

Micro-Randomized Trials



Bari-Fit

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HeartSteps



Substance Abuse Research Assistant (SARA)

- Long Term Goal: Develop mobile intervention for youth who are at high risk (recent binge drinking and/or marijuana use)
- But engagement & adherence is problematic in mobile health
- Short Term Goal: *Develop an engagement JITAI for obtaining self-report data from youth at high risk*

Low engagement

Flurry mobile. 2018. App Engagement: The Matrix Reloaded. (jun 2018).
<http://flurrymobile.tumblr.com/post/113379517625/>

945 app-engagement-the-matrix-reloaded

E Ray Dorsey, Michael V McConnell, Stanley Y Shaw, Andrew D Trister, Stephen H Friend, et al. 2017. The use of smartphones for health research. *Academic Medicine* 92, 2 (2017), 157–160.

Daily Questions

Construct

Question

Answer Choices

Stress: Rate your overall stress today.

“Not at all” to “Very”

Mood: Rate your overall mood today.

“Sad” to “Happy” “Anxious” “Angry” Faces

Coping:

Which of these things did you do today during times of stress (check all that apply):

I took action to try to make the situation better.

I said things to let my unpleasant feelings escape.

I got help and advice from other people.

I tried to see it in a different light, to make it seem more positive.

I tried to come up with a strategy about what to do.

I got comfort and understanding from someone.

I did something to think about it less (such as watching TV, reading, listening to music, playing video games).

I sought comfort in my religion or spiritual beliefs.

Activity Space (combined with GPS location data)

What activities did you do today?

(check all that apply)

Watch TV

Do chores or cleaning

Go to a party

Play video games

Study

Go to School

Go shopping

Drive around

Watch movie at a theatre, play, or concert

Spend time outdoors (at beach, pool, park, lake)

Play on an organized sports teams

Play recreational or pick up sports activity

Work out at gym or fitness center

Volunteer in the community

Work at a paid job

Attend service at place of worship (Mosque, Temple, Church)

Eat at Restaurant

Go to coffee shop

Alcohol Craving

Overall how tempted were you to drink alcohol today?

Not at all 0-10 Very strong (ruler)

Alcohol Consumption

How many drinks of alcohol did you have today?

0-25+

Motives for Drinking or not drinking

If yes: Pick the top reason why you drank:

To enjoy the feeling

To avoid feeling left out

To feel less depressed, anxious or angry

To make social gatherings more fun

If no: Pick the top reason why you didn't drink:

Didn't want to

No chance/time

Out of alcohol

Trying to cut back

More important things to do

Cost

Marijuana Craving

Overall, how tempted were you to use marijuana today?

Not at all 0-10 Very strong (ruler)

Marijuana use

How many times did you use marijuana (hash, weed) today?

0-10+

Motives for Marijuana use or not using

If yes Pick the top reason why you used marijuana:

To enjoy the feeling

To avoid feeling left out

To expand your awareness

To feel less depressed, anxious or angry

To make social gatherings more fun

If no: Pick the top reason why you didn't use marijuana:

Didn't want to

No chance/time

Out of weed

Trying to cut back

More important things to do

Cost

Sensation Seeking

Overall, was your day new and exciting today?

"Not at all" to "Very"

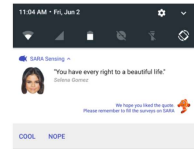
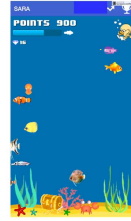
Hopefulness

Overall, do you expect good things will happen to you tomorrow?

"Not at all" to "Very"

SARA Engagement Strategies

- Pull Components
 - Gamified Interface with points and awards
- Push Components: intervention options
 - 4pm inspirational quote : Yes/No
 - 6pm reminder : With or without additional persuasive message
 - After self-report completion : Yes/No reinforcement with a meme



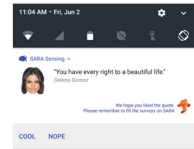
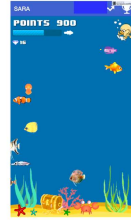
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The additional persuasive message may be

- “Do you know it only takes a minute to fill out the survey and active tasks?” or
- “Do you know you can earn money if you complete a 3-day streak?” or
- “You are close to unlocking the next fish for the aquarium.”

SARA Engagement Strategies

- Pull Components
 - Gamified Interface with points and awards
- Push Components: intervention options
 - *4pm inspirational quote engagement strategy : Yes/No*
 - The underlying conceptual construct is based on reciprocity.



Some Questions to Optimize SARA

- Does the 4pm inspirational quote lead on average, to greater same-day self-report engagement?
- Does the effect of the 4pm inspirational quote change over time? (e.g., do people habituate to the quotes and become less responsive with time?)
- Is prior day engagement (self-report completion/app usage) a tailoring variable?
 - e.g. is the 4pm inspirational quote ineffective when prior day engagement is low?

Traditional evaluation methods don't help with these questions.

Outline

Micro-Randomized Trials (MRTs)

- What is an MRT?
- Elements of a MRT
- Inferential Target
- MRT versus RCT

What is a Micro-Randomized Trial?

For each intervention component:

- At each decision point randomize participant between intervention options
 - Each participant may be randomized 100's or 1000's of times.
- MRTs provide data to construct and optimize a JITAI
- These trials do not evaluate a JITAI!

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SARA

- SARA MRT is a 30 day study
- Inspirational quote component:
 - Decision points are 4pm every day
 - Each day, at 4pm, the participant is randomized with 0.50 probability between the Yes/No options

Micro-Randomized Trial Elements

- 1) Decision Points (Times at which an intervention component might be provided.)
 - 1) Regular intervals in time (e.g. every 10 minutes)
 - 2) At user demand

SARA: 4pm every day of 30 day study

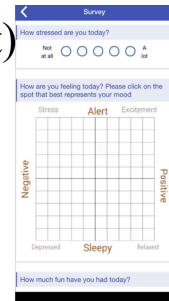
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Here also think of the variety of decision times –this would happen if when you thought about the JITAI there were multiple possible times and it is unclear which to select.

Another example: The phone software monitors a risk measure at regular time intervals and if the risk measures hits a criterion then a treatment is provided.

Micro-Randomized Trial Elements

- 2) Context (observations)
 - 1) Passively collected (via sensors)
 - 2) Actively collected (via self-report)



SARA: Self-report data, App usage data,
Location, Completion of self-report, # of phone
calls and text messages per day

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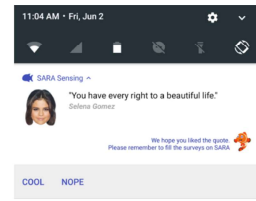
Can include time of day or day of week and present weather.

Micro-Randomized Trial Elements

3) Intervention options

- 1) Types of treatments/engagement strategies that can be provided at a decision point, t
- 2) Whether to provide an intervention

SARA: inspirational
quote (yes/no)



Some Treatment types behavioral, cognitive, motivational, social, self-monitoring, information

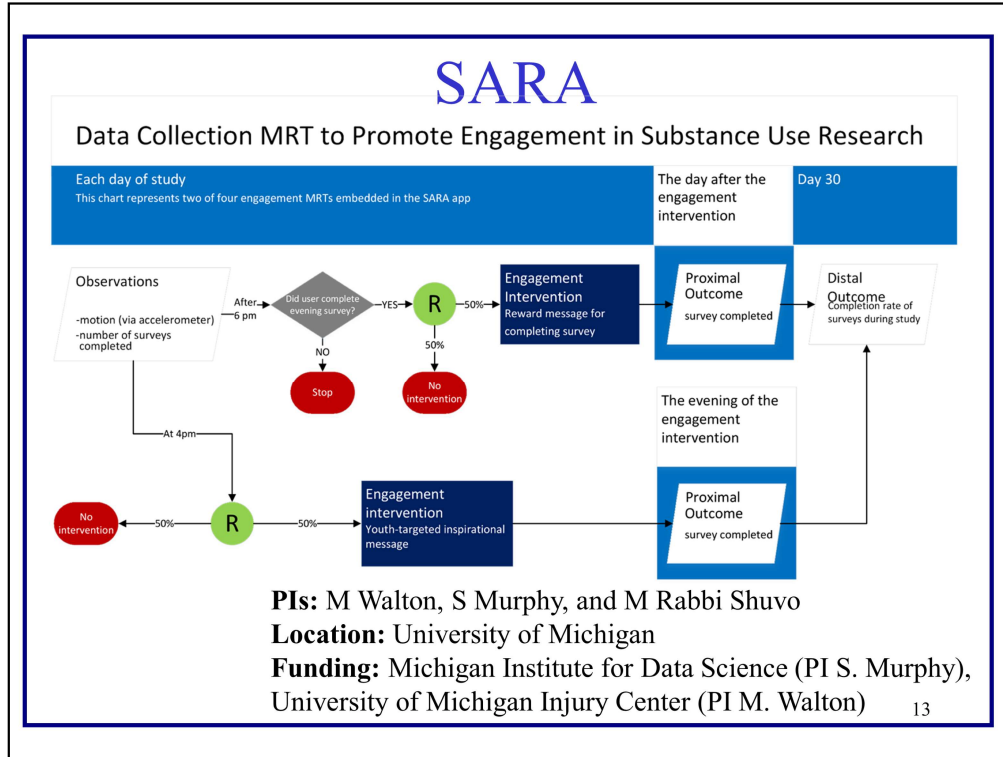
Micro-Randomized Trial Elements

4) Proximal Outcome

SARA: Completion of that day's evening self-report

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Discuss duration over which proximal outcome might be collected



The Substance Abuse Research Assistance (SARA) is an app for gathering data about substance use in high-risk populations. App developers are using an MRT to improve engagement with completion of the self-report data collection measures. At the time this summary was written, this MRT is unique in that it has an engagement component, but not a treatment one. 30 days

PIs: Maureen Walton, Susan Murphy, and Mashfiqui Rabbi Shuvo

Location: Harvard University and University of Michigan

Funding: Michigan Institute for Data Science (PI S. Murphy), the University of Michigan Injury Center (PI M. Walton), NIDA P50 DA039838 (PI Linda Collins), NIAAA R01 AA023187 (PI S. Murphy), CDC R49 CE002099 (PI: M. Walton)

<https://clinicaltrials.gov/ct2/show/NCT03255317>

And

<https://osf.io/whgfp/>

To Do in a Micro-Randomized Trial

1. Record outcomes: distal (scientific/clinical goal) & proximal outcome
2. Record context data (including potential tailoring variables)
3. Randomize among intervention options at decision points
4. At end of trial use resulting data to assess intervention effects, moderation, construct decision rules

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Why Micro-Randomization?

- Randomization (+ representative sample) is a gold standard in providing data to optimize multicomponent interventions.
- Sequential randomizations (+ representative sample) allows us to decide if a time varying component is effective and if so when and in which context.

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How is an MRT different from a JITAI?

- MRTs are experimental trial designs used to optimize JITAIs
 - MRTs always involve randomizing a participant multiple times
 - The purpose of the randomization is to provide data for optimization.
- JITAIs are intervention designs
 - Most JITAIs do not involve randomization
 - If a JITAI involves randomization this is to maintain engagement or to enhance therapeutic effects

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Primary Hypothesis

First Question: Does the intervention component (e.g. inspirational quote) affect the proximal outcome (e.g. evening self-report completion) on average across the study duration?

- This is akin to the main effect in factorial trials
- This is usually our pre-registered *primary* hypothesis (e.g. clinicaltrials.gov, open science)

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Secondary Hypotheses

- Time varying, potentially intensive/repetitive intervention delivery leading to potentially accumulating habituation:
 - Does the effect of the 4pm inspirational quote deteriorate with time?
- Assess potential tailoring variables:
 - Is the effect of the 4pm inspirational quote moderated by prior engagement?

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 change rapidly: Stress, urges to smoke, adherence, physical activity, eating
- NOT USEFUL: Proximal outcome cannot be feasibly assessed.
- USEFUL: Proximal outcome can be unobtrusively sensed or unobtrusively self-reported.

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Sample Size Calculation

We have used 2 approaches

1) Sample Size Calculator:

See workshop references:

<http://people.seas.harvard.edu/~samurphy/seminars/ReferencesRSASatelliteWorkshop.htm>

2) Prespecified recruitment time period

- 1) For feasibility studies
- 2) In the case of SARA this resulted in 74 participants.

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MRT vs. Randomized Control trial (RCT)

A randomized control trial (RCT) is used to evaluate a JITAI as compared to a suitable control.

- Assumes evidence exists to develop a high-quality JITAI including the choice of tailoring variables & decision rules
- The primary aim of an RCT is to evaluate the JITAI's effectiveness compared to an alternative
 - Is not well suited to constructing or optimizing a JITAI
- RCT is optimal for evaluation

Questions?

Your Task!

- Which scientific questions do you need to address in order to optimize your JITAI?
- Formulate an Experimental Study that will help you address your scientific question(s)
- After Pedja discusses the HeartSteps MRT you will get the opportunity to revise!