COMMENTARY ON BORRELLI

The importance of monitoring and maximizing treatment fidelity in public health research

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"If you want to truly understand something, try to change it." This quote by social psychologist Kurt Lewin, an early advocate for the use of scientific approaches in the study of human behavior, succinctly describes the essence of the experimental method. Indeed, "changing something" – manipulating a variable or variables in a controlled manner, and observing the outcome across groups of individuals who have been randomly assigned to receive the "change," "no change," or a "different change" – is a central feature of the randomized clinical trial (RCT), the "gold standard" for determining the efficacy of a medical or behavioral treatment.

Of course, the simplicity inherent in Lewin's prescription is not so simply achieved. This is especially the case for randomized clinical trials of behavioral interventions. Intervening to alter a participant's behavioral or psychosocial condition is an extremely complex undertaking in which the "dose" of a behavioral treatment cannot be as precisely measured and administered as a pill. The highly complex nature of behavioral interventions can result in a lack of standardization and increased variability, obscuring treatment effects where they exist, necessitating increased sample sizes (and thus increased costs), and resulting in interventions that, if found to be successful, cannot be reliably replicated. In her article on treatment fidelity and its importance to behavioral and public health research, Belinda Borrelli provides a roadmap that clearly and cogently outlines a path to maximizing treatment fidelity for the kinds of complex behavioral interventions used in public health research. In this article, Dr Borrelli provides both a compelling argument for the benefits of maximizing treatment fidelity in behavioral RCTs, and a comprehensive guide for researchers wishing to systematically assess and enhance treatment fidelity in their own research.

Dr. Borrelli outlines a model of treatment fidelity, developed by a group of researchers involved in the National Institutes of Health-funded Behavioral Change Consortium program (1) that builds upon previous definitions of treatment fidelity in behavioral research (2,3). Dr. Borrelli and her colleagues' work extends earlier models of treatment fidelity, and addresses the complexity of behavioral intervention research, by expanding the aspects of the research process that require attention to fidelity from more simple models focusing on delivery, receipt, and enactment to a model that incorporates study design and training as well. While these components were embedded in previous models (2), by separating them out as individual components, Dr. Borrelli emphasizes the importance of taking fidelity into account at the earliest stages of the research, beginning with procedures to ensure that the treatment components accurately reflect the theoretical underpinnings of the intervention, that the presumed "active" ingredients of the treatment are described explicitly in the study protocol and operations manuals, and that providers of the intervention are trained in standardized fashion, to criterion, with emphasis on maintenance of provider skills over time. Explicit mapping of the intervention to theory, description of the essential, core components of the intervention, and standardized training, monitoring, and maintenance of provider skills over time are often neglected aspects of behavioral intervention studies that are essential to ensuring that the intervention is being operationalized as intended. This allows one to understand more precisely the elements responsible for an intervention's success or failure, improving replicability and translation to clinical or community settings. Dr. Borrelli's model provides detailed procedures for monitoring and maximizing fidelity in the delivery, receipt, and enactment of behavioral interventions. Her approach also helpfully expands the receipt and enactment categories to include both cognitive and behavioral skills learned in treatment, an additional improvement over past approaches to treatment fidelity.

The model discussed by Dr. Borrelli is a useful guide not only for researchers, but also for sponsors, reviewers, and publishers of behavioral intervention research. Because of the importance of treatment fidelity to both the internal and external validity of public health clinical trials, it would be advisable for funding initiatives, reviewer guidelines, and publishing requirements to include an explicit focus on the

methods used by researchers to enhance and monitor treatment fidelity in studies of health behavior change. By encouraging researchers to address this issue, methods to enhance and measure treatment fidelity are more likely to become standard features in the studies of health-related behavioral and psychosocial interventions, ultimately leading to more successful and replicable behavioral interventions, and to increased credibility for behavioral medicine and public health research.

Conflict of interest

The author was Project Officer for Dr. Borrelli for the Behavioral Change Consortium project and was a member of the Fidelity workgroup which she chaired that developed the treatment fidelity model she describes in this paper. She is also co-author with Dr. Borelli on the article that originally described this treatment fidelity model.

References

1. Borrelli B, Sepinwall D, Ernst D, Bellg AJ, Czajkowski S, Breger R, DeFrancesco C, Levesque C, Sharp DL, Ogedegbe G, Resnick B, Orwig D. A new tool to assess treatment fidelity and evaluation of treatment fidelity across 10 years of health behavior research. *J Consult Clin Psychol.* 2005;**73**(5):852-60.
2. Moncher FJ, Prinz RJ. Treatment fidelity in outcome studies. *Clin Psychol Rev.* 1991;**11**:247-66.
3. Lichstein KL, Riedel BW, Grieve R. Fair tests of clinical trials: a treatment implementation model. *Adv Behav Res Ther.* 1994;**16**:1-29.