

# *Developing Personalized Mobile Health Interventions*

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*Symposium on Big Data, Human Health  
and Statistics*



**The Methodology Center**  
advancing methods, improving health



# mHealth



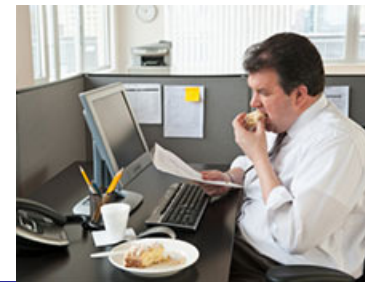
## MD2K Smoking Cessation Coach

- Wearable bands measure activity, stress, cigarette smoking, sleep quality.....
- Smartphone provides four types of support 24/7
- Wrist band provides supportive “cue” and smartphone activates to highlight associated support when stress reaches a criterion

# mHealth

## HeartSteps Activity Coach

- Wearable bands measure activity, phone sensors measure busyness of calendar, location,.....
- Smartphone pings and lockscreen delivers activity ideas when user is receptive and user's calendar is not too busy



# Data from wearable devices that sense and provide treatments

$$S_1, A_1, Y_2, \dots, S_j, A_j, Y_{j+1}, \dots$$

$S_j$ : Context at  $j^{\text{th}}$  decision time (high dimensional)

$A_j$ : Action at  $j^{\text{th}}$  decision time (treatment)

$Y_{j+1}$ : Proximal Response (time-varying response)

# Examples

- 1) Decision Times (Times at which a treatment can be provided.)
  - 1) Regular intervals in time (e.g. every 10 minutes)
  - 2) At user demand

HeartSteps includes two sets of decision times

- 1) Momentary: Approximately every 2-2.5 hours
- 2) Daily: Each evening at user specified time.

## Examples

- 2) Context  $S_j$ 
  - 1) Passively collected (location, stress, busyness of calendar, social context, activity on device, physical activity)
  - 2) Actively collected (self-report)

HeartSteps includes activity recognition (walking, driving, standing/sitting), weather, location, calendar, adherence, step count, whether momentary intervention is on, self-report: usefulness, burden, self-efficacy, etc.

# Examples

## 3) Actions $A_j$

- 1) Treatments that can be provided at decision time
- 2) Whether to provide a treatment

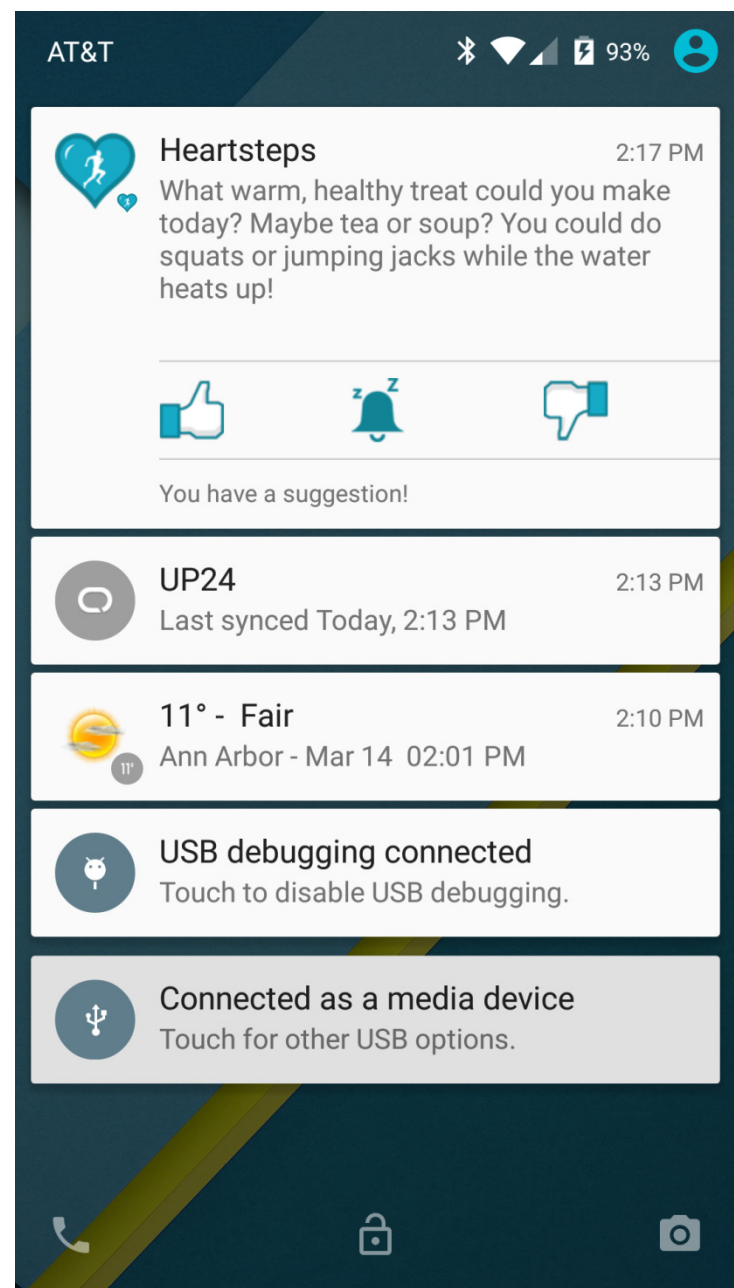
HeartSteps includes two types of treatments

- 1) Momentary Lock Screen Recommendation
- 2) Daily Activity Planning

# Momentary Lock Screen Recommendation

No Message

or





# Examples

## 4) Proximal Response $Y_{j+1}$

HeartSteps: Activity (step count) over next 60 minutes.

Smoking Cessation: Stress level over next  $x$  minutes.

# Our Group's Scientific Goals

- 1) Develop trial designs/data analytics for assessing if there are proximal effects of the actions on the response.
- 2) Develop data analytics for assessing if there are delayed effects of the actions; assess if the effects vary by context.
- 3) Develop data methods for constructing a treatment policy that inputs observations and delivers actions via phone.
- 4) Develop online training algorithms that will result in a Personalized Continually Learning mHealth Intervention

# Experimental Design: Micro-Randomized Trial

Randomize between actions at decision times → Each person may be randomized 100's or 1000's of times.

These are sequential, “full factorial,” designs.

# Micro-Randomized Trial Elements

## 1. Record outcomes

- Distal (scientific/clinical goal) & Proximal Response

## 2. Record context (sensor & self-report data)

## 3. Randomize among intervention options at decision points

## 4. Use resulting data to assess treatment interactions, construct decision rules

# Why Micro-Randomization?

- Randomization (+ representative sample) is a gold standard in providing data to assess the causal effect of an intervention option.
- Sequential randomizations will enhance replicability and effectiveness of data-based decision rules.

# HeartSteps (42 day study)

- Focus on whether to provide a Momentary Lock Screen Recommendation at the decision times.
- 210 decision times for the lock-screen activity recommendations.

Randomization Probability

Lock-screen activity Recommendation?	<b>Yes</b>	$\frac{2}{5}$
	<b>No</b>	$\frac{3}{5}$

# Micro-Randomized Trial

First Question to Address: Do the intervention options have an effect on the proximal response?

--Test for proximal *main effects* of the intervention

# Micro-Randomized Trial

Time varying potentially intensive intervention delivery → potential for accumulating habituation and burden



Allow proximal main effects of the intervention components to vary with time



# Sample Size for a Micro- Randomized Trial

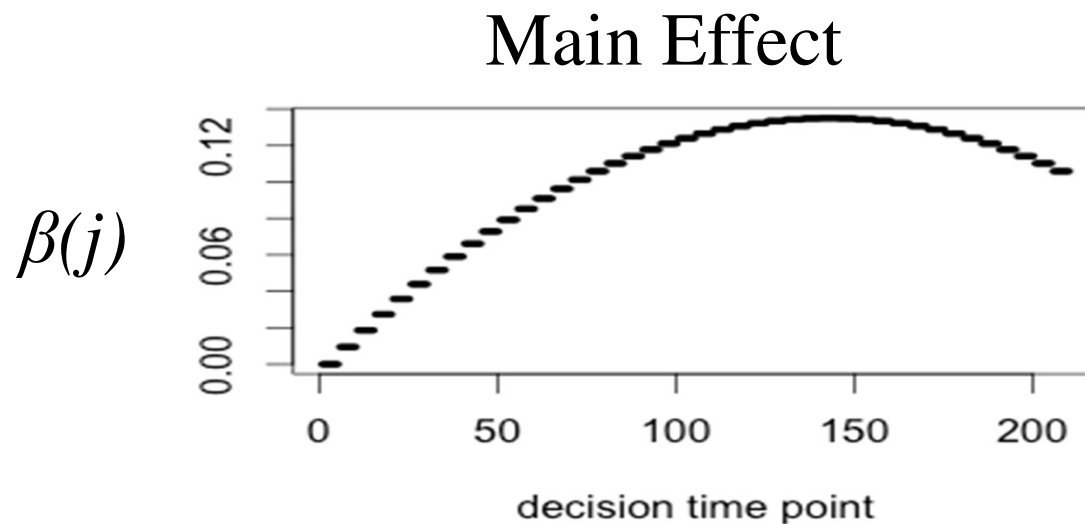
Determine sample size to detect a *time-varying proximal main effect* of the Lock Screen Recommendation on Activity

# Availability & The Main Effect

- Interventions can only be delivered at a decision time if an individual is *available*.
- The proximal main effect of treatment at a decision time is the difference in proximal response between *available* individuals assigned a lock-screen message and *available* individuals who are not assigned a lock-screen message.

# Proximal Main Effect

Main effect of lock-screen message on proximal response is likely time-varying  $\beta(j)$ ,  $j=1, \dots, J$



# Sample Size Calculation

- We calculate a sample size to test:

$$H_0 : \beta(j) = 0, j = 1, 2, \dots, 210$$

- A simple approach is to consider  $\beta(j)$  as a 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

Because we assume the proximal main effect is approximately quadratic, assessment of the effect of the lock-screen message uses not only contrasts of *between person responses* but also contrasts of *within person responses*.

--The required sample size (number of subjects) will be small.

# Sample Size Calculation

- Our test is based on GEE regression.
- To calculate a sample size we need to specify a clinically/scientifically important effect to detect.

# Specify Alternative for Sample Size Calculation

## SPECIFY:

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

# HeartSteps (42 day study)

Standardized effects:

- initial proximal effect: 0
- average standardized proximal effect over trial duration ?
- day of maximal proximal effect: 28



# HeartSteps Sample Sizes

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

**Standardized Average  
Proximal Effect over  
42 Days**

**Sample Size  
For  
70% availability or  
50% availability**

0.06

81 or 112

0.08

48 or 65

0.10

33 or 43

# A Micro-Randomized Trial

- 1) We also micro-randomize other components (e.g. Daily Activity Planning) to obtain a sequential, factorial design.
- 2) Further data analyses concern time varying effect moderation (interactions between treatment and context)

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# mHealth



BASICS Mobile to curb heavy drinking and smoking in college students

- Context/observations: Smartphone sensors + self-report data (3 x per day)
- Actions: “Mindfulness Intervention” vs. General Health Info (2 x per day)
- Is the effect of providing a mindfulness-based intervention (vs general health info) on subsequent smoking rate moderated by increase in need to self-regulate?

# BASICS Mobile

- $\tilde{S}_t$  includes 1 and urge to smoke, prior smoking rate, evening time (yes/no), provided prior self-report (yes/no), increase in need to self-regulate (yes/no),
- $S_t$  includes 1 and self-regulation=1, if increase in need to self-regulate, otherwise =0
- $I_t$  Availability: =1, if available, otherwise =0
- $Y_{t+1}$  smoking rate over next 1/3 day

# BASICS Mobile

Solve an “estimating equation” summed over  $i^{\text{th}}$  person,  $t^{\text{th}}$  decision time:

$$0 = \sum_{i=1}^n \left[ \sum_{t=1}^T (Y_{i,t+1} - \tilde{S}_{it}^T \alpha - A_{it} S_{it}^T \beta) I_{it} W_{it} \begin{pmatrix} \tilde{S}_{it} \\ A_{it} S_{it} \end{pmatrix} \right]$$

for  $\alpha, \beta$

Intuition: Think “linear regression”

# BASICS Results

The weight,  $W_{it}$ , is used to ensure

- robustness to misspecification of the  $\alpha$  part of the regression and
- to consider both a small number of interactions with the treatment action,  $A_{it}$ , as well as a large number of interactions.

The weight,  $W_{it}$ , ensures unbiased estimation of treatment effects,  $\beta$ .

# BASICS Results

Proximal		$\hat{\beta}$	95% CI
	$A_t$	-2.6	(-5.0, -0.1)
	$A_t \text{SelfReg}_t$	2.5	( 0.4, 4.7)



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# Collaborators

