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Community Study of Outcome Monitoring for Emotional Disorders in Teens (COMET): A comparative effectiveness trial of a transdiagnostic treatment and a measurement feedback system

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ABSTRACT

Emotional disorders, encompassing a range of anxiety and depressive disorders, are the most prevalent and comorbid psychiatric disorders in adolescence. Unfortunately, evidence-based psychosocial therapies typically focus on single disorders, are rarely adopted by community mental health center clinicians, and effect sizes are modest. This article describes the protocol for a comparative effectiveness study of two novel interventions designed to address these challenges. The first intervention is a transdiagnostic treatment (the Unified Protocol for Transdiagnostic Treatment of Emotional Disorders in Adolescents, UP-A), a promising new approach that uses a small number of common strategies to treat a broad range of emotional disorders, and their underlying shared emotional vulnerabilities. The second intervention is a standardized measurement feedback system, the Youth Outcomes Questionnaire (YOQ), designed to improve clinical decision making using weekly symptom and relational data. The three study arms are treatment as usual (TAU), TAU plus the YOQ (TAU+), and UP-A (used in combination with the YOQ). The primary aims of the study are to [1] compare the effects of the UP-A and TAU + to TAU in community mental health clinics, [2] to isolate the effects of measurement and feedback by comparing the UP-A and TAU+ condition, and [3] to examine the mechanisms of action of both interventions. Design considerations and study methods are provided to inform future effectiveness research.

1. Introduction

Emotional disorders, encompassing anxiety and depressive disorders, are the most prevalent and comorbid psychiatric disorders in adolescence [1]. They are chronic, impairing, and share common vulnerabilities [2–8]. Researchers have developed and tested dozens of disorder-specific psychosocial treatments for emotional disorders [9]. However, the effectiveness of these evidenced-based treatments (EBTs) in community mental health clinics (CMHCs) has been disappointing. A recent meta-analysis concluded that, although EBTs typically outperformed treatment as usual (TAU), the average effect was small (d = 0.30 for emotional disorders [9];. In addition, the adoption of EBTs into CMHCs has been slow [10].

Several characteristics of EBTs might decrease their "real-world" effectiveness and uptake. Many EBTs are designed to address single diagnoses, whereas comorbidity is common in CMHCs [11]. A related problem is the training burden clinicians face to become competent in multiple single-diagnosis EBTs [12]. Clinicians often perceive EBTs as too rigid for personalized treatment [13,14]; recent data suggest that flexible treatments are more appealing to clinicians [15] and more effective than TAU and traditional EBTs [16].

A recent innovation that addresses many of these limitations is transdiagnostic treatments, which target multiple problems within a single conceptual framework [5,17,18]. Transdiagnostic approaches may be particularly relevant for adolescents, whose high comorbidity rates and shifting symptom profiles complicate the typical treatment approach [19]. The Unified Protocol for Transdiagnostic Treatment of Emotional Disorders in Adolescents (UP-A [20]; applies emotion-focused intervention strategies to a broad range of internalizing symptoms. It has demonstrated efficacy in a research setting [21]; a logical next step is to examine its effectiveness in CMHCs.

Traditionally, effectiveness studies have compared the EBT of

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interest only to TAU. However, interpretation of these studies can be challenging because the EBT clinicians receive regular feedback through standardized assessment and supervision. If treatment is going poorly, the clinician is often informed of this so that treatment can be adjusted. Some EBTs also make explicit use of session-by-session assessment of symptom severity to inform clinical care [22]. If EBTs outperform TAU, it can therefore be difficult to determine the degree to which these differences are due to the treatment techniques, or to the "confounding effects" of increased monitoring and feedback to clinicians. Disentangling these factors has high scientific value and important implications for dissemination and implementation of EBTs.

One strategy to control for these effects is the use of standardized measurement feedback systems (MFSs). MFSs consist of assessment tools, often part of an online system, to regularly track the processes (e.g., therapeutic alliance) and outcomes (e.g., symptom improvement) of therapy, with clinician reports summarizing the results [23]. Extensive research with adults suggests that using an MFS can increase therapy success rates [24,25]. Preliminary evidence also suggests benefits for youth [26,27], although effects vary by organization [28]. Because MFSs are designed to facilitate clinical decision-making across a clinician's entire caseload, they also share many of the same advantages of transdiagnostic treatments.

Given the disadvantages of single disorder EBTs and the need for novel designs focused on disentangling the confounding effects of assessment and feedback, our team designed the *Community Study of Outcome Monitoring for Emotional Disorders in Teens* (COMET).

2. Study design and aims

COMET is funded by National Institute of Mental Health (R01MH106536 & R01 MH106657). It is a two-site randomized controlled effectiveness trial focused on two interventions, the UP-A, and the Youth Outcomes Questionnaire [29] (YOQ), a MFS tracking youth symptoms and therapy alliance. The study will compare three conditions: [1] TAU alone; [2] TAU plus the YOQ (TAU+); and [3] UP-A plus the YOQ (UP-A). The Institutional Review Boards at University of Miami and University of Connecticut School of Medicine have approved all study procedures and the study is registered at ClinicalTrials.gov (NCT02567266).

2.1. Study aims

The primary study aims are:

Aim 1:To compare the effectiveness of UP-A and TAU+ to TAU. Aim 1 will test whether adolescents in the UP-A and TAU+ conditions demonstrate greater clinical improvements in anxiety and depression than those receiving TAU. We hypothesize that adolescents randomized to UP-A and TAU+ conditions will demonstrate greater clinical improvements relative to TAU.

Aim 2: To isolate the effects of evidenced-based measurement and feedback. Aim 2 will examine the relative effectiveness of the UP-A condition to the TAU+ condition. We hypothesize treatment outcomes will be better in the UP-A condition than in TAU+.

Aim 3: To examine mechanisms theoretically associated with UP-A and YOQ. We hypothesize that differences in outcomes between the UP-A and the other two conditions will be mediated by changes in: 1) Distress Tolerance and 2) Emotional Avoidance [30]. We further hypothesize that, among participants in the UP-A and TAU+ conditions, treatment outcomes will be better for participants whose therapists: 1) rate the YOQ results as more credible, 2) view the YOQ reports more frequently, and 3) discuss the reports with them in session more frequently. Moreover, we hypothesize that differences in outcomes between TAU and the two treatments using the MFS (UP-A and TAU+) will be mediated by differences in: 1) therapeutic alliance and 2) therapy engagement.

Exploratory aim. Based on the literature [31] and domains outlined by Burns et al. [32] and Jensen et al. [33], a number of potential predictors and moderators will be examined (gender, age, domain/severity of illness, psychiatric comorbidity, medication usage).

2.2. Participants

Adolescent participants will include 222 adolescents (111 per site) with elevated symptoms of anxiety or depression, as indicated by the presence of an anxiety, depressive, obsessive-compulsive or adjustment disorder with anxiety and/or mood specifier. Participants are drawn from the referral pool of clients from participating CMHCs.

Youth inclusion criteria are: 1) between the ages of 12 and 18 with clinically significant symptoms of anxiety or depression, as defined by a Clinical Severity Rating (CSR) of 4 or higher on any DSM-5 anxiety, obsessive-compulsive or depressive disorder, including adjustment disorders, as determined by the Anxiety Disorders Interview Schedule for the DSM-5, Child Version, Child and Parent Report Forms (ADIS-5-C/P [34]), 2) deemed eligible and appropriate for outpatient services by one of the study clinics, 3) living with a legal guardian at least 50% time who is willing to attend treatment sessions, and 4) and has a caregiver who is able to complete all study procedures in English or in Spanish. Youth exclusion criteria include: 1) receiving concurrent psychosocial interventions, 2) suicidal behavior that warrants a higher level of care than routine outpatient treatment, and 3) other indicators that would make the UP-A contra-indicated (e.g., significant substance abuse; IQ $<$ 80).

Clinician participants are employees or trainees working at the participating clinics. Inclusion criteria are: 1) at least part-time employee or completing an approved practicum or internship of at least one year, and 2) able to speak, read and understand English.

2.3. Procedures

COMET is being conducted in 14 clinics (six in South Florida and eight in Connecticut). Clinicians are recruited through agency administrators, and then go through a study consent procedure and complete baseline measures before being randomly assigned to deliver one of the three study conditions. Clinicians are randomized in blocks of three within each agency, using a random number generator (www.randomization.com). If an agency has three clinicians who speak Spanish, these clinicians are randomized within a separate block. These procedures ensure that each agency has clinicians in all three conditions and, if the agency will be enrolling Spanish-speaking adolescents, that Spanish-speaking clinicians are available in all three conditions. Each clinician will deliver only one of the study conditions to minimize contamination between conditions. Clinicians randomized to the experimental conditions then receive training and consultation in the UP-A, and/or YOQ, and all clinicians see study cases as part of their regular caseload. Clinicians are asked to audio record sessions, complete a session report every session, complete measures at the 8- and 16-week point for each study case, and are also asked to repeat some of the baseline measures after they complete their first study case. Depending on the agency, clinicians are either reimbursed for training and consultation time through their regular agency procedures or directly by the study. In addition, all clinicians receive $60 at the end of each case for completing the study measures.

While specific procedures vary by clinic, families typically receive information about the study at the initial phone contact, or after completing the clinic's intake assessment. If eligible for services at the clinic and interested in participating in the study, adolescents and their caregiver sign assent/consent and take part in a baseline study assessment. Eligible adolescents are then randomized to one of the three study conditions and assigned to the appropriate therapist at their clinic. Randomization lists (in blocks of 3) were generated by the study statistician using www.sealedenvelope.com/simple-randomiser/v1/lists. Randomization lists were stratified by agency, whether or not