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Methods: Mind the Gap Webinar Series

Using Micro-Randomized Trials To Optimize the Design of Mobile Health Interventions

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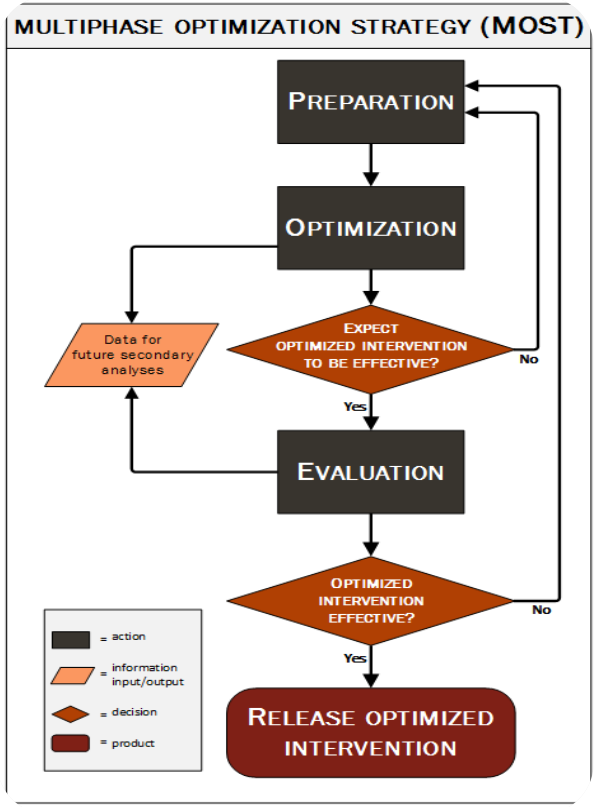


methodology.psu.edu

Goal of Optimization Studies

- Gather evidence that can inform decisions about how to improve the design of an intervention
  - Success defined via a set of optimization criteria
  - Optimization criteria usually include both efficacy/effectiveness and constraints (cost, burden, duration, etc.)

- Optimization studies are not intended to evaluate an intervention package in its current form

Optimization via Factorial Experiments

- Goal: Collect data that can inform *selection of intervention components* to include in an intervention package from a set of options under considerations

- This achieved by examining…
  - Main effects of individual components
  - 2-way interactions between components
  - Moderation by baseline factors (e.g., sex)

Optimization via MRTs

- Goals:
  - Select “push” intervention components to include in an intervention package from a set of components under considerations
  - Determine decision rules for push components that are kept
  - Select the design of the push components
- MRTs can help optimize both an intervention package (by choosing components) and individual components (by refining decision rules and component design)
- How? That’s what this webinar is about!

Scientific Goal: Usable Evidence

Create evidence that can…

- Inform design of effective mHealth interventions
  - Decision rules
  - User experience
- Support granular understanding of mechanisms of behavioral processes in the real world
- Be readily taken up by future projects

Micro-Randomized Trials

When Are MRTs Useful?

- Optimization questions are about “push” components that can be provided repeatedly
  - Reminders
  - Motivational messaging
  - Coping strategies
  - …
- Settings where such components can have measurable near-term impact
  - Physical activity
  - Mood
  - Sleep
  - Adherence
  - …

MRTs in a Nutshell

1. Randomize delivery of a push intervention component at each decision point
2. Capture at each randomization…
   - *Proximal outcome* for randomized component
   - Contextual factors that may influence response
3. Model
   - Component's (time-varying) causal effects
   - How these effects are moderated by time-varying factors (e.g., context of delivery) and baseline characteristics

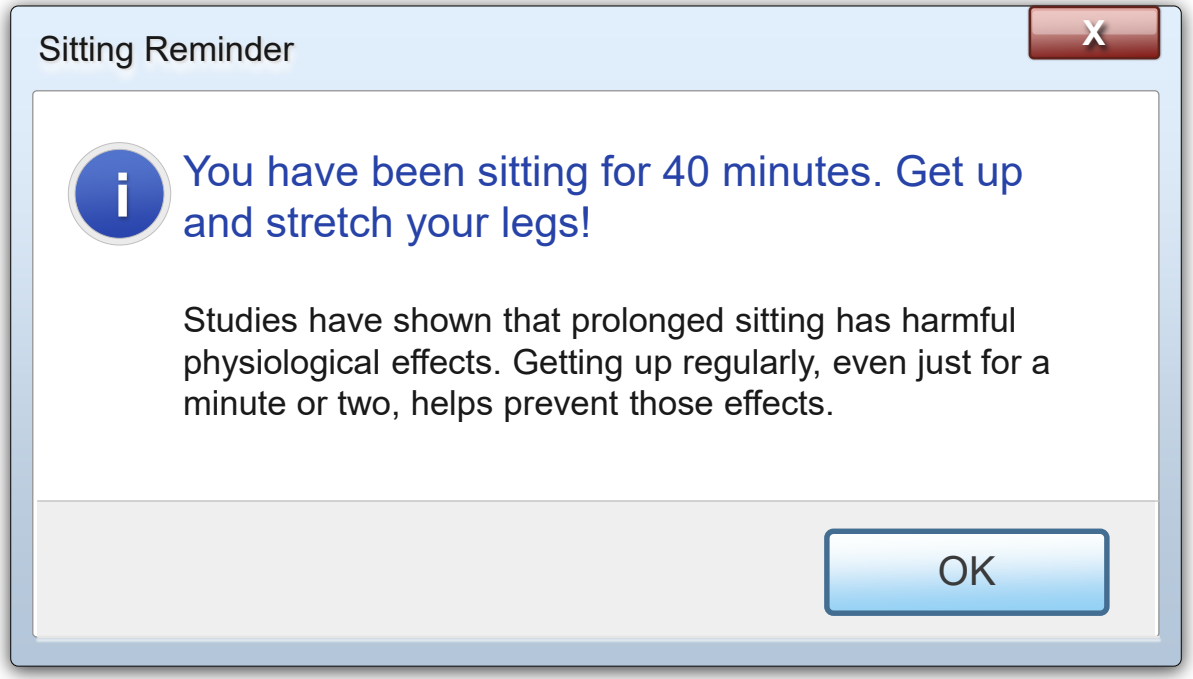
Klasnja, Hekler, …, & Murphy (2015). Health Psychology.
Liao, Klasnja, Tewari, & Murphy (2016). Statistics and Medicine.

Decision Points

Times when an intervention component *may need to be* delivered, based on…

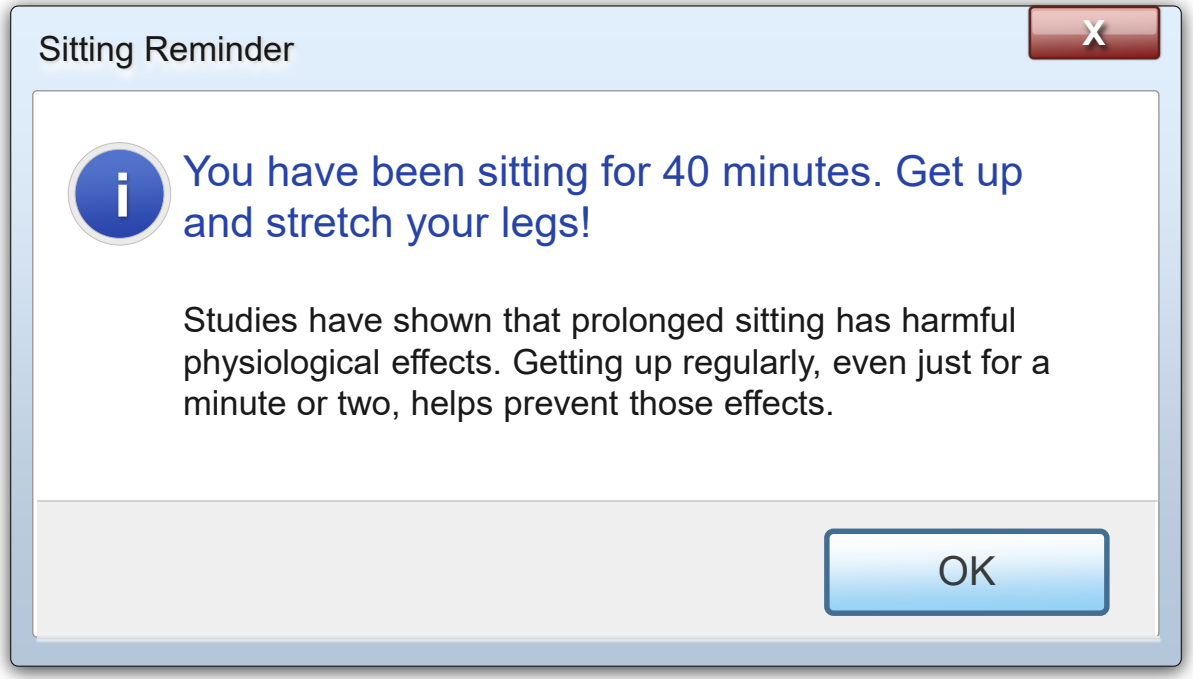
- Dynamics of the target behavior
- Level of activity of interest
- User's context

Example: Reminder to take a blood pressure medication may be provided once a day at a user selected time



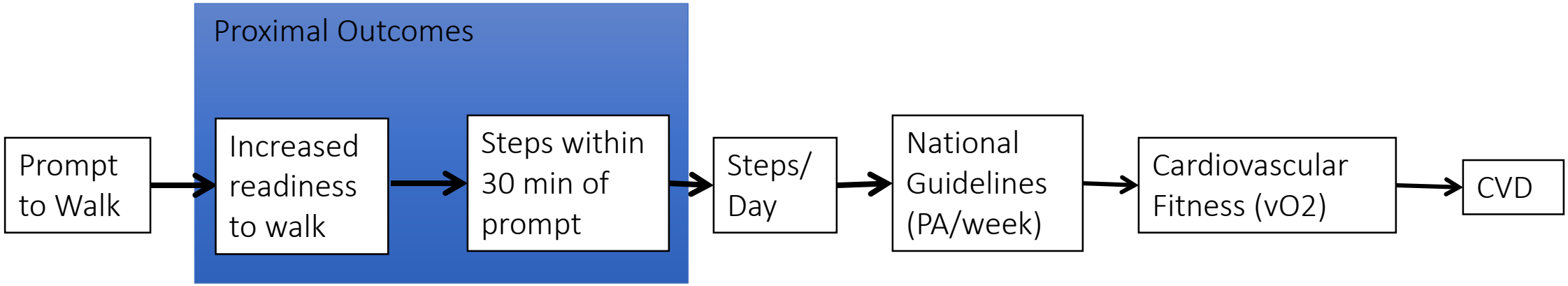
Decision time: when the user has been sitting for 40 minutes

Proximal outcome: Most immediate intended effect of an administration of a single “dose” of an intervention component.



Proximal outcome: whether the user got up after the reminder

Proximal Outcomes in the Causal Pathway



Hekler et al. 2016, TBM; Klasnja, et al. 2017, CHI; Nahum-Shani et al. 2015

Contextual Moderators

Application Due Dates

Search for Activity Code: R21, K series, U13

Activity Codes	Program Description	Cycle I Due Date	Cycle II Due Date	Cycle III Due Date
P Series *All - new, renewal, resubmission, revisions*	**Program Project Grants and Center Grants** NOTE: Applicants should check with the relevant Institute or Center (IC), since some do not accept P series applications for all three receipt/review/award cycles.	January 25	May 25	September 25
R18, U18 R25 *All - new, renewal, resubmission, revision*	**Research Demonstration** **Education Projects**	January 25	May 25	September 25
T Series D Series *All - new, renewal, resubmission, revision*	***Institutional*** **National Research Service Awards** **Other Training Grants** NOTE: Applicants should check with the relevant Institute or Center (IC), since some do not accept T series applications for all three receipt/review/award cycles. Applicants should refer to the IC Table of Contacts for information for each IC's scientific/research contact for the NRSA T32 program.	January 25	May 25	September 25

Randomization in MRTs

- A component is randomized at each decision point for each participant
- During a study, each person randomized many times
- Multiple components can be randomized concurrently

MRTs are sequential, full factorial designs

What We Can Learn From MRTs

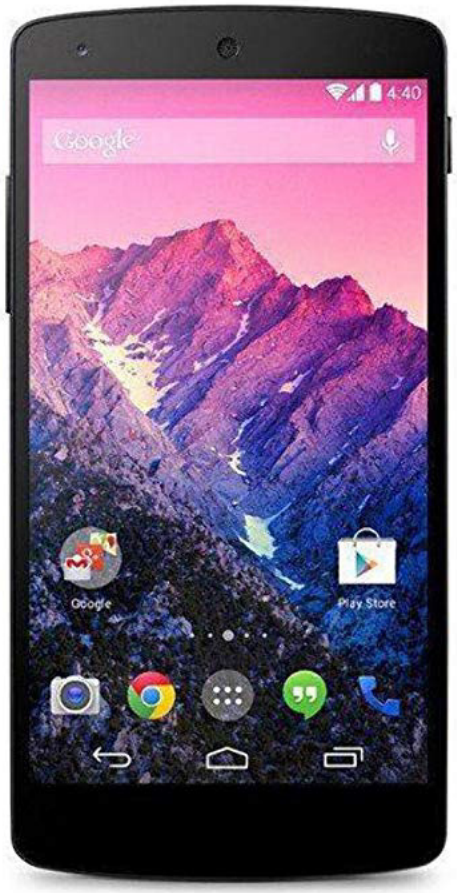
- If a component has a proximal main effect
- How the treatment effect changes over time
- How a component's effect is moderated by time-varying contextual factors (e.g., location, weather, previously provided treatment)
- If a component has lagged effects

MRTs are highly efficient as they take advantage of both within-person and between-person contrasts

HeartSteps v1

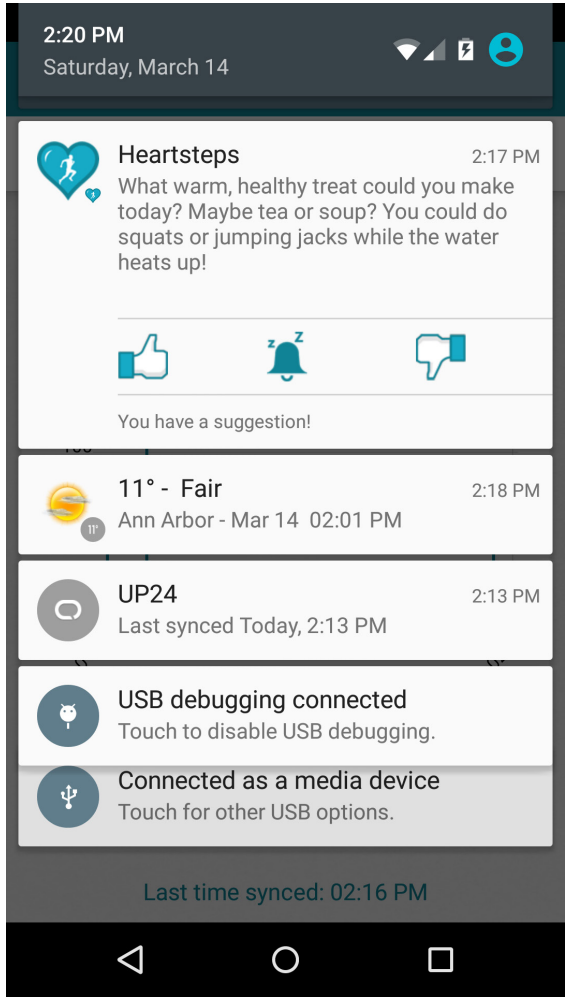
HeartSteps v1 Goals

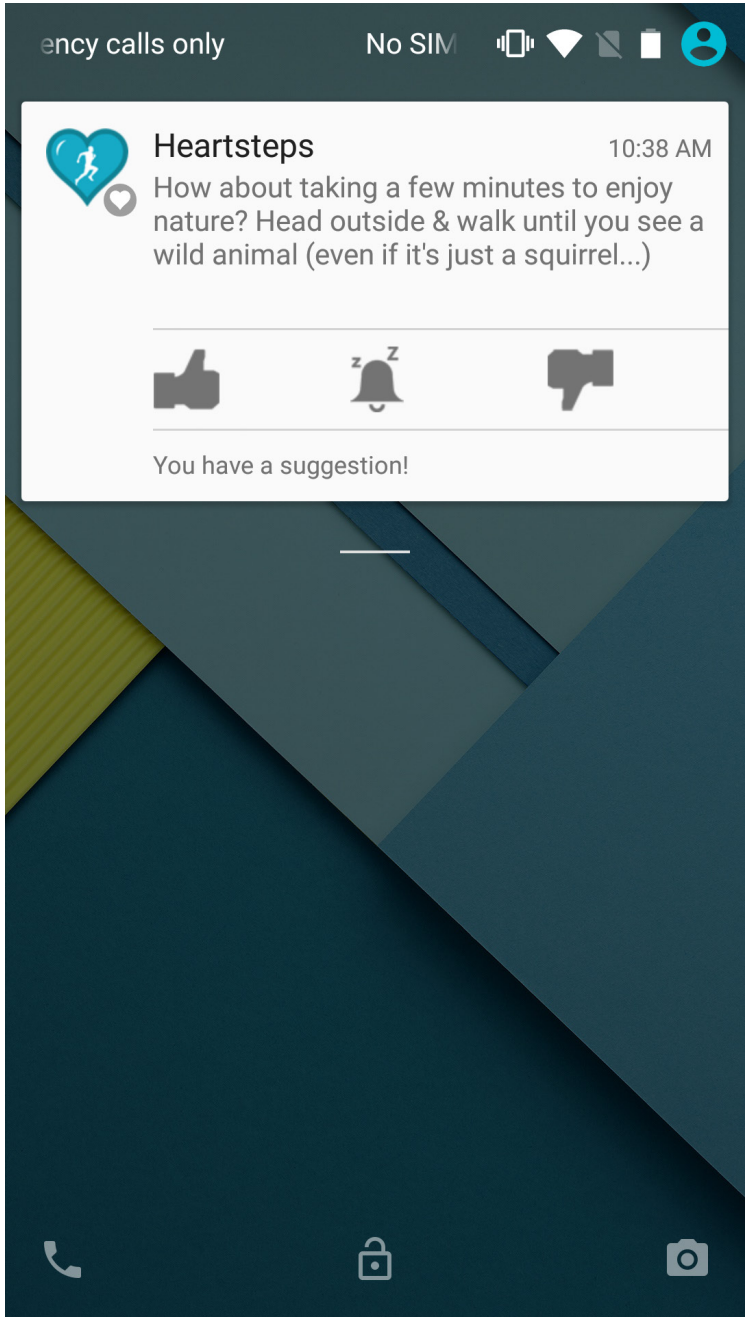
- Develop mHealth tool to help sedentary adults increase physical activity through walking
- Support getting activity throughout the day
- Pilot MRT methods



Push Intervention Components

- Actionable, context-aware activity suggestions
- Planning of when, how, and where one will be active the next day





Activity Suggestions

Intended to support short bouts of activity throughout the day

Suggestions tailored on:

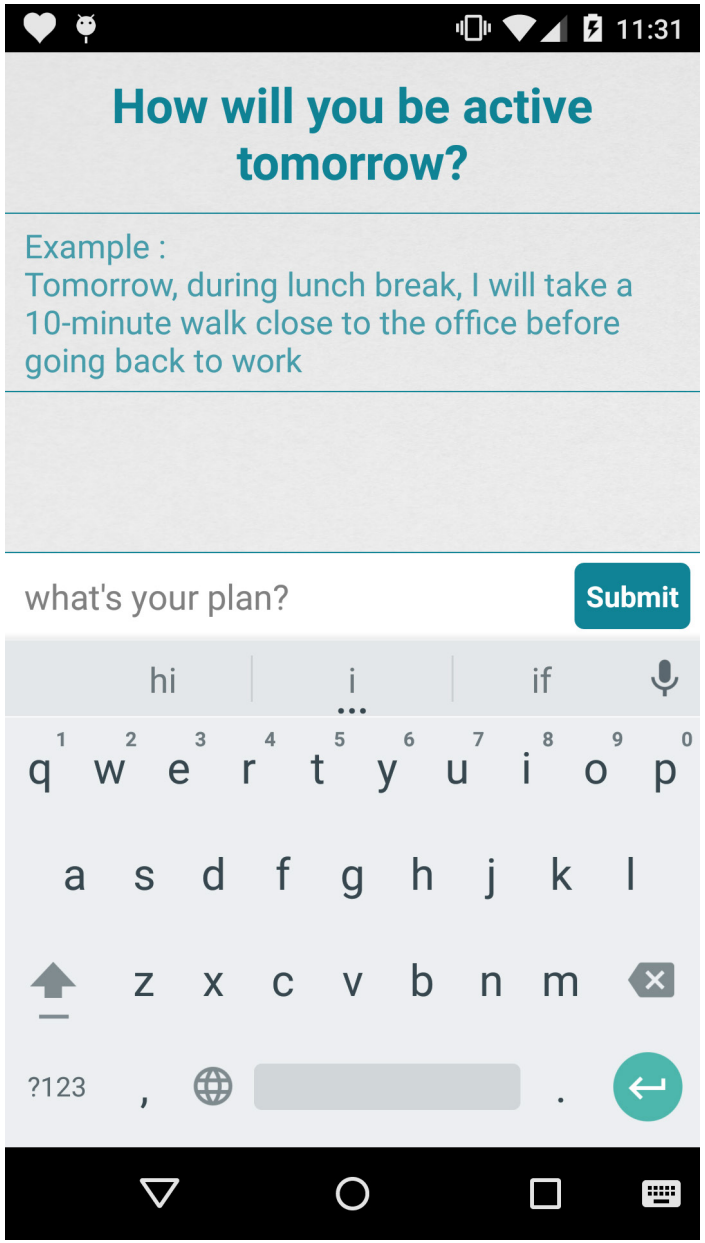
- time of day
- weekday vs. weekend
- location
- weather

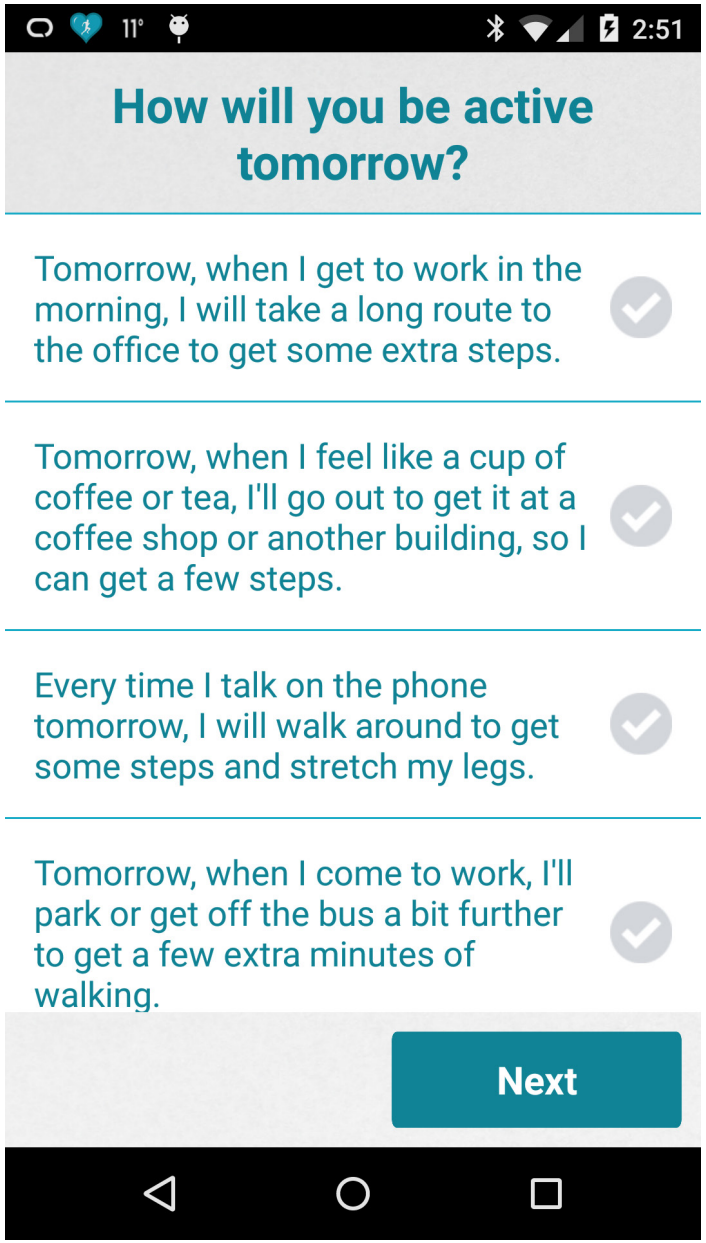
Two types of suggestions:

- to walk
- to disrupt sedentary time

Questions About Activity Suggestions

- Does providing a suggestion increase activity shortly after it's delivered?
- Do suggestions' effects change over time?
- Do walking suggestions and anti-sedentary suggestions have different effects on near-term activity?
- Do activity suggestions work differently when they are delivered in different contexts? (location, time of the day, day of the week, weather)?
- Does the dose of the suggestions matter (i.e., how many suggestions are sent in a short period of time)?





Planning

Intended to increase likelihood of longer activity bouts by creating concrete plans for their execution

Two types of planning:

- Generate a new plan
- Select a plan from a list of previously made plans

Questions About Planning

- Does prompting people to plan increase activity on the next day?
- Does the effect of planning change over time?
- Does the interface used to plan (open-ended vs. choosing from a list) matter?
- Does the context when people are asked to plan matter (e.g., day of the week, weather next day)?

Pilot Optimization Trial of HeartSteps

- 6-week study with 42 sedentary adults
- Both push components micro-randomized

Klasnja et al., 2018. *Annals of Behavioral Medicine*.

Randomization of Activity Suggestions

- Activity suggestions randomized 5 times a day for each person on each day of the study
- Randomization scheme:
  - No suggestion at p = .4
  - Walking suggestion at p = .3
  - Anti-sedentary suggestion at p = .3
- Activity suggestions randomized only if the person is available for treatment (e.g., not walking, not in vehicle)

Proximal Outcome for Activity Suggestions

- Activity suggestions intended to act as cue to action—proximal outcome should account for immediacy of the intended effect
- Chosen outcome: step count in the 30 minutes after the decision point
- Rationale:
  - A longer window may be too noisy, especially for anti-sedentary suggestions
  - Users might not see the suggestion immediately, so a shorter window may not capture acting on a suggestion seen late
- Limitation of the outcome: doesn't capture sit-to-stand transitions

Data Captured at Decision Points for Activity Suggestions

- Step count in 30 minutes following randomization (proximal outcome)
- Step count in 30 minutes prior to randomization
- Response to suggestion: thumbs-up, thumbs-down, no response
- Location
- Weather
- Time of day
- Day of the week
- Day in study

Randomization of Planning

- Planning randomized every evening for each participant each day of the study
- Randomization scheme:
  - No planning at p= .5
  - Open-ended planning at p = .25
  - Choose from a list at p = .25

Proximal Outcome: Planning

- Chosen outcome: step count on the next day
- Rationale:
  - Captures changes in plans
  - Closely aligned with desired distal outcome
  - But only captures step-based activities

Data Captured for Planning

- Next day’s step count (proximal outcome)
- Current day’s step count
- Weather for the next day
- Day of the week
- Day in study
- Amount of time spent on the planning screen

Primary Analyses for Activity Suggestions

- Treatment effect analyses conducted using centered and weighted least square method (Boruvka et al., 2017)

$$Y_{t+1} \sim \alpha_0 + \alpha_1 Z_t + \beta_0 (A_t - 0.6)$$

$$Y_{t+1} \sim \alpha_0 + \alpha_1 d_t + \alpha_2 Z_t + \beta_0 (A_t - 0.6) + \beta_1 (A_t - 0.6) d_t$$

- A_t: Indicator if suggestion delivered at occasion t
- Y_{t+1}: Log of 30-min step count after occasion t
- Z_t: Log of 30-min step count prior to occasion t (for noise reduction)
- d_t: Day in the study for occasion t

Main Effects for Activity Suggestions

- Averaged across time, providing vs. not providing a suggestion adds 35 steps ($p = .059$) to 253-step average in 30-min post-randomization
- Initially, delivering a suggestion vs. not adds 167 steps ($p= .002$), but effect gets smaller over time and disappears after one month
- Averaged across time, providing vs. not providing a *walking* suggestion adds 60 steps ($p=.02$) in 30 minutes post randomization
- Initially, delivering a *walking* suggestion adds 271 steps ($p < .001$), but the effect decreases over time and disappears after a month
- No effects for anti-sedentary suggestions

Other Findings for Activity Suggestions

- Effect of walking suggestions is negatively impacted by the dose of suggestions provided in the recent days
- Walking suggestions only have an effect when delivered while participants were at home or work. No effect at “Other” locations
- Anti-sedentary suggestions strongly preferred in exit interviews

Optimization Decisions for Activity Suggestions

- Keep the component
  - Walking suggestion initially very effective
  - Anti-sedentary suggestions really well liked
- Provide anti-sedentary suggestions based on real-time data (i.e., redefine decision points)
- Minimize probability of sending suggestions when the person is at “other” location
- Manage habituation by reducing probability of providing suggestions based on number of recently provided suggestions

Main Effects for Planning

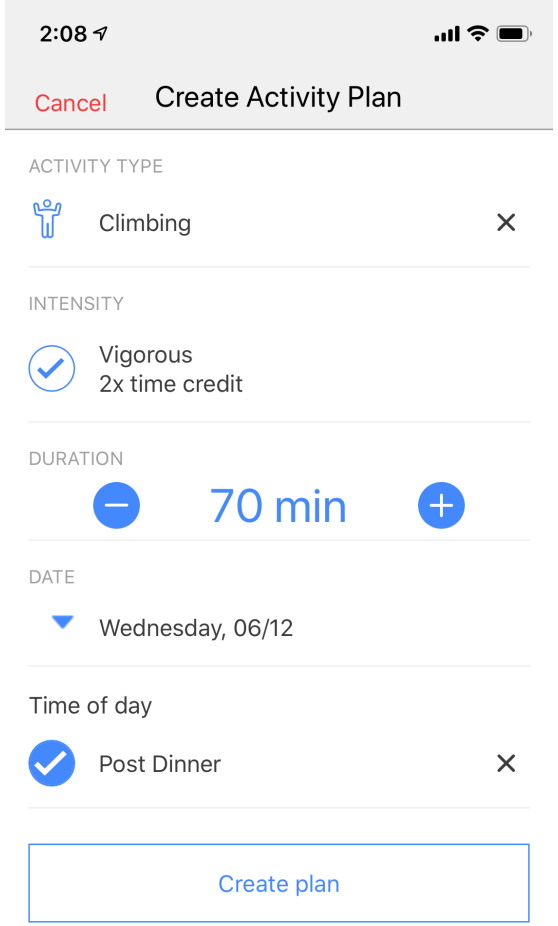
- Averaging across both types of planning, there is no effect for planning vs. no planning (p=.192)
- Open-ended planning vs. no planning adds 523 steps per day (p=.068). No effect for choosing from a list (p=.672)

Contextual Moderators of Planning Effects

- On weekdays, planning vs. no planning adds 661 steps per day (p=.011). No effect on weekends
- On weekdays, open-ended planning vs. no planning adds 903 steps per day (p=.003). No effect on weekends. No effect for choosing from a list
- There are no significant interactions with day in study. Effects for open-ended planning stay stable throughout the study
- Participants report that planning was too frequent

Optimization Decisions for Planning

- Change design to balance need for attention and burden
- Make planning a weekly push component, as well as make it available as a pull



HeartSteps v.1 High-Level View

A small, inexpensive study that provided…

- Useful data for informing intervention design
  - Need for some effortful engagement for planning interfaces
  - Need for high level of contextual tailoring for suggestions
  - Need to deal with habituation
- Intriguing data about underlying behavior-change processes
  - Role of attention in planning
  - Stability of planning effects over time
  - Rate of habituation for messaging interventions

Stepping Back: What Do We Gain from MRTs?

- Generation of evidence that can directly inform intervention design
  - Efficient testing of multiple push components
  - Information about factors (context, person's state, etc.) that moderate response and should be incorporated into decision rules
- Granular understanding of conditions and boundaries of effectiveness for push components
- Accumulation of intervention components—with associated evidence—that can be re-used and adapted
- Building of an evidence base that more readily informs future work

When Are MRTs Not Useful?

- Primary optimization questions are about selection of “pull” components
- Events of interest (i.e., decision points) occur rarely
  - e.g., just-in-time prevention alerts for suicide attempts
- The outcome targeted by a push intervention is expected to change very slowly (e.g., identity formation)
- Proximal outcome cannot be feasibly measured