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

Statistical Analysis Plan

NCT04428580

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DATA ANALYSIS

Aims

Aim 1: The overall aim of the study is to assess the feasibility of conducting a randomized clinical trial comparing two implementation strategies (online training vs webinar training) for training clinicians in private practice in FBT for AN.

Aim 2: Patient outcomes (reflecting therapist effectiveness) will be assessed by comparing patient weight gain from session 1 to 4 of FBT before and after training (target for training effect) and compared between randomized groups.

Aim 3: Validate training effect by examining the association between therapist fidelity to FBT and patient outcomes. We predict that fidelity will be correlated (target validation) with patient outcome. The effects of therapeutic alliance, participation in supervision, and self-efficacy on both fidelity and patient outcome will be explored.

Aim 4: Explore BL factors associated with implementation processes (e.g., prior training, experience, family work).

Data Analytic Plan

The analytic plan for each aim is as follows:

In **Aim 1**, we will first examine how well we can retain clinicians in our study. We will consider retaining 50% by end of study (6 months from the baseline) as neither success nor failure and at least 65% as successful retention. We will employ simple one-sample chi-square test (2-tailed, alpha=.05) comparing the sample retention to 50%. We will then examine whether therapist fidelity and competency in implementing FBT significantly improves from pre training to post training. For this investigation, we will employ longitudinal mixed effects modeling, which enables us to fully utilize outcome data repeatedly measured for most clinicians (3 assessments: 0 (pre), 3 and 6 month). Data points that are missing due to clinician attrition or intermittent dropout will be handled assuming that data are missing at random conditional on observed information. In this procedure, all available cases including the ones with missing information will be included in the analyses. We believe such missing data assumption is reasonable given that we will include variables (e.g., clinician fidelity/competency) supposedly related to attrition in our mixed effects modeling. Nonetheless, as a way of sensitivity analysis, we will conduct mixed effects analyses with and without including other possible predictors of attrition, which we believe is important to support the validity of our study findings as we expect a considerable level of attrition. For estimation of mixed effect models, we will employ maximum likelihood (ML) estimation embedded in the Mplus program.

In **Aim 2**, using the same mixed effects modeling approach, we will examine whether the patient outcome (weight gain) significantly improves from pre to post training.

In **Aim 3**, we will examine the relationship between the changes in clinician outcomes (fidelity/competency) and the change in patient outcome (weight gain). This will be investigated in the latent variable modeling framework, by formally relating the parallel longitudinal processes (esp. by correlating the slopes) of patient and clinician outcomes. This investigation is of particular

interest in our study as it serves as a way of validating the effect of online ET-FBT training on clinician outcomes by correlating them with a clinically relevant patient outcome. Further, the results of this investigation will be the basis for formally investigating clinician outcomes as possible mediator of online ET-FBT training effects on patient outcomes in future randomized studies.

In **Aim 4**, we will explore various baseline variables as possible predictors of pre to post training changes in clinician and patient outcomes. This investigation will also be conducted in the mixed effects modeling framework. The results of this study will inform future randomized studies about possible moderators of online ET-FBT training effects on patient and clinician outcomes.