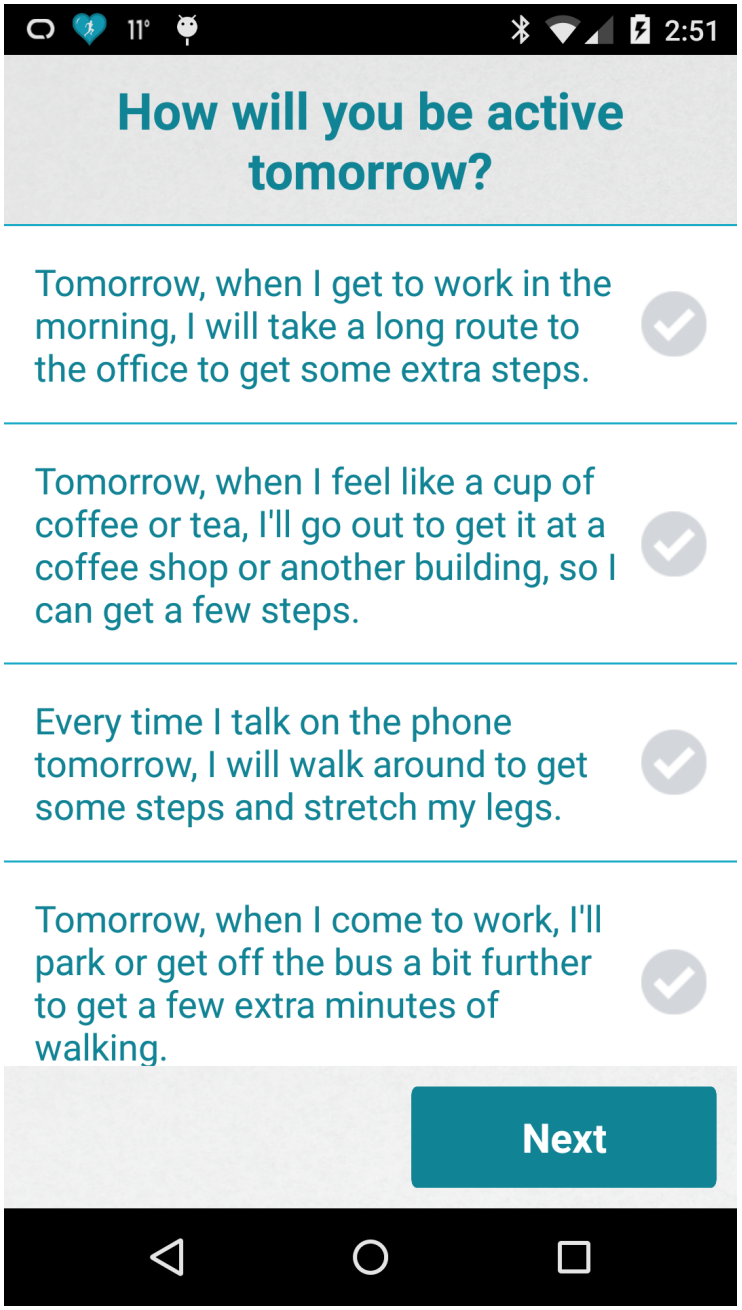
Steps in the next hour

Message Examples

Have a long conference call today? Walking in place or pacing while you talk can keep you engaged and increase your step count!

There's no better way to spend a weekend evening than taking a walk around the neighborhood! Are you up for it?

It’s important to hydrate. If you walk to the water fountain now, you can refill your bottle while also stretching your legs!



Planning

Two types of planning:

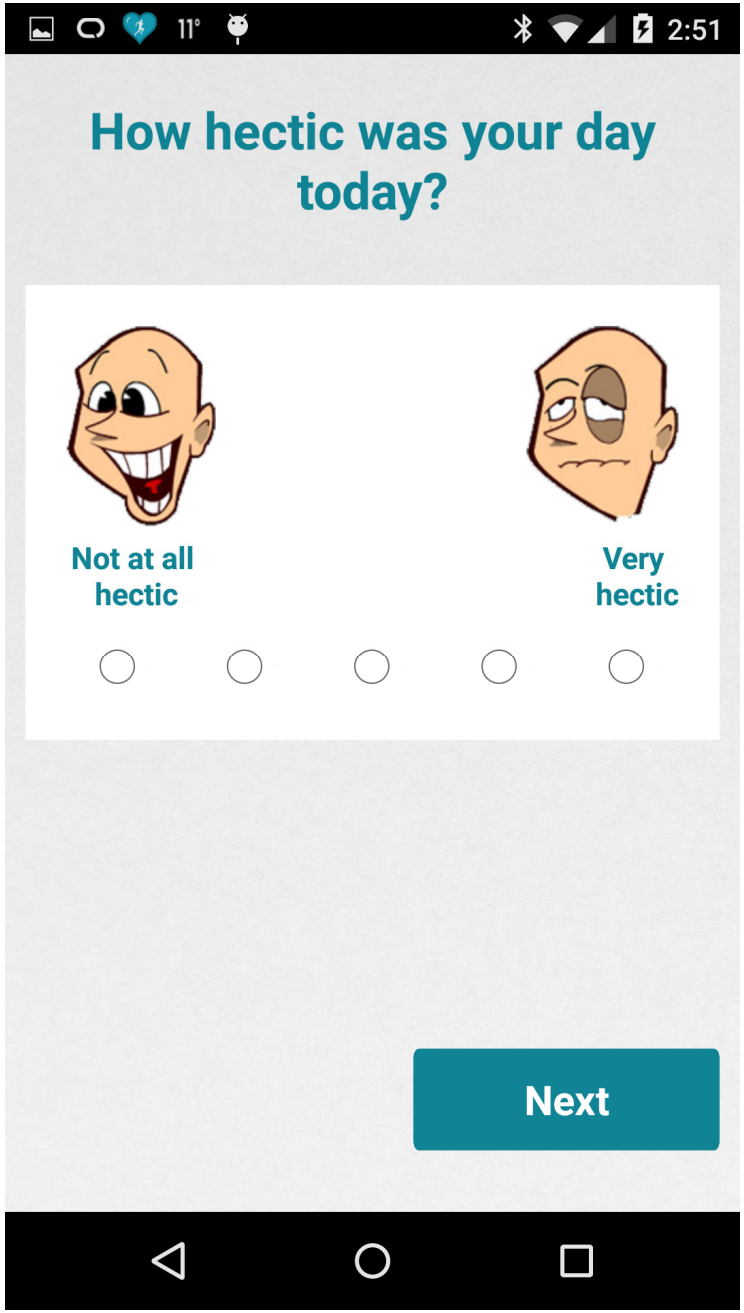
- Generate a new plan
- Select a plan from a list of previous and suggested plans

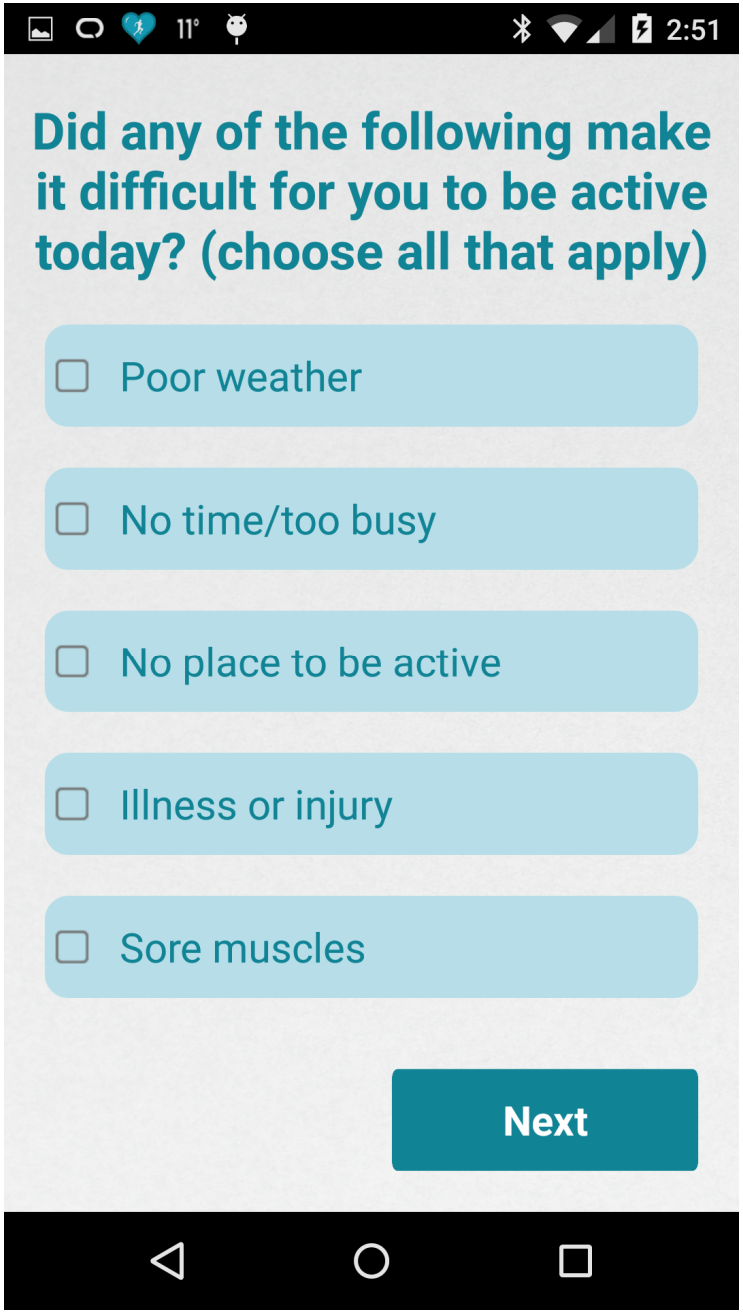
Proximal outcomes:

- Step count the next day
- Self-report if plan followed

Context captured at each randomization

- Time of day
- Location (home/work/other)
- State of participant's calendar (free/busy)
- Temperature and precipitation
- Participant's activity (sedentary, walking, running, in vehicle)
- Phone activity


2:51
How hectic was your day today?
Not at all hectic
Very hectic
Next


2:51
Did any of the following make it difficult for you to be active today? (choose all that apply)
Poor weather
No time/too busy
No place to be active
Illness or injury
Sore muscles
Next

Pilot Study Methods

- Six-week study with 40 sedentary adults
- Both components micro-randomized:
  - Suggestions 5 times a day (morning, lunch time, mid-afternoon, evening commute, post-dinner)
    - No suggestion, walk suggestion, get-up suggestion
  - Planning every night (yes/no planning)
- Capturing steps, location, weather, calendar, phone application use, user burden, answers to daily questionnaires

Pilot Study Goals

- Assess time-varying proximal effects for each intervention component
- Understand for whom, when, and in what circumstances components have an effect
- Understand how components affect user burden

Determine default decision rules for adaptive version of HeartSteps