

# JITAI Development in Mobile Health



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The Methodology Center  
advancing methods, improving health



# Overview

- Session 1: Introduction to JITAIs: Just-in-Time Adaptive Interventions
- Session 2: Micro-Randomized Trials for Developing mHealth JITAIs
- Session 3: Data Analytics for Developing JITAIs

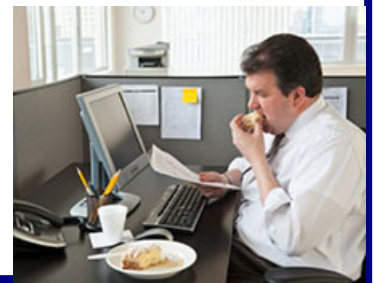
# Session 2: Micro-Randomized Trials

- HeartSteps
- Micro-Randomized Trial
- Sample Size Considerations

# HeartSteps

## HeartSteps Activity Coach

- Wearable band measures activity, phone sensors measure busyness of calendar, location, weather, .....
- In which contexts should the smartphone ping and deliver activity recommendations?



# HeartSteps

- Goal: Develop a Just-in-Time Adaptive Intervention for Encouraging and Maintaining Physical Activity



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# HeartSteps

## **Distal Outcome:**

Activity over the 42 day study.

## **Proximal Response:**

Proximal activity (step count) over next 30 minutes.

# HeartSteps

## **Treatments:**

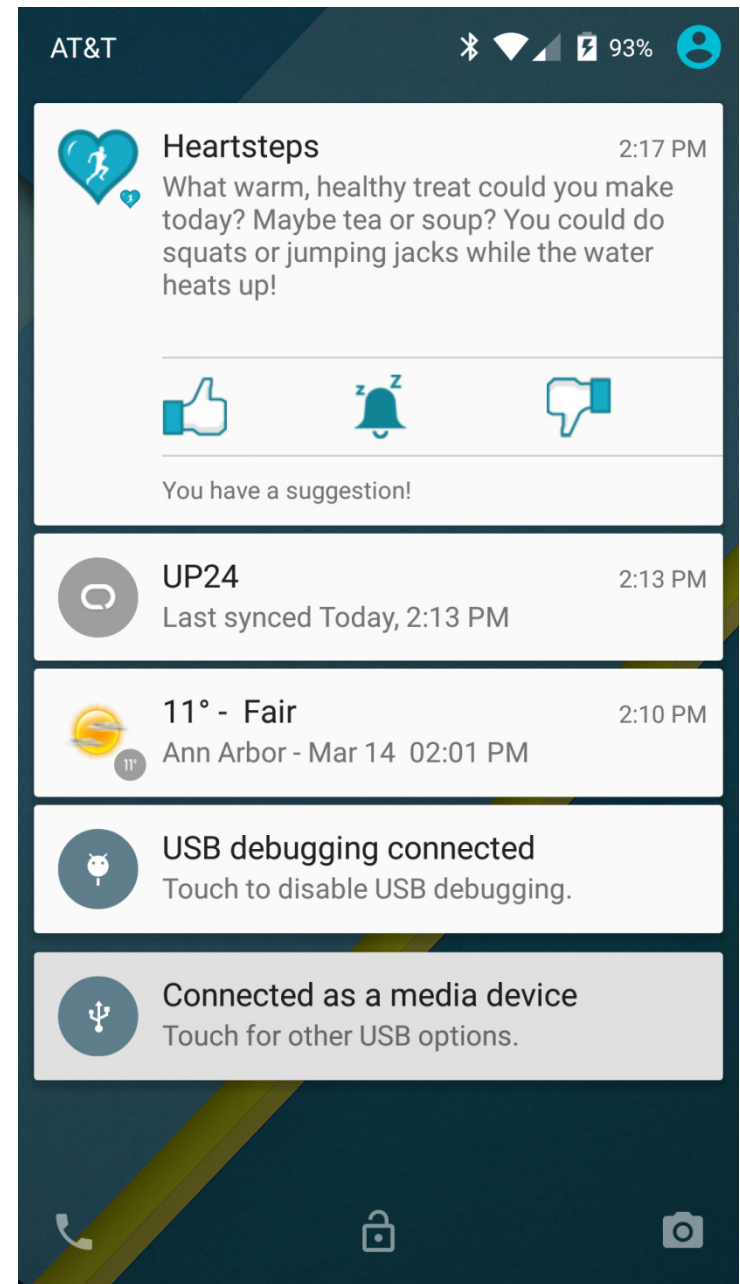
Whether to provide Tailored Activity Recommendation? Yes/No

## **Decision points:**

Approximately every 2-2.5 hours

# Tailored Activity Recommendation

No Message or





# HeartSteps

## **Potential Tailoring Variables:**

Sensor data: activity recognition (walking, driving, standing/sitting), weather, location, busyness of calendar, adherence, step count

Self-report: usefulness, burden

# Session 2: Micro-Randomized Trials

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# Micro-Randomized Trial

Randomize each participant between treatments at each decision point

→ Each person may be randomized 100's or 1000's of times.

These are sequential, “full factorial,” designs.

*Extension of A/B testing & Single Case Designs*

# Examples

- **HeartSteps:** 5 times/day\*42 days=210 possible randomizations
- **Sense2Stop:** 60 times/hour\*10 hours/day\*10 days=6000 possible randomizations

# Micro-Randomized Trial Elements

1. Record outcomes
  - Distal (scientific/clinical goal) & Proximal Response
2. Record potential tailoring variables
3. Randomize among treatments at decision points
4. At end of trial use resulting data to assess effects, moderation, construct decision rules

# Why Micro-Randomization?

- Randomization (+ representative sample) is a gold standard in providing data to assess the causal effect of a treatment.
- Sequential randomizations will enhance replicability of data analyses (moderation, decision rule development) .

# HeartSteps

- Whether to provide a tailored activity recommendation (at the decision points).
- Aim for an average of 2 recommendations/day.
- 210 decision points for the tailored activity recommendations.

Randomization Probability

|                                   |            |               |
|-----------------------------------|------------|---------------|
| Tailored Activity Recommendation? | <b>Yes</b> | $\frac{2}{5}$ |
|                                   | <b>No</b>  | $\frac{3}{5}$ |

# Sense2Stop

- Whether to provide a reminder to practice stress-regulation exercises (at the decision points).
- Aim for an average of 3 reminders/day over 10 days post-quit.
- Randomization probabilities depend on current stress and are determined by an algorithm.



# Micro-Randomized Trial

These sequential factorial trials are used to build JITAIs...

First Question to Address: Do the treatments differentially impact the proximal response?  
AKA: is there a signal here?!

--Test for *main effects* of the treatments on the proximal response

# Time-varying Main Effects

Time varying potentially intensive/intrusive treatments → potential for accumulating habituation and burden



Allow main effect of the treatments on proximal response to vary with time

# Sample Size

Determine sample size to detect a *time-varying main effect* of the treatments on the proximal response

- **HeartSteps:** Aim to detect time-varying effect of a tailored activity recommendation on step count over the 30 minutes following each decision point.
- **Sense2Stop:** Aim to detect time-varying effect of reminder to use stress regulation exercise on % time stressed over the hour following each decision point.

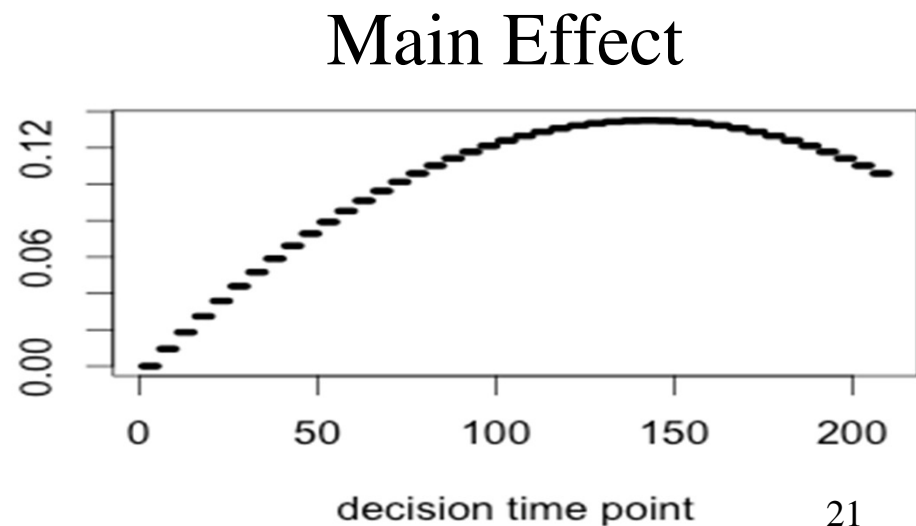
# Availability & the Main Effect

- Treatments can only be delivered at a decision point if an individual is *available*.
- The main effect of a treatment at a decision point is the difference in proximal response between *available* individuals assigned an treatment and *available* individuals who are not assigned a treatment.
- Availability is not the same as adherence!

# Main Effect (Example: HeartSteps)

Main effect of activity recommendation on proximal response is likely time-varying  $\beta(t)$ ,  $t=1, \dots, T$

- What does  $\beta(t)$  this main effect mean?



# Micro-Randomized Trial Elements

1. Record outcomes
  - Distal (scientific/clinical goal) & Proximal Response
2. Record potential tailoring variables
3. Randomize among Treatments at decision points
4. At End of Trial use Resulting Data to assess effects, moderation, construct decision rules

# Outline

- Adaptive Interventions and Just-in-Time Adaptive Interventions
- HeartSteps
- Micro-Randomized Trial
- Sample Size Considerations

# Sample Size Calculation

- We calculate the number of participants to test  $H_0$ : no effect of the treatment, i.e.,

$$H_0 : \beta(t) = 0, t = 1, 2, \dots, T$$

- Size to detect a low dimensional, smooth alternate  $H_1$ .

– Example:  $H_1$ :  $\beta(t)$  quadratic with intercept,  $\beta_0$ , linear term,  $\beta_1$ , and quadratic term  $\beta_2$  and test

$$\beta_0 = \beta_1 = \beta_2 = 0$$



# Sample Size Calculation

- Our test statistic uses estimators from a “generalization” of linear regression.
- The test statistic is quadratic in the estimators of the  $\beta$  terms.
- To calculate a sample size we need to specify a clinically/scientifically important effect size to detect.

# Sample Size Calculation

Alternative hypothesis is low dimensional  
→ assessment of the effect of the activity recommendation uses contrasts of *between participant responses* + contrasts of *within participant responses*.

--The required number of participants will be small.

# Specify Alternative for Sample Size Calculation

## SPECIFY:

- Standardized main effects:
  - main effect on first day,
  - average main effect over trial duration
- Day of maximal main effect.
- Average availability

# HeartSteps (42 day study)

Standardized effects:

- Initial effect: 0
- average standardized main effect over trial duration: ?
- day of maximal effect: 28
- average availability: ?

# HeartSteps Sample Sizes

Power=.8,  $\alpha$ =.05

| <b>Standardized Average Main Effect over 42 Days</b> | <b>Sample Size For 70% availability or 50% availability</b> |
|--|---|
| 0.06   | 81 or 112   |
| 0.08   | 48 or 65  |
| 0.10   | 33 or 43  |

# Sample Size Calculations

Beta version of the sample size calculator:

<https://pengliao.shinyapps.io/mrt-calculator/>

Try calculator for Sense2Stop study:

- 10 days, 600 decision points per day
- Availability of 25% so essentially  $600 * .25 = 150$  available points per day
- For an average of 3 interventions per day  $3/150 = .02$  randomization probability

# Micro-Randomized Trial

- 1) Be conservative in planning the trial!
  - 1) Under-estimate the amount of time participants are available for treatment.
  - 2) Under-estimate the average proximal effect

# Micro-Randomized Trial

- 2) Power to detect effect of treatment on the proximal response is robust to interactions and to delayed effects (e.g., burden)
- 3) Secondary data analyses concern time varying effect moderation and data analyses to construct data-driven decision rules for the JITAI



# Micro-Randomized Trials: When are they (not) useful?

- **NOT USEFUL:** When malleable circumstances are rare: Want to learn the best type of alert to prevent suicide attempt
- **USEFUL:** When malleable circumstances occur frequently: Stress, urges to smoke, adherence, physical activity, eating
- **NOT USEFUL:** Proximal response cannot be feasibly assessed.
- **USEFUL:** Proximal response can be unobtrusively sensed or unobtrusively self-reported.

# Practice designing a micro-randomized trial!

Some Questions:

1. Which treatments do you want to (micro-) randomize?
2. How long should your study last?
3. How many decision points are there per day?
4. On average, how many treatments do you want per day?
5. What will determine availability in your study?
6. What level of availability might you expect?
7. What should your randomization probabilities be?
8. What might the time-varying main effect look like?

# Collaborators

