Developing Personalized Mobile Health Interventions

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Symposium on Big Data, Human Health and Statistics
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

\[ S_1, A_1, Y_2, \ldots, S_j, A_j, Y_{j+1}, \ldots \]

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

\( A_j \) : Action at j\( ^{th} \) 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.

<table>
<thead>
<tr>
<th>Lock-screen activity Recommendation?</th>
<th>Randomization Probability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>$\frac{2}{5}$</td>
</tr>
<tr>
<td>No</td>
<td>$\frac{3}{5}$</td>
</tr>
</tbody>
</table>
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
$\beta(j), j=1,...,J$
Sample Size Calculation

• We calculate a sample size to test:

\[ H_0 : \beta(j) = 0, j = 1, 2, \ldots, 210 \]

• 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, α=.05**

<table>
<thead>
<tr>
<th>Standardized Average Proximal Effect over 42 Days</th>
<th>Sample Size For 70% availability or 50% availability</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.06</td>
<td>81 or 112</td>
</tr>
<tr>
<td>0.08</td>
<td>48 or 65</td>
</tr>
<tr>
<td>0.10</td>
<td>33 or 43</td>
</tr>
</tbody>
</table>
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)
Our Group’s Scientific Goals

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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
Solve an “estimating equation” summed over $i^{th}$ person, $t^{th}$ 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

<table>
<thead>
<tr>
<th>Proximal</th>
<th>$\hat{\beta}$</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>$A_t$</td>
<td>-2.6</td>
<td>(-5.0, -0.1)</td>
</tr>
<tr>
<td>$A_t \text{SelfReg}_t$</td>
<td>2.5</td>
<td>(0.4, 4.7)</td>
</tr>
</tbody>
</table>
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Collaborators