COMMENTARY ON BORRELLI

Fidelity in public health clinical trials: considering provider-participant relationship factors in community treatment settings

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Treatment fidelity in health behavior research is vital for obtaining results that are interpretable. Dr. Borrelli provides a comprehensive review and "state of the science" guidelines for implementing trials with rigorous fidelity. Certain fidelity challenges occur in behavioral trials, particularly those conducted in community treatment settings which are often effectiveness studies involving diverse samples of providers and participants.

Health behavior interventions typically occur within the context of relationships between providers and participants. Individual characteristics may act as moderators that influence outcomes. In community settings, provider characteristics, including demographics, education, training, and experience, often vary widely. Strict criteria for provider selection may neither be feasible, nor preferable for assessing external validity. Similarly, participant samples may be quite diverse. With careful fidelity monitoring, contributions of treatment effects and those of provider and participant moderators can be identified with greater confidence, informing both research and practice in patient–provider-treatment matching when it is possible.

Relationships create processes that impact outcomes. One of the most studied is the therapeutic alliance (TA), found to operate in many behavioral treatments including pharmacotherapy and placebo pharmacotherapy (1). Relationship variables should be addressed when considering study design, training, and treatment delivery monitoring. In study design, both content and relational components of behavioral treatments should be considered as potential active ingredients when operationalizing treatments. For example, Motivational Interviewing (MI) specifies provider behaviors including empathy, acceptance, and MI spirit as crucial to its efficacy (2).

Training providers explicitly in treatment relationship skills is important regardless of whether they are postulated as active treatment mechanisms. This is particularly relevant in community-based research, using providers whose skills may vary widely at inception. Resources for training are often stretched thin, leaving skill training to the last minute. The result can mean that wide variations in provider relationship skills remain after training content, a challenge that can be minimized by planning sufficient training time to include this focus.

Fidelity monitoring of treatment delivery is a third important element; ratings typically measure intervention adherence and skill (i.e., competence), although measures of skill are rarely operationalized and should be. Clearly, fidelity ratings should measure all relationship skill elements that are considered active treatment ingredients; they should also measure relationship elements that are non-specific factors, such as therapeutic alliance or empathy. Ratings of these variables inform supervision and, if validated, can be used to examine contributions to outcomes. In a meta-analytic study, Webb *et al.* (3) found that studies that controlled for TA reported significantly smaller effect sizes for competence–outcomes relationships.

Finally, community-based research often uses "treatment-as-usual" control conditions. Borrelli raises the important issue of fidelity monitoring of control groups. Ideally, both treatment content and relationship skill should be measured. Providers in the experimental condition may have had the benefit of both content and relationship skill training; differences in both the treatment content and provider relationship skills between experimental and control conditions may contribute to outcomes; fidelity monitoring of control conditions allows this to be examined.

Health behavior trials offer the opportunity to identify active treatment ingredients within the complexities of provider–participant relationships. Community-based trials

offer the rich experience of working with diverse, "front line" providers, and a wide range of patients to identify treatments that apply in "real world" settings. Fidelity monitoring that takes these factors into account enhances both internal and external validity.

Conflict of interest

The author declares no conflict of interest.

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