Fogarty International Center

Global mHealth Research Training Institute

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Center for Global Health Studies





Experimental Designs for Optimizing Interventions Inbal (Billie) Nahum-Shani

How do you evaluate? Global mHealth Research Training May 2016





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 or adherence (e.g., reminder emails)

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?



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Open Questions

- Efficacy of Individual components
 - Which components are effective?
 - Which level is more appropriate?
 - Which components work well together?
- Sequencing of components
 - Which component to offer first?
 - Which to offer subsequently?
 - How should I tailor components over time?



Open Questions



- 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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Experimental conditions 2X2 factorial N=400			
Experiment Factor			
Condition	Text Meal		
1 (N=100)	On	On	
2 (N=100)	On	Off	
3 (N=100)	Off	On	
4 (N=100)	Off	Off	

- 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)
- Main effect: **On** (N=200) vs. **Off** (N=200)
- Should I include *Meal Replacement*?
- Factor 2: Meal (On/Off)

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- Factor 2: Meal (On/Off)
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• Factor 3: Buddy (On/Off)

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 - Factor 3: Buddy (On/Off)

Experimental conditions 2X2X2 factorial N=400				
Condition	Factor			
	Text Meal Buddy			
1 (N=50)	On	On	On	
2 (N=50)	On	On	Off	
3 (N=50)	On	Off	On	
4 (N=50)	On	Off	Off	
5 (N=50)	Off	On	On	
6 (N=50)	Off	On	Off	
7 (N=50)	Off	Off	On	
8 (N=50)	Off	Off	Off	

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4 (N=50)	On	Off	Off	
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2 (N=50)	On	On 🔳	Off	
3 (N=50)	On	Off \	On	
4 (N=50)	On	Off 🤳	Off	
5 (N=50)	Off	On	On	
6 (N=50)	Off	On 🔳	Off	
7 (N=50)	Off	Off 7	On	
8 (N=50)	Off	Off _	Off	

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3 (N=50)	On	Off	On 🔶	
4 (N=50)	On	Off	Off ←	
5 (N=50)	Off	On	On 🗲	
6 (N=50)	Off	On	Off ←	
7 (N=50)	Off	Off	On 🗲	
8 (N=50)	Off	Off	Off 🗲	

Power for comparing package vs. control?

	Experimental conditions 2X2 factorial N=400				
	Experiment	Factor			
	Condition	Text	Meal		
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	6 (N=50)	Off	On	Off
	7 (N=50)	Off	Off	On
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- Adaptive Intervention:
 - Intervention design that uses ongoing/dynamic information about the individual to decide which component to offer, when and how.
- Hypothetical Example: (NIH/NIDDK R01DK108678; Spring & Nahum-Shani)



Motivation in the context of technology-supported interventions:



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



Boredom: Lack of interest in and difficulty concentrating on the task.



Burden: The "workload" required from participants and the impact on their well-being.

- SMARTs can help us build empirically-based adaptive interventions:
 - Randomized Trials
 - Multiple stages of randomization
 - Each stage corresponds to a critical question concerning the sequencing and adaptation of intervention options over time

- 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?



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



- 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



Embedded adaptive interventions

Stage 1 = {Text}, Then IF response = {NO} THEN stage 2 = {Add Buddy} ELSE IF response = {YES} THEN stage 2 = {Step-Down}



Embedded adaptive interventions



Embedded adaptive interventions

Stage 1 = {Phone}, Then IF response = {NO} THEN stage 2 = {Add Phone} ELSE IF response = {YES} THEN stage 2= {Step-Down}



Embedded adaptive interventions

```
Stage 1 = {Phone}
Then,
IF response = {NO}
THEN stage 2 = {Add Buddy}
ELSE IF response = {YES}
THEN stage 2= {Step-Down}
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Embedded adaptive interventions

Stage 1 = {Phone},Stage 1 = {Text},ThenThenThenIF response = {NO}VS.IF response = {NO}THEN stage 2 = {Add Phone}THEN stage 2 = {Add Buddy}ELSE IF response = {YES}ELSE IF response = {YES}THEN stage 2 = {Step-Down}THEN stage 2 = {Step-Down}



Summary

- Factorial Designs:
 - Efficacy of Individual components
 - Which components are effective?
 - Which level is more appropriate?
 - Which components work well together?

SMART Designs:

- Sequencing and adaptation of components
 - Which component to offer first?
 - Which to offer subsequently?
 - How should I tailor components over time?

Experts + Resources

- Collaborators:
 - U of Michigan: Statistical Reinforcement Learning Lab
 - Susan Murphy: http://dept.stat.lsa.umich.edu/~samurphy/
 - Danny Almirall: <u>http://www-personal.umich.edu/~dalmiral/</u>
 - Penn State: Methodology Center
 - Linda Collins: <u>http://methodology.psu.edu/people/lcollins</u>
 - John Dziak: http://methodology.psu.edu/people/jdziak
- Resources:
 - SMART:
 - Projects using SMARTs: <u>https://methodology.psu.edu/ra/adap-inter</u>
 - Lei, H., Nahum-Shani, I., Lynch, K., Oslin, D., & Murphy, S. A. (2012). A "SMART" design for building individualized treatment sequences. *Annual Review of Clinical Psychology*, 8, 14.1 14.28
 - Factorials:
 - Q&A: <u>https://methodology.psu.edu/ra/most/fefaq</u>
 - Collins, L. M., Dziak, J. J., & Li, R. (2009). Design of experiments with multiple independent variables: A resource management perspective on complete and reduced factorial designs. *Psychological Methods*, 14, 202-224.

Questions

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