

Micro-randomized Trials in Mobile Health¹

2020 Environmental Statistics Discussion

Zhenke Wu

Assistant Professor

zhenkewu@umich.edu

Department of Biostatistics

School of Public Health

University of Michigan

2020-09-22

¹some slides sourced from Tim Necamp and Ambuj Tewari

Discussion Goals

1. Review micro-randomized trial (MRT) design: background and objectives (we will not cover data structure or analysis techniques today)
2. (All) Discuss the potential role of MRT in environmental health studies with a sensor or mobile app component

“Mobile Health?”

- ▶ Mobile health (mHealth) refers to the use of tools and platforms for health research and healthcare delivery
- ▶ In 2015 there were more than 7 billion mobile telephone subscriptions across the world, over 70% of which were in low- or middle- income countries.
 - ▶ In many such countries, people are more likely to have access to a mobile telephone than to clean water, a bank account or electricity.¹
- ▶ Software support for mHealth has greatly improved: ResearchKit (Apple), Open mHealth Data Framework, ...
- ▶ “Telemedicine”, “digital health”, “digital medicine”,...

Common Challenges in Mobile Health

1. Many health-related behavior change apps (fitness, weight loss and mental health) are not all based on solid science
2. Rapid innovation and cautious scientific approach
3. User retention: low frequency of usage, abandon or delete after a few uses
4. Barrier between domain scientists and backend developers of the apps

...

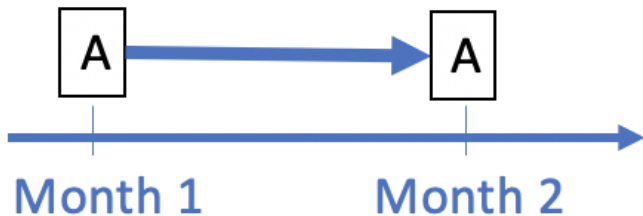
This Talk: Micro-randomization to empirically inform mHealth intervention development

Key value of MRT during intervention development:

- ▶ Generate data for informing decisions about many specifics - from the design of interface to the adaptation algorithms - that must be determined to implement an mHealth intervention

Background: Adaptive Interventions

- ▶ An intervention may not work for all people at all times



Background: Adaptive Interventions

- ▶ An intervention may not work for all people at all times
 - ▶ There may be
 - ▶ Heterogeneity over time



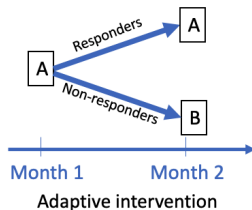
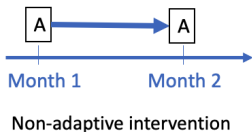
Non-adaptive intervention



Adaptive intervention

Background: Adaptive Interventions

- ▶ An intervention may not work for all people at all times
 - ▶ There may be
 - ▶ Heterogeneity over time
 - ▶ Heterogeneity across people



Background: Adaptive Interventions

1. Intervention options are adapted to address the unique and changing needs of the individual
2. Broadly speaking, the ultimate objective is to achieve the best outcome for each individual
3. Adaptive interventions are needed because
 - ▶ chronic nature of many health outcomes (mental health or behavior outcomes)
 - ▶ treatment effect heterogeneity within and between people

Background: Just-In-Time Adaptive Intervention (JITAI)

1. JITAIs are special cases of adaptive interventions where the intervention/support is provided just at the right time (e.g., within 50 meters of a liquor store based on GIS information)
2. Provide support when needed, as much as needed and only when needed
3. Adapt to changes at finer time scales (minutes, hours, instead of weeks/months)
4. Advances in sensor technology and increase in computational power of mobile devices is driving up interest in JITAIs

JITAI Example: Mobile-BASICS (Witkiewitz et al. 2014)

- ▶ behavioral intervention that targets heavy drinking and smoking
- ▶ 3 times per day, assesses smoking urge, affect and drinking behavior
- ▶ if high urge reported, the app delivers an urge-management intervention

JITAI Example: HeartSteps (NHLBI project)

1. Behavioral maintenance in physical activity year-long for patients after cardiac rehab
2. Momentary interventions: up to 5 times a day, provide context-specific suggestion for increasing physical activity
3. Daily interventions: up to once a day, ask user to plan an activity for the following day
4. Passively collected variables: weather, GPS location, activity (walking/cycling/driving), step count (via wristband), calendar busyness
5. Actively collected variables (once a day): appropriateness of suggestions, how hectic/stressful was day

JITAI Components (continued)

1. Decision points: Points in time when a treatment decision can be made
2. Intervention options
 - ▶ “Pull” intervention - participant initiated, e.g., entering the app to see her own past activity/sleep information, or goal-setting
 - ▶ “Push” intervention - intervention scientists specified; motivational messages, pointer to useful materials (**we focus on push interventions**)

JITAI Components (continued)

3. Tailoring variables: information that is used to make treatment decisions
 - ▶ Passively collected: time of day, day of week, weather, GIS, ...
 - ▶ Actively collected: ecological momentary assessments - on mood, urge, craving, burden, stress, etc.
4. Decision rules:
 - ▶ Key to making JITAI adaptive
 - ▶ If within 50 meters of a liquor store, then deliver a push notification intervention; otherwise, do not send anything

JITAI Components (continued)

5. Outcomes

- ▶ Distal outcome: ultimate goal - more longer term (e.g., quit smoking)
- ▶ Proximal outcomes: shorter time scales - JITAI can impact - the hope is to influence proximal outcomes frequently enough to influence the pathway related to the distal outcomes.

Examples of proximal outcomes:

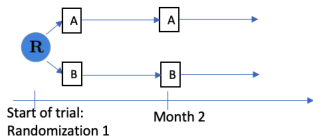
- ▶ number of cigarettes smoked in the next 3 hours
- ▶ number of episode of high smoking urge in the next 3 hours
- ▶ number of steps walked in the next 30 minutes

Typical Trials are Inadequate for Developing Adaptive Interventions

Unfortunately, typical trial designs limit the number of questions we can answer when developing adaptive interventions

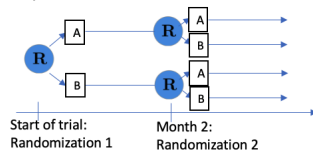
Sequential randomized trials (SRT) are designed to answer questions about sequencing, timing and personalization in adaptive interventions

Non-Sequential Randomized Trial



Answer questions about: Sequencing

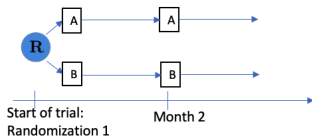
Sequential Randomized Trial



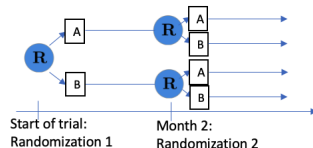
Answer questions about: Timing Personalizing

Sequential Randomized Trials for Developing Adaptive Interventions

Non-Sequential Randomized Trial



Sequential Randomized Trial



Answer questions about:

Sequencing

Timing

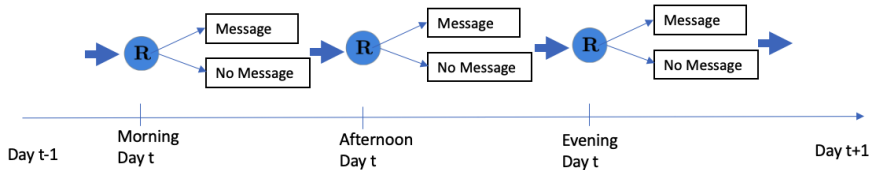
Personalizing

Re-randomization allows us to figure out how to change subsequent treatment based on data collected during the trial.

For example, I can use data collected during month 1 to figure out how to deliver treatment in month 2.

For non-sequential version, I cannot do this - I can only use data collected at baseline or before the first randomization

Micro-Randomized Trial (MRT)



Micro-Randomized Trial (MRT)

1. MRTs are useful for interventions that can be delivered quickly and frequently (such as delivering text messages or notifications to a subject's phone).
2. Typically, the goal of an MRT is to estimate the short-term effect of these interventions and understand how that effect depends on time and context.
3. MRTs have been mostly used in the mobile health space.
4. Due to the high frequency of intervention delivery, users in an MRT are typically re-randomized hundreds or thousands of times.

Proximal effect assessment. Answers questions of timing, and personalizing

Micro-Randomized Trial (MRT) - continued

Data is used to

1. Assess whether the intervention options have intended effect - main effect and moderation effect (by contextual information)
 - ▶ the options are often grouped in to buckets (“components”), we can use MRT to identify a subset of useful components
 - ▶ Further improvements (e.g., using reinforcement learning) based on the selected subset of components
2. Estimate “warm start” decision rules for more complex algorithms (reinforcement learning algorithms) over even a longer period of time

Summary

1. Mobile technology to make behavior changes that can help individuals make and sustain lifestyle changes needed to improve their health
2. JITAs have the potential to unleash the power of mobile devices for mHealth
 - ▶ Key components: decision points, intervention options, tailoring variables, decision rules, proximal/distal outcomes
 - ▶ Continuously adapt to provide optimal support to individuals as their needs and circumstances change.
3. key value of MRT during intervention development:
 - ▶ generate data for informing decisions about many specifics - from the design of interface to the adaptation algorithms - that must be determined to implement an mHealth intervention

Discussion (wild example 1)

1. GPS information to sense the locations, which helps adapt or warn an individual about her general smoking locations (church, grocery stores, parking lot, etc.). We can survey the number of cigarettes smoked and assess if such an app has any effect in reducing smoking.

Discussion (wild example 2)

2. Mobile phone can monitor the level of ambient noise; subjects receive adaptive push notification interventions depending on how noisy her environment is; MRT can evaluate whether the intervention helps reduce short-term exposure to noise

Discussion (wild example 3)

3. Dietary intake; an app that records each diet - track daily diet using the app; push notifications to change diet or do exercise; use MRT to assess if any effect towards “desired diet” or “desired level of energy expenditure”

References

1. Power calculation in MRT:
 - ▶ R package: MRTSampleSize²
 - ▶ ShinyApp³
 - ▶ Readings⁴
2. Easy-to-access analysis techniques: Qian et al. (2020+)⁵
3. The technical paper - continuous outcomes: Boruvka et al. (2018), JASA⁶
4. JITAI foundation paper: Nahum-Shani et al. (2017) Annals of Behavioral Medicine⁷
5. MRT Overview: Klasnja et al. (2015) Health Psychology⁸

²<https://rdrr.io/cran/MRTSampleSize/man/calculatePower.html>

³<https://pengliao.shinyapps.io/mrt-calculator/>

⁴<https://www.methodology.psu.edu/news/sample-size-calc-for-mrt/>

⁵<https://arxiv.org/abs/2004.10241>

⁶[https://amstat.tandfonline.com/doi/abs/10.1080/01621459.2017.](https://amstat.tandfonline.com/doi/abs/10.1080/01621459.2017.1305274#.X2qnaJNJEEY)

1305274#.X2qnaJNJEEY

⁷<https://academic.oup.com/abm/article/52/6/446/4733473>

⁸<https://psycnet.apa.org/doiLanding?doi=10.1037%2Fhea0000305>

Thanks for your attention!