SOCIETY FOR PREVENTION RESEARCH
23RD ANNUAL MEETING
WASHINGTON, DC

Pre-Conference Workshop III

Date: Tuesday, May 26, 2015
Time: 8:30 am – 5:00 pm

Getting *SMART*: Experimental Design Methods for Developing Adaptive Interventions

Presenters:

Daniel Almirall, PhD, Research Assistant Professor, Survey Research Center, University of Michigan

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Description

The prevention and management of many health disorders often entails a sequential, individualized approach whereby intervention is adapted and re-adapted over time in response to the specific needs and evolving status of the individual. Adaptive interventions provide one way to operationalize the strategies (e.g., continue, augment, switch, step-down) leading to individualized sequences of treatment. An adaptive intervention is a sequence of decision rules that specify whether, how or when (timing), and based on which measures, to alter the dosage (duration, frequency or amount), type, or delivery of treatments in the course of an individual or patient's care. Often, a wide variety of critical questions must be answered when developing a high-quality adaptive intervention. Yet, there is often insufficient empirical evidence or theoretical basis to address these questions. The Sequential Multiple Assignment Randomized Trial (SMART)—a type of experimental design—was developed explicitly for the purpose of building efficacious adaptive interventions. SMARTs represent an attractive alternative to the standard randomized clinical trial when the overarching aim is to construct (as opposed to evaluate) a high-quality adaptive intervention.

Learning objectives of workshop: The learning objectives of this one-day pre-conference workshop are to (a) provide an introduction to adaptive interventions and (b) help you to gain the background you need to use the SMART design.

Targeted workshop audience and prerequisites: The targeted audience is behavioral intervention researchers interested in designing and conducting experimental studies for developing and evaluating high-quality behavioral interventions. The main prerequisite for this workshop is familiarity with the basic principles of experimental (e.g., randomized trial) design.

Specific topics covered:

- What is an adaptive intervention
- When and why adaptive interventions are necessary
- How adaptive interventions differ from fixed (one-stage) interventions

- Key elements of an adaptive intervention: decision points, tailoring variables, intervention options and decision rules
- The role of theoretical, practical and empirical evidence in building adaptive interventions
- Examples of adaptive interventions from the literature
- What is a SMART: SMART study principles
- Why SMARTs are needed: How to provide a rationale for designing a SMART
- How SMARTs differ from standard randomized clinical trials
- Different types of SMART designs
- Common types of primary and secondary scientific aims in a SMART
- Sample size considerations in designing a SMART

Suggested Advanced Reading:

1. Collins, L. M., Murphy, S. A., & Bierman, K. A. (2004). A conceptual framework for adaptive preventive interventions. *Prevention Science, 5,* 185-196.
2. Lei, H., Nahum-Shani, I., Lynch, K., Oslin, D., & Murphy, S.A. (2012). Using Sequential, Multiple Assignment, Randomized Trial (SMART) Designs to Build Individualized Treatment Sequences. *Annual Review of Clinical Psychology*, 8, 21-48.
3. Nahum-Shani, I., Qian, M., Almirall, D., Pelham, W.E., Gnagy, B., Fabiano, G., Waxmonsky, J., Yu, J., & Murphy, S. (2012). Experimental Design and Primary Data Analysis for Developing Adaptive Interventions. *Psychological Methods*, 17(4), 457.
4. Almirall D., Nahum-Shani, I., Sherwood, N.E., & Murphy S.A. (2014). Introduction to SMART Designs for the Development of Adaptive Interventions: With Application to Weight Loss Research. *Translational Behavioral Medicine*, 4(3) 260-274.

Materials to be provided to attendees: Slides will be provided to attendees ahead of the workshop.

Presenters: Drs. Nahum-Shani (a behavioral scientist by training: http://www-personal.umich.edu/~inbal/) and Almirall (a statistician by training: http://www-personal.umich.edu/~dalmiral/) are experts in the area of adaptive interventions and SMART. Nahum-Shani is the leading author of two consecutive articles on SMART methodology in *Psychological Methods.* She is expert on the application of the SMART methodology for developing behavioral interventions, and particularly technology-mediated interventions. Almirall has published on the design, conduct and analysis of SMART in journals such as *Statistics in Medicine* and the *Journal of the American Statistical Association*. He is an expert in methods for causal inference in which treatments, covariates, and outcomes are all time-varying. Drs. Nahum-Shani and Almirall have conducted over 30 workshops on adaptive interventions and SMART methodology. Both were trained by Dr. Susan A. Murphy, a NIDA grantee and pioneer in methods for the development of adaptive interventions and SMART, and by Dr. Collins, Director of the NIDA-funded Methodology Center and leader in the use of experimental designs for building, optimizing, and evaluating behavioral interventions.

Getting *SMART*: Experimental Design Methods for Developing Adaptive Interventions
Society for Prevention Research, Pre-conference Workshop
Daniel Almirall, Billie Nahum-Shani, and Susan A. Murphy

May 26 -- 8:30AM-5:00PM		
Session	**Time**	**Topic**
INTRO	**8:30-9:00PM (30 min)**	**Introductions, Course Outline & Structure, Discuss Three Practicums** • Choose groups to work in based on mutual substantive interest
MODULE 1	**9:00-10:15PM (75 min)**	**Introduction to Adaptive Interventions** • What are adaptive interventions (AI)? • What are the components of an AI? • Compare simple vs deeply-tailored AIs. • Why are AIs needed? • The use of theory in designing an AI • How AIs inform clinical practice?
BREAK	**10:15-10:30PM**	**15 Minute Break for Bathroom, Coffee, Snacks (Recall Lunch is at 12:30PM)**
PRACTICUM	**10:30-11:30PM (60 min)**	**Interactive, Small-Group Exercises with Discussion & Feedback** • Review questions / discussion • Develop initial example adaptive interventions in your area of study • List 4 critical questions that need to be answered to develop a high-quality AI
MODULE 2	**11:30-12:30PM (60 min)**	**Sequential Multiple Assignment Randomized Trials (SMARTs)** • What are SMARTs? Why do we need SMARTs? • Utilizing theory to plan a SMART • SMARTs versus using a multiple-RCT approach to develop an AI • Discuss SMART design principles • What are typical primary and secondary aims in a SMART? • Sample size considerations in designing a SMART
LUNCH	**12:30-01:30PM**	**1 Hour Working Lunch + Q&A: Lunch Provided**
MODULE 3	**01:30-02:45PM (75 min)**	**Case Studies: Five SMART Studies Completed or in the Field** • Present SMARTs in autism, child ADHD, women who are pregnant and abuse substances, adult alcohol use, depression in implementation science • For each SMART: Present and discuss the rationale for

		the SMART, primary and secondary scientific questions, range of treatments/components examined, type of SMART (e.g., restricted, balanced), sample size
BREAK	**02:45-03:00PM**	**15 Minute Break for Bathroom, Coffee, Snacks**
PRACTICUM	**03:00-04:30PM (90 min)**	**Interactive, Small-Group Exercises with Discussion & Feedback** • Sketch a SMART design to addresses your 4 critical questions • Outline/sketch the argument/rationale for your SMART design • List and discuss your top 2 major concerns about the proposed SMART design
WRAP-UP / TIME BUFFER	**04:30-5:00PM (30 min)**	**Point to literature and where to learn more, including about analysis of data arising from a SMART. Allow some time to address any remaining FAQs or in case we go over on time.**