Micro-Randomized Trials & mHealth

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8/2014
mHealth

• Goal: Design a Continually Learning Mobile Health Intervention: “HeartSteps”

• Designing a “Micro-Randomized” Trial
Data from wearable devices that sense and provide treatments

\[ S_1, A_1, Y_1, \ldots, S_j, A_j, Y_j, \ldots \]

- \( S_j \): State at \( j^{th} \) decision time (high dimensional)
- \( A_j \): Action at \( j^{th} \) decision time (treatment)
- \( Y_j \): 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) State $S_j$
   1) Passively collected (location, weather, busyness of calendar, social context, activity on device)
   2) Actively collected (answers to questions)

HeartSteps includes activity recognition (walking, driving, standing/sitting), weather, location, calendar, adherence, step count, self-report (usefulness, burden, self-efficacy, etc.), whether momentary intervention is on.
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
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
Daily Activity Planning
Momentary Lock Screen Recommendation

It looks like you have been at your workplace for some time. Why don’t you take some time out of your lunch break to jog a little?
Examples

4) Proximal Response $Y_j$

HeartSteps: Activity (step count) between decision times or daily activity.
Scientific Goals

1) Assess if there are proximal causal effects of the actions on the response.

2) Assess if there are delayed causal effects; assess if the proximal/delayed causal effects vary by particular state variables.

3) Construct a treatment policy, aka “Just-in-Time Adaptive Intervention” that inputs state and outputs actions.

4) Construct an online training algorithm that will result in a “Continually Updating Just-in-Time Adaptive Intervention”
Today’s Focus

1) Assess if there are proximal causal effects of the actions on the reward.

2) Assess if there are delayed causal effects; assess if the proximal/delayed causal effects vary by particular state variables.

3) Construct a treatment policy, aka “Just-in-Time Adaptive Intervention” that inputs state and outputs actions.

4) Construct an online training algorithm that will result in a “Continually Updating Just-in-Time Adaptive Intervention”
Proposed Experimental Design: Micro-Randomized Trial

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

These are sequential, “full factorial,” designs.
Why Micro-Randomization?

• Factorial designs are the gold standard when collecting data to build a treatment involving many components

• Actions are often intended to have a proximal effect.
  – randomization is the gold standard in providing data to assess a causal effect

• Sequential randomization will enhance quality of many interesting subsequent data analyses.
Justifying the Sample Size for a Micro-Randomized Trial

• Focus on whether to provide a Momentary Lock Screen Recommendation, e.g.
  \[ A_j \in \{0, 1\} \]
  \[ P[A_j = 1] = .4 \]

• Randomization in HeartSteps

• Size to Detect a Proximal Causal Effect
Proximal Causal Effect

• Recall that $Y_j$ is the proximal response recorded after action $A_j$

• $A_j$ is only delivered if the momentary intervention is on at time $j$.

• Set $R_j = 1$ if the momentary intervention is on at time $j$, otherwise $R_j = 0$
Proximal Causal Effect

• Define

\[ \bar{A}_j = \{A_1, A_2, \ldots, A_j\}, \bar{a}_j = \{a_1, a_2, \ldots, a_j\} \]

• Define \( Y_j(\bar{a}_j) \) to be the observed response, \( Y_j \) if \( \bar{A}_j = \bar{a}_j \), e.g., \( Y_j = Y_j(\bar{A}_j) \)

• Define \( R_j(\bar{a}_{j-1}) \) to be the observed “intervention on” indicator if \( \bar{A}_{j-1} = \bar{a}_{j-1} \)
Proximal Causal Effect

• Define the Proximal Causal Effect at time $j$ as

$$E\left[ Y_j(\bar{A}_{j-1}, 1) - Y_j(\bar{A}_{j-1}, 0) \mid R_j(\bar{A}_{j-1}) = 1 \right]$$

• What does this estimand mean?
Proximal Causal Effect

• The randomization implies that

\[ E[Y_j(\bar{A}_{j-1}, 1) - Y_j(\bar{A}_{j-1}, 0)|R_j(\bar{A}_{j-1}) = 1] = \]

\[ E[Y_j|R_j = 1, A_j = 1] - E[Y_j|R_j = 1, A_j = 0] \]

• Put

\[ \beta_j = E[Y_j|R_j = 1, A_j = 1] - E[Y_j|R_j = 1, A_j = 0] \]
• $t^{th}$ time on $j^{th}$ day:

$$
\beta_{tj} = E[Y_{tj} \mid R_{tj} = 1, A_{tj} = 1] - E[Y_{tj} \mid R_{tj} = 1, A_{tj} = 0]
$$
Test for Sample Size Calculation

• We construct a test statistic for
  \[ H_0 : \beta_{tj} = 0, \forall t, j \]

• A simple approach is parameterize
  \[ \beta_{tj} = \beta_0 + \beta_1 (j - 1) + \beta_2 (j - 1)^2 \]
  and test
  \[ H_0 : \beta_i = 0, i = 0, 1, 2 \]
Alternative for Sample Size Calculation

• One calculates a sample size to detect a given alternative with a given power.

• Alternative:

$$H_1 : \beta_i = d_i \sigma, i = 0, 1, 2$$

where $\sigma^2$ is the residual variance.
Test Statistic for Sample Size Calculation

- Residual variance is

\[ \sigma^2 = VAR(Y_{tj} - E[Y_{tj}|R_{tj} = 1]) \]
Specify Alternative for Sample Size Calculation

- Scientist specifies standardized $d_i$’s
  - initial proximal treatment effect: $d_0$,
  - average proximal effect over trial duration:
    \[
    \frac{1}{5J} \sum_{j=1}^{J} \sum_{t=1}^{5} \left( d_0 + d_1(j - 1) + d_2(j - 1)^2 \right),
    \]
    - and day of maximal proximal effect: $- \frac{d_1}{2d_2}$
- We solve for $d_i$’s.
Test Statistic for Sample Size Calculation

• The model

\[ E[Y_{tj} | R_{tj} = 1] = \alpha_{tj} + \gamma_{tj} * R_{tj} + \beta_{tj} R_{tj} (A_{tj} - p_{tj}) \]

where \( p_{tj} \) is the randomization probability

• \( p_{tj} \) is .4
Test Statistic for Sample Size Calculation

• Use “GEE” to fit model

\[ E[Y_{tj} | R_{tj} = 1] = \alpha_{tj} + \gamma_{tj} * R_{tj} + \beta_{tj} R_{tj} (A_{tj} - p_{tj}) \]

where

\[ \beta_{tj} = \beta_0 + \beta_1 (j - 1) + \beta_2 (j - 1)^2 \]

• You select parameterization of \( \alpha_{tj}, \gamma_{tj} \)
Test Statistic for Sample Size Calculation

- Put \( Y = (Y_{11}, \ldots, Y_{51}, Y_{12}, \ldots, Y_{5J})^T \)

\( p \) is the total number of parameters \((p > 3)\);
\( X \) is the associated design matrix \((5J \text{ by } p)\)
\( N \) is sample size

Last 3 columns of \( X \) are

\[
R_{tj}(A_{tj} - p_{tj}), \quad R_{tj}(A_{tj} - p_{tj})(j - 1), \quad R_{tj}(A_{tj} - p_{tj})(j - 1)^2
\]
Test Statistic for Sample Size Calculation

- You choose your favorite correlation matrix associated with $Var(Y|X)$.

$$\hat{\Sigma} = \hat{\sigma}^2 N \left( \sum_{i=1}^{N} X_i^T X_i \right)^{-1} \left\{ \sum_{i=1}^{N} X_i^T \text{Corr}(Y_i|X_i) X_i \right\} \left( \sum_{i=1}^{N} X_i^T X_i \right)^{-1}$$

- $K$ is 3 by $p$ matrix picking out $\beta$ coefficients
Test Statistic for Sample Size Calculation

- GEE test statistic is
  \[ N \hat{\beta}^T (K \hat{\Sigma} K^T)^{-1} \hat{\beta} \]

- The asymptotic distribution is a Chi-Squared on 3 degrees of freedom with non-centrality parameter:
  \[ d^T (\Sigma_\beta)^{-1} d \]
Test Statistic for Sample Size Calculation

• The asymptotic distribution is a Chi-Squared on 3 degrees of freedom with non-centrality parameter: $d^T (\Sigma_\beta)^{-1} d$

• $\Sigma_\beta$ only depends on polynomials in $(j-1)$, the distribution of $R_{tj}$ and on the variance of the sequential randomizations.
The asymptotic distribution of the test statistic does not depend on the form of $\alpha_{tj}, \gamma_{tj}$ or on the correlation matrix.

The asymptotic distribution does depend on the distribution of $R_{tj}$.
Example

- Standardized $d_i$’s
  - initial proximal effect: $d_0 = 0$
  - average proximal effect:
    \[
    \frac{1}{5J} \sum_{j=1}^{J} \sum_{t=1}^{5} (d_0 + d_1(j - 1) + d_2(j - 1)^2)
    \]
  - day of maximal proximal effect: $-\frac{d_1}{2d_2} = 28$

\[
P[R_{tj} = 1|A_{jt,j-1} = 0] = .9, \quad P[R_{tj} = 1|A_{t,j-1} = 1] = .8
\]
Average Proximal Effect

\[ P[R_{tj} = 1|A_{jt,j-1} = 0] = .9, \quad P[R_{tj} = 1|A_{t,j-1} = 1] = .8 \]
$P[R_{tj} = 1|A_{jt,j-1} = 0] = .7$, $P[R_{tj} = 1|A_{t,j-1} = 1] = .5$
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Email if you have questions!

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