

Testing FIRST in Youth Outpatient Psychotherapy: SPECIFIC AIMS

Children and adolescents (herein “youths”) treated in outpatient mental health clinics span a broad range of problems and disorders, with substantial comorbidity and shifts during treatment in their most pressing problems. This has given rise to flexible, *multidiagnostic* treatments, such as *Modular Approach to Therapy for Children* (MATCH), comprised of 33 treatment techniques and four protocols spanning multiple disorders and problems. MATCH fared well in early randomized controlled effectiveness trials (RCETs) using rather costly implementation support (e.g., 5-6 days of training, then weekly individual clinician consultation), but it may be challenging for settings where less support is available; MATCH effects were nonsignificant in two recent RCETs using less costly group consultation. A recent *transdiagnostic* treatment, *FIRST*, created in concert with community practitioners, uses a principle-based approach to reduce complexity and to support efficient uptake by clinicians. FIRST is built upon five *empirically supported principles of change* (ESPCs—i.e., calming-relaxation, cognitive reappraisal, problem-solving, practicing adaptive opposites, using incentives), each applicable to a range of clinical problems. Using low-cost training and group consultation, FIRST has shown clinical outcomes very similar to the most successful MATCH studies in three open benchmarking trials with youths in community settings. The proposed RCET will provide a more definitive test of FIRST and an initial test of a candidate mechanism of change: regulation of negative emotions. A type 1 hybrid effectiveness-implementation design will be used to evaluate proposed predictors and moderators of implementation.

Aim 1. Conduct a randomized controlled effectiveness trial of FIRST. The sample will be ethnically and economically diverse youths, aged 7-15, from the greater metropolitan areas of Boston, MA, and Austin, TX, referred for treatment and scoring in the borderline or clinical range on measures of depression, anxiety, post-traumatic stress, and/or conduct problems. Clinicians in the participating Boston and Austin community mental health clinics will be randomized to learn FIRST or to employ their own preferred Usual Care (UC), and youth participants will be randomized to treatment by FIRST or UC clinicians. Clinical and functional outcomes will include trajectories of change on internalizing and externalizing (e.g., CBCL, YSR) assessed quarterly for 18 months, brief measures of internalizing and externalizing problems collected weekly during treatment, MINI-Kid parent-report DSM-5 diagnoses assessed at pre- and post-treatment, and functional idiographic top problems assessed weekly via youth and parent report.

Aim 2. Test candidate mechanisms of change. Consistent with the NIMH experimental therapeutics framework, we will assess our hypothesized transdiagnostic therapeutic mechanism—*regulation of negative emotions*—via repeated assessments using multiple informants, methods, and measures. A measure of negative affect (PANAS items) and a measure of ability to regulate emotions during personally identified upsetting situations (the Coping Questionnaire) will be collected from youths and caregivers weekly during treatment. Latent growth curve models will be estimated to test whether FIRST impacts slopes of change in negative affect regulation during treatment (i.e., target engagement); and whether the long-term patterns of clinical improvement on CBCL/YSR outcomes are mediated by change in the candidate mechanism.

Aim 3. Explore candidate predictors of implementation. Prominent theoretical models suggest that clinician factors may influence implementation of evidence-based practices. We will assess whether clinicians’ baseline knowledge of, attitudes toward, and motivation to use evidence-based practices, as well as perceived organizational climate, predict their implementation of FIRST practices, as assessed through coding of therapy session recordings. We will also test whether the same clinician factors moderate FIRST vs. UC differences in implementation, including both adherence to and competence in delivery of the practices.

Impact: The breadth of psychopathology, comorbidity, and flux commonly seen in referred youths may be addressed via personalizable treatment that spans internalizing and externalizing problems and disorders. A challenge is to limit the complexity and cost of such flexible transdiagnostic treatment to support practitioner uptake and effective implementation. FIRST was designed, with practitioner guidance, to meet that challenge via a streamlined approach built upon five ESPCs. Three open benchmarking trials, using low-cost training and clinician support, showed encouraging outcomes; the proposed RCET is needed to fairly test whether FIRST outperforms UC in clinical practice settings—crucial to determining whether FIRST can enhance outcomes in everyday practice. This RCET will also be the first to examine the role of a promising candidate mechanism through which FIRST may produce effects: *regulation of negative emotions*, measured via multimethod, multi-informant assessment. The study will also explore whether implementation of the evidence-based practices found in FIRST can be explained in part by clinicians’ baseline knowledge of, attitudes towards, and motivation to use evidence-based practices, as well as a perceived organizational climate. The study will thus provide the first randomized trial of this new practice-adapted transdiagnostic treatment, plus an inquiry into a mechanism through which it may work and factors that may affect its implementation—all bearing on the potential of this next-generation treatment approach to advance personalized youth mental health care.