Micro-Randomized Trials in mHealth: A Method for Optimizing Just-in-Time Adaptive Interventions

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97,000+ mobile apps for health & fitness

$20 billion: mHealth industry size by 2018
Ubiquity

>90% of U.S. adults have mobile phones. 65% have smartphones.
Close at Hand

Intimate Connection

Fast, Connected, Aware

Proximity
Wi-Fi
Camera
Microphone
GPS
Compass
Accelerometer
Gyroscope
Light
Bluetooth
Mobile Health

- Highly accessible
- Can sense individuals’ context & activities
- Enables sophisticated interventions
- Can provide just-in-time support throughout the day
Evidence So Far

• mHealth effective for smoking cessation and ART adherence
• Evidence for other conditions “promising” but insufficient

Free et al., 2014. PLOS Medicine
26% downloaded mHealth apps used only once

74% abandoned by the 10th use

Consumer Health Information Corporation, 2011
mHealth Design Challenges

We should aim to develop systems that...

• Can be used long-term
• Adjust to an individual’s changing goals and capabilities
• Deliver interventions at the right times and places
Anatomy of an mHealth intervention
Pull Interventions

Made available to users on the phone but accessed at will

- Graphs and charts for self-monitoring
- Coping strategies, educational materials
- “Help” button to receive coping support
Pull Interventions

• Allow inclusion of many components
• Put user in control of access
• Low burden

But…

• Depend on users to know when to access them and remember to do it
Push Interventions

Delivered based on time, context, user’s state and activities

• Reminders
• Suggestions, tips, motivational messages
• Prompts to set goals, complete EMA...
• Rewards for goal attainment
Push Interventions

• Can use sensing and user modeling to determine right delivery time
• Don’t rely on user’s awareness of times of need or remembering to access

But...

• High burden
Design Goal

Develop mHealth systems that include the right combination of pull and push components, delivered at the right times.
JITAIls: Interventions that continuously adapt their functioning in order to optimize health (and user-experience) outcomes.
JITAls: Just In Time Adaptive Interventions

- Delivered via mobile devices
- Anytime, anywhere
- When the person is in need and/or vulnerable
- When the person is receptive
**Methodological Challenge:** We need methods for intervention optimization and evaluation that assess whether, how and why an intervention is working over time.
What We Need to Know to Optimize a JITAI

• Do individual components work as intended?

• For whom and in what contexts do they work?

• How does component effectiveness change over time and what factors moderate these changes?

• How do different components in a complex intervention interact?
Micro-randomized trials: 
A Method for optimizing JITAls

MRTs in a Nutshell

1. Randomize delivery of a push intervention component each time that component *may be delivered*

2. Capture at each randomization...
   - Proximal outcome for randomized component
   - Contextual factors that may influence response

3. Model
   - Component’s time-varying causal effects
   - Time-varying contextual moderation of effects
Decision Times

Times when a push intervention component can be delivered, based on...

• Theory and prior experience
• User’s context
• Level of activity of interest
You have been sitting for 40 minutes. Get up and stretch your legs!

Studies have shown that prolonged sitting has harmful physiological effects. Getting up regularly, even just for a minute or two, helps prevent those effects.

Decision time: when user has been sitting for 40 minutes
Proximal Outcomes

Most immediate intended outcomes of an intervention component
You have been sitting for 40 minutes. Get up and stretch your legs!

Studies have shown that prolonged sitting has harmful physiological effects. Getting up regularly, even just for a minute or two, helps prevent those effects.

Proximal outcome: whether the user got up after the reminder
Proximal & Distal Outcomes

• Proximal outcomes are presumed mediators of desired distal outcomes
  • Micro versions of distal outcome
    15-min walk for walking 10,000 steps a day
  • Part of causal pathway to distal outcome
    interactions with abstinence-supporting friends for remaining drug-free

• Different intervention components can target different proximal outcomes
Unintended Outcomes

Intervention components can also have unintended outcomes

• Burden
• Annoyance
• Alert fatigue
Contextual Moderators

Sitting Reminder

You have been sitting for 40 minutes. Get up and stretch your legs!

OK
Randomization in MRTs

• A component is randomized at each decision point for each participant

• What can be randomized:
  • Whether component is delivered or not
  • What type of component is delivered
  • Combination of the two
    50% No intervention, 25% Type A, 25% Type B
• Multiple components can be randomized concurrently
• During a study, each person randomized 100s or 1000s of times
• MRTs are sequential, full factorial designs
Availability & Randomization

Delivery is randomized only if the person is available to receive the intervention
• It makes sense to deliver the intervention
• It is safe to deliver the intervention

Availability taken into account in effect estimations
Data Captured at Randomization

- Relevant outcomes:
  - Intended proximal outcomes
  - Likely unintended outcomes
- Potentially relevant contextual moderators
What We Learn From MRTs

• Does a component have a proximal main effect and how that effect changes over time?
• Does a component have unintended effects and how they change over time?
• How is a component’s effect moderated by time-varying contextual factors (e.g., location, weather, level of busyness)?
• Does a component have a lagged effect?
Heartsteps
HeartSteps: An mHealth Tool for Regular Walking

Intervention components:
• Actionable, contextually-relevant suggestions for physical activity
• Planning of when, how, and where one will be active the next day

Intended outcome: steps
Suggestions

Suggestions tailored on:
- time of day
- weekday vs. weekend
- location (work, home, other)
- weather

Two types of suggestions:
- to walk
- to interrupt sitting

Proximal outcome:
Steps in the next hour
Message Examples

Have a long conference call today? Walking in place or pacing while you talk can keep you engaged and increase your step count!

There's no better way to spend a weekend evening than taking a walk around the neighborhood! Are you up for it?

It's important to hydrate. If you walk to the water fountain now, you can refill your bottle while also stretching your legs!
Planning

Two types of planning:
• Generate a new plan
• Select a plan from a list of previous and suggested plans

Proximal outcomes:
• Step count the next day
• Self-report if plan followed
Context captured at each randomization

- Time of day
- Location (home/work/other)
- State of participant’s calendar (free/busy)
- Temperature and precipitation
- Participant’s activity (sedentary, walking, running, in vehicle)
- Phone activity
How hectic was your day today?

Not at all hectic

Very hectic

Did any of the following make it difficult for you to be active today? (choose all that apply)

- Poor weather
- No time/too busy
- No place to be active
- Illness or injury
- Sore muscles
Pilot Study Methods

• Six-week study with 40 sedentary adults
• Both components micro-randomized:
  • Suggestions 5 times a day (morning, lunch time, mid-afternoon, evening commute, post-dinner)
    • No suggestion, walk suggestion, get-up suggestion
  • Planning every night (yes/no planning)
• Capturing steps, location, weather, calendar, phone application use, user burden, answers to daily questionnaires
Pilot Study Goals

• Assess time-varying proximal effects for each intervention component

• Understand for whom, when, and in what circumstances components have an effect

• Understand how components affect user burden

Determine default decision rules for adaptive version of HeartSteps