Study Protocol and Statistical Analysis Plan

Trial Name: Optimizing Provider Training in Eating Disorders (OPTED)

NCT Number: NCT05389657

Document Date: 6/25/2025

Study Protocol

The Optimizing Provider Training in Eating Disorders (OPTED) trial is a cluster randomized hybrid type III effectiveness-implementation trial[1] that compared two different training methods and two different types of post-training implementation support for behavioral health providers working in publicly-funded settings over a 12-month period (NCT 05389657). Given the nested design, randomization to training (online asynchronous self-paced online training vs. live virtual training) was done at the agency level. Following completion of training, interested participants were randomized to consultation groups (expert only vs. expert + peer consultation). Study procedures were approved by the Institutional Review Board at the University of California, San Francisco.

Setting

Department of Public Health (DPH) leaders in the child systems of care across six San Francisco Bay Area counties (i.e., Alameda, Contra Costa, Marin, San Francisco, San Mateo, and Solano) were informed about a planned clinical trial examining FBT training. Leaders across all six counties agreed to support the effort and directly distributed information about the study (including a study flyer) to agencies/clinicians within their county's system of care. Clinician participants were recruited via county leaders' distribution of the study flyer to various contacts and listservs within the county. Leaders within each county devised their own strategy for informing clinics about the study, often balancing several factors, including clinical deficit (i.e., patient demand for ED treatment in relation to the clinical capacity of clinicians trained in EDs), total deficit in eating disorders clinical capacity, language need, and geographical region. Other recruitment efforts were administered through UCSF Eating Disorders Program Twitter account and Facebook pages. Interested clinicians who completed the online screener and deemed

eligible were contacted directly by the research team.

Participants

Participants (N = 85) were mental health providers employed in publicly-funded outpatient agencies who were actively seeing youth clients with Medi-Cal insurance within one of the six participating counties. Participants were required to speak and read English. Given the large number of unlicensed clinicians formally working within county behavioral health systems, eligibility did not require clinicians to be licensed, but it did require that unlicensed clinicians be formally employed as clinical staff and have a supervisor licensed in the state of California who was willing to assume legal responsibility for any cases treated.

Evidence-based intervention

FBT is the first-line psychological treatment for children and adolescents with anorexia nervosa. FBT empowers caregivers to support their child's recovery, initially by managing eating disorder behaviors and assisting with renourishment efforts through a firm and compassionate stance (Phase I). As treatment progresses, management of eating and exercise decisions gradually transitions back to the child (Phase II), and treatment concludes with helping the child get back on track with typical development and maintain gains (Phase III).

Randomization

Randomization to training condition (online vs. live training) was done at the agency level, stratified by agency enrollment (low = fewer than 5 clinician participants, large = 5 or more clinician participants), in a 2:1 ratio for online to live training using a random sequence generator. Following completion of training, participants who completed training and expressed interest in providing care to youth with EDs were offered one year of group-based FBT consultation. Within training condition, participants were assigned to consultation groups based

on individual preferences for consultation group day/time and group capacity. The resulting consultation groups were then randomized using a random sequence generator to receive either 1) expert consultation or 2) expert (6 months) + peer consultation (6 months).

FBT Training

Although the primary focus of the training was in FBT for restrictive eating disorders, training also incorporated foundational knowledge in ED assessment and overarching ED treatment principles. Substantial education was provided about the psychological and medical consequences of EDs and appropriate medical management, given the importance placed in FBT on emphasizing the severity of the ED and urgency of treatment. The training emphasized that the implementation of FBT is flexible. Families determine the best way to support their child, and clinicians adapt treatment to the family's characteristics, strengths, constraints, culture, and values, while still following the key tenets of FBT. Adaptations to the training were made in response to learning from prior dissemination and implementation efforts, considering the needs of clinicians who work with lower-resourced families and/or work in lower-resourced settings. Clinical considerations and resources specific to lower-income, racially and ethnically diverse populations who are served in publicly-funded settings were added (e.g., flexibility with different family members' roles and methods of engaging in treatment, additional focus on addressing mental health stigma and externalizing the illness), while still emphasizing how to retain fidelity to core treatment principles. A resource library was also created that was accessible to all participants via a shared Box folder, including resources for clinicians and patients/caregivers in both English and Spanish given the high number of Spanish-speaking youth with EDs insured by Medi-Cal and their families. The content presented was identical in both trainings to minimize differences in *what* was presented and for *how long* (14 hours of active content), but the *who,*

how, and *when* differed.

Online training. Participants in the online training condition were allowed to progress through a module-based course on the web-based platform as desired, with a goal of completion within eight weeks. The online self-guided version was on a web-based platform hosted by the 3C Institute, which the study team designed in collaboration with software developers. Training videos were primarily delivered by an expert FBT clinician. Additional training videos were delivered by one of the treatment developers, a pediatrician/child psychiatrist, and a dietitian with extensive expertise in EDs.

Live training. The live virtual training was led by two expert FBT clinicians over two consecutive days on a web-based meeting platform (Zoom), scheduled towards the end of the eight-week online training completion period so that participants would be completing training around the same time. The live virtual training offered greater opportunities for interactivity, live questions, and discussion.

Post-Training Consultation

Interested participants were randomized to one of two different consultation group models following initial training. Across both consultation models, participants received weekly expert consultation with one of two clinical psychologists for the first six months, and then they transitioned to less frequent (every other week) expert consultation or peer-led consultation for the remainder of the year. In addition to the peer consultation group meetings every other week, peer leaders (1-2 per group) across consultation groups had access to a once-monthly consultation group with one of the expert consultants. The expert consultants met twice monthly with the study PI to ensure consistency across leaders and consultation groups with respect to the consultation model.

Assessment

At pre-training, information was collected on clinician demographics (e.g., languages spoken in practice, race/ethnicity), current practices (e.g., preferred treatment modalities, theoretical orientation), and employment setting (e.g., length of time working at current agency, number of clients receiving Medi-Cal on caseload, levels of care available through agency). Clinicians were asked about their clinical training background and experiences, including discipline, years of experience with EDs, number of ED cases treated, and experience in FBT and other evidence-based interventions (e.g., parent management training, dialectical behavior therapy). Clinicians also reported on the extent to which they had been exposed to or received training in FBT using a five-point scale (1 = no formal training or exposure, 2 = no formal training but some exposure, 3 = very little training, 4= moderate training, 5 = extensive training). Additional data were collected at pre-training and repeated at post-training, 6-month, and 12-month follow-up.

Primary outcomes.

Training completion. Clinician completion of training (yes/no) measured 10 weeks from the start of WBT, and on day 2 of the live training, was used as an initial metric of training reach, adoption, and acceptability. To be considered as having completed training, participants were required to complete 100% of their assigned training (i.e., completing every lesson of the online training, or attending the full two days of training).

Knowledge acquisition. The FBT Knowledge Assessment (FBT-KA) is an 18-item measure co-created by the first author that assesses knowledge about FBT for AN and atypical AN, which was administered at pre-training, post-training, and follow-up (6 and 12 months). The assessment focuses on general knowledge about FBT (e.g., contraindications, treatment phases),

key principles (e.g., externalization, agnosticism, clinician as consultant), and key procedures (e.g., taking regular open weights).

Secondary outcome.

Engagement in consultation. Clinician engagement in consultation groups at 12-month follow-up (i.e., engagement in at least one hour of FBT consultation in the prior 6 months) was used as a metric of the impact of training on continued interest and clinical engagement with FBT-related learning, with the potential to influence clinicians' decision to adopt FBT and the fidelity with which FBT is implemented.

Additional implementation-level outcomes.

Acceptability, Appropriateness, and Feasibility of FBT. The Acceptability of Intervention, Intervention Appropriateness, and Feasibility of Intervention Measures (AIM-IAM-FIM) are comprised of three, four-item measures with high reliability and good content and structural validity.[2] These were used to assess the acceptability, appropriateness, and feasibility of FBT, and were administered at post-training and follow-up (6 and 12 months).

Attitudes towards FBT. The FBT Attitude Scale (FBT-AS) is a 20-item measure assessing clinicians' attitudes towards FBT, which was administered at post-training and follow-up (6 and 12 months). The FBT-AS has good reliability and validity, including predicting intent to change practice to be more consistent with FBT.[3]

Acceptability of FBT for restrictive eating disorders. The Treatment Evaluation Inventory Short Form (TEI-SF)[4] is a nine-item clinician-reported measure of treatment acceptability with good reliability and validity,[5] which was administered at post-training and follow-up (6 and 12 months). Instructions were modified to ask that clinicians rate each item with respect to how they felt about using FBT in the context of restrictive eating disorders. Generic language in the items

was modified (e.g., *this treatment*, *problem behavior*, and *child* were replaced with *FBT*, *eating disorder*, and *client*).

Acceptability of training. The Training Acceptability Rating Scale (TARS-2)[6] is a 12-item measure with face and concurrent validity[7,8] that assesses the competency of the training leaders and training usefulness, which was administered at post-training.

Adequacy of training. The Workshop Evaluation Form (WEVAL)[9] is a 22-item measure with good reliability and predictive validity that evaluates training satisfaction, relevancy, and the feasibility of implementation,[10] and was administered at post-training.

Satisfaction with training. The Workshop Assessment Follow-Up Survey (WAFU)[9] is an eight-item measure with good reliability and convergent validity that assesses training satisfaction and resource utilization,[10] and was administered at follow-up (6 and 12 months).

Use of FBT Principles. The Therapeutic Strategy Checklist for Adolescent Anorexia Nervosa (TSC-AN)[11] is a 25-item measure with good reliability that assessed therapist reported use of various FBT principles in their work with patients who have AN or atypical AN at 12-month follow-up.

FBT fidelity. The FBT Therapeutic Techniques Scale (FBT-TTS) is a 23-item measure assessing overall self-rated clinician adherence and adaptations to FBT, which was collected at follow-up (6 and 12 months).

Intent to use FBT. Clinicians' intent to take an ED case in the next six months, use FBT informed care (i.e., implement some elements of FBT), and/or join a consultation group was measured using Likert scales at pre-training and follow-up (6 and 12 months). These questions were adapted from an existing measure of intention to implement EBIs with good predictive validity.[12]

Confidence. The degree to which providers felt confident in their ability to effectively treat restrictive EDs at post-training relative to their confidence prior to training was assessed using a five-item scale with a neutral mid-point (much less confident to much more confident).

Adoption. To assess clinicians' adoption of ED cases and FBT, they were asked to provide quantitative (e.g., number of ED assessments, active cases, and cases using elements of FBT) and qualitative (e.g., reasons why cases did not progress to treatment or why clinicians did not start treatment with an ED case) information at follow-up (6 and 12 months).

Other measures.

Training preference. Training preference was assessed at baseline using a seven-point scale from -3 (strong preference for online training) to +3 (strong preference for live training), with a neutral mid-point.

Attitudes towards evidence-based treatments. The Modified Practice Attitudes Scale (MPAS) is an eight-item measure with good reliability and validity[13] that assesses clinician attitudes towards evidence-based treatments, which was administered at pre-training, post-training, and 12-month follow-up. Attitudes towards evidence-based interventions were assessed given their importance in clinicians' decision to implement such interventions.[14,15]

Workplace environment. The Organizational Readiness for Change (ORC-D4)[16] measure is a 30-item measure with acceptable reliability and validity that assesses attitudes, barriers, and facilitators within the working environment (e.g., collaboration and trust amongst peers, openness to change, management effectiveness) and was administered at pre-training and follow-up (6 and 12 months). Organizational culture and climate were assessed given their strong link to the fidelity with which evidence-based interventions are delivered.[17]

Importance of eating disorders to organization. A five-item scale (extremely unimportant

to extremely important) with a neutral mid-point was used to rank the extent to which eating disorders were perceived (by the clinician) to be of importance to their organization (e.g., agency) at baseline.

Importance of eating disorders to own practice. A five-item scale (extremely unimportant to extremely important) with a neutral mid-point was used to rank the extent to which eating disorders were important to clinicians' own practice at baseline.

Comfort. A five-item scale (extremely uncomfortable to extremely comfortable) with a neutral mid-point was used to rank the degree to which clinicians feel comfortable treating EDs (e.g., currently, how comfortable are you with treating EDs) at pre-training and follow-up (6 and 12 months). At post-training, comfort treating EDs with or without further support was additionally assessed.

Burnout. A single item 6-point Likert scale with good reliability and validity for clinicians in primary care settings[5] measured clinicians' level of burnout at post-training and follow-up (6 and 12 months).

Statistical Analysis Plan

All analyses were conducted in Stata version 16.1 (StataCorp LLC, 2023).

Missing data.

We used multivariate imputation using chained equations (MICE), a form of multiple imputation, to account for missingness. MICE models included all variables in the analytic model for a given outcome (dependent and independent variables), as well as several axillary variables to inform imputed values: post-training MPAS score, importance of ED treatment in provider's own practice, total years of experience, licensure status, treatment caseload, training completion (for models in which this was not an outcome), and county (except for supplemental

analyses of any FBT consultation, for which inclusion of county led to convergence issues, likely due to relatively small cell size). Imputation was conducted with predictive mean matching with a knn value of 5 for continuous variables and logistic regression for dichotomous variables. We used 100 imputations with a burn-in period of 100 iterations.

Analytic models.

We used logistic multilevel models to examine the impact of training assignment on training completion and engagement in FBT consultation at 12-month follow-up, and linear multilevel models with restricted maximum likelihood (REML) estimation to examine the impact of training assignment on knowledge acquisition at post-training. All models included a random intercept at the agency level. All models included prior FBT experience, baseline attitudes toward evidence-based practice, perceived organizational importance of ED treatment, and training preference as covariates. Analyses of participation in FBT consultation also covaried baseline intent to engage in consultation, and analyses of post-training FBT knowledge also covaried baseline knowledge.

We first examined main effects of training assignment on outcomes, accounting for covariates. We then conducted interaction models to explore whether associations between training assignment and outcomes depended on baseline preference for live versus online training.

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