Experimental Designs for Optimizing Tech-Based Interventions

INBAL (BILLIE) NAHUM-SHANI

mHealth Summer Institute
August 2017
Key Definition

- Multi-Component Interventions
  - Component:
    - The content of the intervention (e.g., topics in prevention program)
    - The intervention modality (e.g., phone calls/emails)
    - Features to promote compliance, engagement (e.g., reminder, prompt)

- Example:
  - Optimizing a technology supported intervention for weight loss:
    - Telephone Caching
    - Report to Primary Care Provider
    - Text Messages
    - Meal Replacements
    - Buddy Training

Bonnie Spring, PI. DK097364
How do We Typically Develop Interventions?

1. Scientific Model
2. Intervention Components
3. Intervention Package
4. Confirm Effectiveness
How do We Typically Develop Interventions?

1. Theoretical Model
2. Intervention Components
3. Intervention Package
4. Confirm Effectiveness
Open Questions

Fixed Intervention
- Efficacy of individual components
  - Which component is effective?
  - Which level of a component is most appropriate?
  - Which components work well together

Adaptive Intervention
- How to select and adapt components over time
  - Which component to offer at each decision point
  - How to individualize components to address the changing needs of participants

Just-In-Time Adaptive Intervention (JITAI)
- How to select and adapt components over time
  - Which component to offer at each decision point
  - How to individualize components to address the rapidly changing needs of participants
## Open Questions

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### Just-In-Time Adaptive Intervention (JITAI)
- How to select and adapt components over time
  - Which component to offer at each decision point
  - How to individualize components to address the rapidly changing needs of participants

### Factorial Designs

### SMART

### MRT
Factorial Designs
Factorial Designs

- Factorials: More than 1 factor; levels of each factor crossed with levels of other factors.

  ➤ Should I include *Text Messages*? ??
  - Factor 1: Text *(On/Off)*

  ➤ Should I include *Meal Replacement*? ??
  - Factor 2: Meal *(On/Off)*
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## Factorial Designs

- Power for comparing package vs. control?

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SMART Designs

- **Adaptive Intervention:**
  - Intervention design that uses ongoing/dynamic information about the individual to decide whether and how to modify components.

- **Hypothetical Example:** (NIH/NIDDK R01DK108678; Spring & Nahum-Shani)

At week 0
Stage 1 = \{Text\},
Then, at week 2
\textbf{IF} response = \{NO\}
\textbf{THEN} stage 2 = \{Add Buddy\}
\textbf{ELSE IF} response = \{YES\}
\textbf{THEN} stage 2 = \{Continue\}

Week 0
---
Text
Non-Responders
Add Buddy
Week 2
Responders
Continue

Add Buddy
At week 0
Stage 1 = {Text},
Then, at week 2
IF response = {NO}
THEN stage 2 = {Add Buddy}
ELSE IF response = {YES}
THEN stage 2 = {Continue}
SMART Designs

Components of Adaptive Interventions

At week 0
Stage 1 = \{Text\},
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\textbf{IF} response = \{NO\}
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\textbf{THEN} stage 2 = \{Continue\}
SMART Designs

- Components of Adaptive Interventions

3. Decision rule

At week 0
Stage 1 = {Text},
Then, at week 2

IF response = {NO}
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ELSE IF response = {YES}
THEN stage 2 = {Continue}
SMART Designs

Components of Adaptive Interventions

At week 0
Stage 1 = {Text},

Then, at week 2

IF response = {NO}
    THEN stage 2 = {Add Buddy}

ELSE IF response = {YES}
    THEN stage 2 = {Continue}
At week 0
  Stage 1 = {Text},
Then, at week 2
  IF response = {NO}
    THEN stage 2 = {Add Buddy}
  ELSE IF response = {YES}
    THEN stage 2 = {Continue}

5. Outcomes
Distal ➔ Long-term goal of intervention:
  5% weight loss by month 12
Proximal ➔ Short-term goal of decision rules
  Ongoing weight loss in the course of the program
**Components of Adaptive Interventions**

- **Decision Points**
  - Tailoring Variable
  - Decision rule
  - Intervention Options

- **Trigger**
  - Monitoring
  - Individualizing
  - Delivering

- **Outcomes:** Proximal + Distal

**Adaptation process**

**Guide**
SMART Designs

Why do we need AIs?

- **Heterogeneity**: what works for one person might not work for another

- **Cost**: Some mHealth components are costly; resources are often limited

Week 2

- Text
- Responders
- Non-Responders

- Add Buddy
- Continue
SMART Designs

- Why do we need AIs?
SMART Designs

- SMARTs can help us build empirically-based adaptive interventions:
  - Randomized Trials
  - Multiple stages of randomization
  - Each stage corresponds to a decision point
    - at which we have scientific questions about the selection and individualization of components
Hypothetical Example (NIH/NIDDK R01DK108678; Spring & Nahum-Shani)

- Aim: Develop an adaptive technology-supported weight loss intervention
- Open scientific questions
  - Q1. Which component to offer first: Text or Phone?
  - Q2. Which component to add for non-responders: Buddy or Phone?
Hypothetical Example (NIH/NIDDK R01DK108678; Spring & Nahum-Shani)

- Aim: Develop an adaptive technology-supported weight loss intervention
- Open scientific questions
  - Q1. Which component to offer first: Text or Phone?
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SMART Designs

Questions we can address with a SMART

- First-stage intervention component:
  - Is it better to start with Phone Coaching or Text Messages?
  - (SG1+SG2+SG3) vs. (SG4+SG5+SG6)
  - Main effect of Phone Coaching vs. Text Messages

Controlling for subsequent intervention component

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<tr>
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$N=400$
SMART Designs

Questions we can address with a SMART

• Second-stage intervention component:
  ▶ For non-responders: Is it better to add Phone or Buddy?
  ▶ (SG2+SG5) vs. (SG3+SG6)
  ▶ Phone Coaching vs. Buddy Training
SMART Designs

Questions we can address with a SMART

- Embedded adaptive interventions

At week 0

Stage 1 = {Text},

Then, at week 2

IF response = {NO}

THEN stage 2 = {Add Buddy}

ELSE IF response = {YES}

THEN stage 2 = {Continue}
SMART Designs

Questions we can address with a SMART

- Embedded adaptive interventions

At week 0
Stage 1 = \{Text\},
Then, at week 2
IF response = \{NO\}
 THEN stage 2 = \{Add Phone\}
ELSE IF response = \{YES\}
 THEN stage 2 = \{Continue\}
SMART Designs

Questions we can address with a SMART

- Embedded adaptive interventions

At week 0
Stage 1 = {Phone},

Then, at week 2
  IF response = {NO}
  THEN stage 2 = {More Phone}
  ELSE IF response = {YES}
  THEN stage 2 = {Continue}
SMART Designs

Questions we can address with a SMART

- Embedded adaptive interventions

At week 0

Stage 1 = \{Phone\},

Then, at week 2

IF response = \{NO\}

THEN stage 2 = \{Add Buddy\}

ELSE IF response = \{YES\}

THEN stage 2 = \{Continue\}
SMART Designs

Questions we can address with a SMART

At week 0

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\textbf{IF} response = \{NO\}

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\textbf{ELSE IF} response = \{YES\}

\textbf{THEN} stage 2 = \{Continue\}

\textbf{VS.}

At week 0

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\textbf{ELSE IF} response = \{YES\}

\textbf{THEN} stage 2 = \{Continue\}

\textbf{N=400}

\begin{itemize}
  \item Phone \quad \text{Response} \quad \text{Continue (SG1)}
  \item Phone (SG2) \quad \text{Non-Response} \quad \text{Buddy (SG3)}
  \item Text \quad \text{Response} \quad \text{Continue (SG4)}
  \item Phone (SG5) \quad \text{Non-Response} \quad \text{Buddy (SG6)}
\end{itemize}
MRT Designs
• Decision point at weeks 0 and 2
• Why? because meaningful changes in tailoring variable are expected to occur over 2 weeks.
• What if meaningful changes in the tailoring variable are expected to occur over a minute?

From AI to JITAI

At week 0
Stage 1 = \{Text\},
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Decision point at weeks 0 and 2

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From AI to JITAI

- Decision point at weeks 0 and 2
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What is a JITAI?

At week 0
Stage 1 = {Text},
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IF response = {NO}
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ELSE IF response = {YES}
THEN stage 2 = {Continue}
Example of a JITAI

- Goal: smoking cessation support
- Stress presents risk for lapse (slip)
  - Stress: a state characterized by high arousal and displeasure (Kristensen, 1996; Posner et al., 2005)
  - Can be triggered by various circumstances in real-life
- Wearable sensors monitor physiology
- Algorithm uses this info to decide on every given minute whether stress occurs
- If stress is detected → recommendation to engage in a stress-regulation exercise
Example of a JITAI

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Why is this a JITAI?
What is Just-In-Time?

- Do the right thing / the right type of support
- At the right time
- While minimizing waste (disruptions)
What is Just-In-Time?

- Assumptions:
  - Timing is salient in support effectiveness
  - Timing => ‘event-based’
  - Event-based timing is unexpected (Ancona et al., 2001)
    - Hence, the need to monitor
  - Time is salient when it’s running out (Wessman & Gorman, 1977)
    - Conditions that define the ‘right time’ change rapidly, over short time-frames
      - a few days, hours, minutes, seconds
What is Just-In-Time?

- An attempt to provide support to addresses condition that change
  - Rapidly
  - Unexpectedly

- How?
  - Monitor continuously
    - Identify the right time
  - Provide the right type of support
    - As soon as the right time occurs
    - Only when the right time occurs
What is Just-In-Time?

- An attempt to provide support to addresses condition that change
  - Rapidly
  - Unexpectedly

How?

- Monitor continuously
  - Identify the right time
- Provide the right type of support
  - As soon as the right time occurs
  - Only when the right time occurs
What is Adaptation?

- Use of ongoing information about the person to decide whether/when/how to modify components
- Operationalized via decision rules

*Every minute*

**IF** stress = Yes  
**THEN**, IO = {Prompt}

**ELSE IF** stress ≠ Yes  
**THEN**, IO = {Nothing}
Every minute

**IF stress** = Yes

**THEN**, IO = {Prompt}

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1. Tailoring Variable
Every minute

IF stress = Yes

THEN, IO = \{Prompt\}

ELSE IF Stress ≠ Yes

THEN, IO = \{Nothing\}

2. Intervention options

What is Adaptation?
Every minute

**IF** stress = *Yes*

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3. Decision rule

- What is Adaptation?
What is Adaptation?

Every minute

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MRT

- What is Adaptation?

Every minute
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5. Outcomes
Distal ➔ Long-term goal of intervention:
- Smoking cessation
Proximal ➔ Short-term goal of decision rules
- Reduce lapse probability;
- Increase time to next stress episode
Elements of a JITAI?

- Decision Points
  - Tailoring Variable
  - Decision rule
  - Intervention Options

- Trigger
  - Monitoring
  - Individualizing
  - Delivering

- Outcomes: Proximal + Distal

- Guide

MRT

Elements of a JITAI?
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Just In Time Support

Address conditions that are likely to occur

- Rapidly
- Unexpectedly
- Vulnerability and/or Opportunity
Just In Time Support

Address conditions that are likely to occur

- Rapidly
- Unexpectedly
- Vulnerability and/or Opportunity
- In the person’s natural environment
- Elements of a JITAI?
  - Stress can occur anywhere
    - Outside of standard treatment setting
    - As people go about their daily lives
Elements of a JITAI?

Every minute

IF stress = Yes
  THEN, IO = {Prompt}
ELSE IF stress ≠ Yes
  THEN, IO = {Nothing}

Therapist in the pocket to...

- Monitor the participant physiology continuously
- Use this information to decide whether stress occurs
- Deliver the intervention as soon as stress occurs
- In the person’s natural environment
Elements of a JITAI?

- The phone is always in your pocket
  - Wide range of embedded sensors: e.g., accelerometer, camera, GPS, microphone, and the touchscreen sensors.
  - Other wearable sensors: e.g., hand movement sensors, electrocardiogram, galvanic skin response sensors.
  - Ecological Momentary Assessment (EMAs)
  - Deliver the intervention as soon as needed, in the natural environment.

Advances in mobile and wireless technology open new possibilities for the delivery of JITAIs
Elements of a JITAI?

- In the person’s natural environment
- Multiple demands compete for his/her time and effort
Elements of a JITAI?

- Address conditions that
  - change rapidly,
  - unexpectedly,
  - and in the person’s natural environment.
- While minimizing disruptions to the daily life and routine of the participant.
Every minute

**IF** stress = Yes *and* min since last intervention > 60 *and* driving = No  
**THEN**, IO = {Prompt}

**ELSE IF** stress ≠ Yes *or* min since last intervention ≤ 60 *or* riving = Yes  
**THEN**, IO = {Nothing}
Open scientific questions about the construction of a JITAI

- Should we provide a prompt when the person is stressed?

**State of vulnerability:** Heightened risk for lapse
- Prompt when stress occurs
- Break the link between stress and lapse.

**State of unreceptivity:** Limited cognitive capacity
- Don’t prompt when stress occurs
- If you do, it would be wasteful/disruptive

MRT
What is a Micro-Randomized Trial (MRT)?

- MRT to A JITAI is what a SMART is to an AI
- Randomize each participant between intervention options at each decision point
- Each person may be randomized 100’s or 1000’s of times, multiple times per day.
  - These are sequential, “full factorial,” designs.
  - Extension of A/B testing & Single Case Designs
What is a Micro-Randomized Trial (MRT)?

- Do the intervention options impact the proximal outcome?
  - Under stress, is the prompt better in preventing a lapse compared to no prompt?
### Sense2Stop MRT

- **10 day study**
- **Smokers, >1 cigs/day**
- **Following the person’s quit date.**

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<th>Day</th>
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<th>Treatment</th>
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<tbody>
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<td>4</td>
<td>TAPERING</td>
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</table>
• Sense2Stop MRT

• Every minute in which the person is receptive: is evidence of stress sufficient?

• If yes-- micro-randomize to prompt vs. no prompt

• When the person is receptive and there is sufficient evidence of stress, would a prompt result in better proximal outcome compared to no prompt
Summary

**Fixed Intervention**
- Efficacy of individual components
  - Which component is effective?
  - Which level of a component is most appropriate?
  - Which components work well together

**Adaptive Intervention**
- How to select and adapt components over time
  - Which component to offer at each decision point
  - How to individualize components to address the changing needs of participants

**Just-In-Time Adaptive Intervention (JITAI)**
- How to select and adapt components over time
  - Which component to offer at each decision point
  - How to individualize components to address the rapidly changing needs of participants

**Factorial Designs**
- SMART
- MRT
Experts + Resources

Design expert collaborators:

• Factorial Designs
  ► Linda Collins: http://methodology.psu.edu/people/lcollins
  ► John Dziak: http://methodology.psu.edu/people/jdziak

• SMART+MRT
  ► Susan Murphy: http://dept.stat.lsa.umich.edu/~samurphy/
  ► Danny Almirall: http://www-personal.umich.edu/~dalmiral/
Experts + Resources

- **Resources:**
  - **Factorials:**
    - Q&A: [https://methodology.psu.edu/ra/most/fefaq](https://methodology.psu.edu/ra/most/fefaq)
  - **SMART:**
    - Projects using SMARTs: [https://methodology.psu.edu/ra/adap-inter/projects](https://methodology.psu.edu/ra/adap-inter/projects)
  - **MRT**
    - Boruvka, A., Almirall D., Murphy, S.A. (in press). Assessing Time-Varying Causal Effect Moderation in Mobile Health... JASA
Questions

Inbal (Billie) Nahum-Shani
University of Michigan
inbal@umich.edu