Implementing Family-Based Treatment for Adolescent Anorexia Nervosa for Providers in Private Practice: A Feasibility Study

Study Protocol

NCT04428580

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We will employ the same recruitment strategy that was successful in our initial study and advertise throughout the United States (US) on the Academy for Eating Disorders (AED) websites, Eating Disorder Research Society (EDRS) listserve, and the National Eating Disorder Association (NEDA) listserve. In addition, we will use Facebook and Twitter advertisements to augment these approaches.

Therapists will be trained in one of two ways for this study: 1) online training x 3 months, followed by expert supervision for 3 months; or 2) recorded webinar training provided in 12 1-hour webinar lectures provided weekly, followed by expert supervision for 3 months. UCSF, listed as a collaborating institute, will aid in training and supervising the participating therapists in one of these two arms of Family-based Treatment training (see description of research activities at UCSF below).

Therapists are eligible to participate if they have completed a masters or doctoral training in their field (psychology, psychiatry, family therapy, social work), are licensed in their respective state, have no reports of malpractice or loss of privileges at relevant clinical institutions, have computer/web access for online training and assessments and no previous 2-day in-person workshop training in FBT, and submit baseline data on weight gain from week 1-4 from a previously treated adolescent with AN they have treated in the last 6 months or alternatively one that they treat within 3 months of the initial screening before starting the training. Therapists who have had previous training in FBT are not eligible to be randomized.

Therapists will complete an online screen. If they appear to be eligible, an online consent form will be triggered (waiver of documentation included on the application). If they do consent, they will be asked to complete online questionnaires that will amount to be the baseline assessment prior to randomization. Demographic and practice characteristics of all therapists (age, gender, ethnicity, race, months of experience treating eating disorders, specialized trainings, practice setting, payments accepted), self- report of fidelity, knowledge of FBT, skills of FBT using responses to role played videotapes, and expert ratings of fidelity will be collected. The total assessment burden for therapists will be about one hour to an hour and a half for the entire screen, consent, and baseline assessment.

Once this is complete the research team will review the assessment and double check eligibility before randomizing the participant to either arm of training. The research team will then reach out to the therapist to inform them of which arm of training they were randomized to and go over again what that entails as well as get them set up with either:

1) Online training which consists of 10 lectures that are self-paced with a maximum of three months to complete with each lecture bundle comprising of 5- 8 short (about 4 minutes in length), didactic videos that discuss the treatment model and provide mock therapy session video clips (modeling FBT with a typical adolescent AN case), as well as supplementary readings and videotaped role- plays. Enrollees complete each lecture bundle and complete the assignments as they move through the training at their own pace, but to have completed all within the 3-month time frame.

2) Webinar training which consists of 1-hour weekly webinar lectures that essentially is the FBT training that is conducted in person, just recorded. There will be lectures discussing the scientific evidence supporting FBT, how therapists set up treatment for FBT, main interventions used in FBT during each phase, and recorded role-plays illustrating interventions throughout the 3 phases. Enrollees watch each webinar video as it is released weekly over a 12 week (3 month period).

When the training is completed, therapists will proceed to schedule post- online supervision for a minimum of 1 case and a maximum of 2 cases over the course of 3 months with one of two clinicians at UCSF. At the 4 week treatment mark for each case, therapists will complete a self-report on FBT fidelity to key components and patient weight change. Therapist video skill assessments related to key components will take place at baseline and at the end of online ET-FBT and end of supervision. Once the therapist completes a minimum of one case, the therapist will receive CE credit and a certificate of completion of FBT training. Therapists who enter the online training protocol will be compensated for their time for the completion of all assessments ($100 for each assessment point).

UCSF's role in research activities are as such: Two UCSF clinicians will be responsible for conducting individual work with each therapist participant weekly for 1 hour per week for 12 weeks during the supervision timepoint of the study. They will use the published supervision manual for FBT (Forsberg et. al) published by Guilford. They will rate fidelity using a therapist version of self-report (described below) and will rate the recorded responses to the

clinical vignettes (described below). They will have access to all of the fidelity assessments (the self-reports and the vignettes all outline below) in order to complete these ratings. Access will be through RedCap in order to make sure the data they receive is secure and HIPAA compliant in accordance with Stanford's IT recommendations. They will also know the patient weight change data (solely session 1 through 4 weights and dates taken no patient PHI will be collected in the study) as they need this information to teach the therapist using supervision.

Therapists will complete the following measures/assessments:

Demographic and professional survey: This is a basic demographics questionnaire asking for age, race, gender, geographic location (City and State), specialty (psychology, psychiatry, social work), treatment setting (private practice, group private practice, full or part-time); specialty training in anorexia nervosa, experience treating anorexia nervosa (years), numbers of adolescents with AN treated in the last two years, willingness to pay for this training. This measure will take approximately 10 minutes to complete and is completed only at baseline (BL). This measure will be used to examine possible predictors (candidate-moderators) for fidelity and patient outcome (Aim 4).

The therapist version of Parents versus Anorexia Nervosa Scale(PVAN): This is measure of therapist self-efficacy specific to key components knowledge and skill in FBT. We use this measure as a learning tool in ET-FBT. It takes 5 minutes to complete. This measure will be completed at BL, ~3 months (end of online training-EOT), and end of supervision (EOS) ~6 months. This measure will be used as a possible predictor (candidate moderator) for fidelity and patient outcome (Aim 4).

Evidence-based Practice Attitude Scale-36 (EBPAS-36): This is a brief version of EBPAS-5O and is a measure of therapist attitudes about evidence-based practice. It has sound psychometric properties and takes about 10 minutes to complete. This measure will be used as a possible predictor (candidate moderator) for fidelity and patient outcome and will be given at BL only (Aim 4).

Motivation for training in FBT: This is a new measure asking for therapist to choose one of the following reasons for seeking training in FBT: belief that this is the best approach; customer demand; curiosity about the approach; increased income; professional development. Therapists may choose as many reasons as they wish but will rank those they choose. This measure will take 5 minutes to complete. This measure will be used as a possible predictor (candidate moderator) for fidelity and patient outcome (Aim 4).

Treatment Outcome Measures:

Weight change in patients treated pre and post-training: Weight change from sessions 1 to 4 will be collected on one adolescent patient with AN treated pre-training (baseline eligibility) and post online ET-FBT per participating therapist during supervision or within 3 months following completion of supervision. No patient identifying information will be collected. This will take 5 minutes to complete. This measure will be used as the main outcome for treatment (patient outcome) efficacy (Aim 2).

Key component skills: Therapists will be asked to view mock therapy session video clips and play the role of the therapist. These clinical videotapes are actors playing families using a script and usually lasting less than three minutes. The therapist in training watches the video and records their verbal intervention response to the clinical scene. The specific skills assessed are related to how effectively the therapist used externalization or agnosticism (as appropriate clinically) and will be scored by expert clinicians using standardized coding. This was the approach used in our preliminary study. This measure will be completed at BL, ~3 months (end of online training-EOT), and end of supervision (EOS) ~6 months. This is a measure of fidelity and change will be correlated with patient weight change outcome (Aim 3) for target validation.

Key component knowledge: This is a brief 10 question multiple choice measure of knowledge of key components of FBT that was used in our preliminary study. These will be conducted at BL, ~3 months (end of online training-EOT), and end of supervision (EOS) ~6 months. This is a measure of fidelity and change will be correlated with patient weight change outcome (Aim 3) for target validation.

Consultation Questions: The brief 8 questions ask participants about their experience with supervision in the research study. This measure will be administrated at ~3 months (end of training-EOT), and end of supervision (EOS) ~ 6 months.

Fidelity to FBT Self-Report: This is a new measure that has been piloted at the two study sites and found acceptable to therapists to use as a brief measure of self- reported fidelity to key component of FBT during the first 4 sessions. It consists of 8 multiple choice questions and takes approximately 5 minutes to complete. This will be conducted at BL, end of training (~ 3 months), and end of supervision (~6 months). This is a measure of fidelity and change will be correlated with patient weight change outcome (Aim 3) for target validation.

Supervisor reported fidelity to key components of FBT: Using a published coding frame that was used in our previous studies, supervisors will rate therapists during supervision on their fidelity to FBT during the first 4 sessions. This will be completed only at the end of supervision by therapy supervisors. This measure is a measure of fidelity and change will be correlated with patient weight change outcome (Aim 3) for target validation.

Working Alliance Inventory: This is a 12-item Likert measure derived from the original 36 item version with satisfactory psychometrics. The therapist will be asked to complete the measure as it relates to the patient for whom post- training weight change is provided. It will take 5 minutes for the therapist to complete. These will be conducted at BL, end of training (~ 3 months), and end of supervision (~6 months). This is a measure of fidelity and change will be correlated with patient weight change outcome (Aim 3) for target validation.

For the purpose of this study adverse events will be defined as “unanticipated problems involving risk to the study participant.” A serious adverse event will be defined as “any untoward occurrence that results in death; is life-threatening; or creates persistent or significant disability.” All such events will be immediately reported to the IRB and DSMB. These events will be reviewed by the Data and Safety Monitoring Board (DSMB) at their regular meeting, however, deaths and suicide attempts will be immediately reported to the DSMB and IRB.

The initial reporting of adverse events (of any kind) will take place with the study staff consulting with the PI. The PI will then decide whether the event is of such a severity that requires discontinuation of a particular training, and whether the participant should remain in the study or be withdrawn. All study withdrawals together with a detailed explanation of the withdrawal will be reported to the DSMB.