

**Society for Prevention Research
25th Annual Meeting
Washington, DC**

Pre-Conference Workshop III

Date: Tuesday, May 30, 2017

Time: 8:30 am – 5:00 pm

The Nuts and Bolts of Group Randomized Trials

Organizer: Jocelyn A. Lee, National Institutes of Health, Office of Disease Prevention

Presenter: David M. Murray, PhD, National Institutes of Health, Office of Disease Prevention

Description:

The goals of the workshop are to provide attendees with training on the technical issues and statistical analyses distinctive to Group Randomized trial design and analysis. By the end of the workshop, attendees should have the tools and skills needed to describe the strengths, weaknesses, and appropriate uses of randomized clinical trials (RCTs), group-randomized trials (GRTs), and Individually randomized group treatment trials (IRGTs); discuss the strengths and weaknesses of design and analytic alternatives available for these trials; critique published trials that used these designs; and perform sample size calculations for these designs.

Target workshop audience:

The target workshop audience will be academic researchers and graduate students with graduate level training in experimental design and multivariate statistics.

Materials to be provided to attendees:

Attendees will be provided with (a) the slides used in the workshop; (b) a list of references for methodological papers on GRTs and IRGTs; (c) several published papers employing GRT and IRGT designs; and (d) excel spreadsheets useful for sample size calculations for GRTs and IRGTs.

Workshop Outline:

- a. **Part 1: Introduction and Overview** – Part 1 will provide an introduction and overview of the three kinds of randomized trials and their distinguishing characteristics. The differences between group-randomized trials (GRTs) and individually randomized group-treatment trials (IRGTs) will be discussed.
- b. **Part 2: Designing the Trial** - Part 2 will consider the design of group-randomized trials (GRTs), with a focus on internal and statistical validity, the factors that influence precision, and the major features that define variations in group-randomized trial designs, including cohort vs. cross-sectional designs; matching, stratification, and constrained randomization; and time as a factor.

- c. **Part 3: Analysis Approaches** - Part 3 will provide analysis approaches to group-randomized trials (GRTs), including a review of model-based approaches, randomization tests, marginal methods like generalized estimating equation (GEE), methods for complex survey samples, two-stage methods, methods for unbalanced designs, methods used with constrained randomization, and methods for individually randomized group-treatment trials (IRGTs).
- d. **Part 4: Power and Sample Size** - Part 4 will explore power and sample size for group-randomized trials (GRTs). The lecture will focus on Cornfield's two penalties of extra variation and limited degrees of freedom (df); strategies to reduce extra variation and increase df; the seven steps involved in any power analysis; estimating the intraclass correlation coefficient (ICC); and adaptations required for unbalanced designs. This lecture will also provide an example of a sample size calculation for a simple GRT.
- e. **Part 5: Examples** - Part 5 will provide examples of group-randomized trials (GRTs) from a 2016 NIH/CDC collaborative analysis of GRTs focused on cancer and lifestyle-based interventions.
- f. **Part 6: Review of Recent Practices** - Part 6 will review recent practices in group-randomized trials (GRTs) based on a paper soon to be published by Murray, et al., in 2016 in the Journal of the National Cancer Institute. The lecture will also explore recent practice[s] for individually randomized group-treatment trials (IRGTs) based on a paper published by Murray et al. in 2009 in the Journal of the National Cancer Institute 2009 and by Pals et al. in 2008 in the American Journal of Public Health. All three papers review published studies and critique the methods used for design, sample size calculation, and analysis.
- g. **Part 7: Alternative Designs** - Many alternative designs have been proposed to evaluate interventions delivered to or through groups, including multiple baseline designs, time series designs, quasi-experimental designs, stepped wedge designs, and regression discontinuity designs. Part 7 will examine these designs in comparison to group-randomized trials (GRTs) and individually randomized group-treatment trials (IRGTs) with a focus on internal validity and cost in terms of time and participants.

Presenter:

David M. Murray, PhD, Associate Director for Prevention and Director of the Office of Disease Prevention, NIH

Dr. Murray completed his B.A. in Psychology from Denison University in 1973. He completed his Ph.D. in Experimental Psychology at the University of Tennessee, Knoxville, in 1978. In 1981, he completed a National Heart Lung and Blood Institute-funded postdoctoral fellowship in Cardiovascular Health Behavior in the Laboratory of Physiological Hygiene, a division of the School of Public Health at the University of Minnesota. He joined the faculty of the Laboratory immediately after his fellowship. The Laboratory was founded by Ancel Keys and was the home of Henry Taylor, Henry Blackburn and other pioneers in cardiovascular epidemiology.

Dr. Murray began his work in prevention research during his postdoctoral fellowship at Minnesota, working closely with C. Anderson Johnson and Russell V. Luepker on the Robbinsdale Anti-Smoking Project, and later on several followup studies funded by the National Institute of Child Health and Human Development and by the National Cancer Institute. After he joined the faculty in the Laboratory of Physiological Hygiene in 1981, he expanded into

prevention research on alcohol, tobacco, and other drugs in adolescent populations, working closely with Cheryl Perry. Those projects were funded by the National Institute on Drug Abuse.

At about the same time, he became involved in the Minnesota Heart Health Program (MHHP), serving initially as Co-Youth Education Director with Cheryl Perry, then as Associate Health Program Director with Maury Mittelmark, and later as Health Program Director and Co-Principal Investigator with Henry Blackburn, Russell Luepker, David Jacobs, Neil Bracht and the other MHHP investigators. At the time, the Minnesota Heart Health Program was the largest NIH grant ever awarded to the University of Minnesota. It was one of three community-based heart disease prevention programs funded by the National Heart Lung and Blood Institute in the 1980s and early 1990s and helped create the basis for the community-based health promotion and disease prevention programs we see today.

Many other studies developed out of the Minnesota Heart Health program, including the Promotion of Healthy Eating Patterns in Youth (Cheryl Perry, PI), Children's Activity Trial for Cardiovascular Health (Cheryl Perry, PI), and Models for Treating High Blood Cholesterol (Russell Luepker, PI). All were funded by the National Heart Lung and Blood Institute.

Most of these studies were examples of group-randomized trials. In these studies, identifiable social groups are the unit of assignment, while members of those groups are the units of observations. The design and analytic issues inherent in these studies were not well understood in the 1980s and 1990s, though Jerome Cornfield's classic paper, Randomization by Group: A Formal Analysis, was published in 1978. Dr. Murray became increasingly interested in these issues, collaborating with Peter Hannan and others at Minnesota, and learning from pioneers in this area including Allan Donner.

Dr. Murray's first interaction with the Office of Disease Prevention occurred in 1992, when the Office sponsored a meeting of methodologists from survey research, educational statistics, biostatistics, and epidemiology for the first NIH conference on the design and analysis of group-randomized trials. Dr. Murray coordinated that meeting, which was convened under the auspices of Dr. William Harlan, the third Associate Director for Prevention and Director of the Office of Disease Prevention.

Dr. Murray continued to work on group-randomized trials, and to investigate their design and analytic issues, through the 1990s. In 1998, he published the first textbook on this material.

Dr. Murray left the University of Minnesota in 1998 to become the first Lillian and Morrie Moss Chair of Excellence in Psychology at the University of Memphis. In 2005, he moved to Ohio State University as the Chair of the Division of Epidemiology in the College of Public Health. He continued to work on group-randomized trials, and on the methods for their design and analysis, throughout his time at Memphis and at Ohio State.

Over the past 34 years, Dr. Murray has worked on more than 50 health promotion and disease prevention research projects funded by the NIH and other agencies. He served on more than 40 grant review panels for the NIH and as the first Chair of the Community Level Health Promotion study section. He has published more than 250 articles in the peer-reviewed literature.

Dr. Murray has a passion for prevention research done well and believes that we can best advance the nation's health by ensuring that prevention programs are based on good science, that they are carefully designed and evaluated, that effective interventions are disseminated,

and that ineffective interventions are identified and discarded. This view is entirely consistent with the mission of the Office of Disease Prevention, which is to work with the NIH Institutes and Centers and other partners to provide leadership and direction for the development, refinement, implementation, and coordination of a trans-NIH plan to increase the scope, quality, dissemination, and impact of NIH disease prevention and health promotion research. As the Associate Director for Prevention and as Director of the Office of Disease Prevention, Dr. Murray led the development of the first Strategic Plan for the office.