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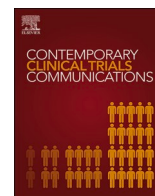
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Augmenting family based treatment with emotion coaching for adolescents with anorexia nervosa and atypical anorexia nervosa: Trial design and methodological report

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ABSTRACT

This article characterizes the design, recruitment, methodology, participant characteristics, and preliminary feasibility and acceptability of the Families Ending Eating Disorders (FEED) open pilot study. FEED augments family-based treatment (FBT) for adolescents with anorexia nervosa (AN) and atypical anorexia nervosa (AAN) with an emotion coaching (EC) group for parents (i.e., FBT + EC). We targeted families high in critical comments and low warmth (assessed by the Five-Minute Speech Sample), known predictors of poor response in FBT. Eligible participants included adolescents initiating outpatient FBT, diagnosed with AN/AAN, ages 12–17, with a parent high in critical comments/low in warmth. The first phase of the study was an open pilot which demonstrated feasibility and acceptability of FBT + EC. Thus, we proceeded with the small randomized controlled trial (RCT). Eligible families were randomized to either 10 weeks of FBT + EC parent group treatment or the 10-week parent support group (control condition). The primary outcomes were parent critical comments and parental warmth, while our exploratory outcome was adolescent weight restoration. Novel aspects of the trial design (e.g., specifically targeting typical treatment non-responders), as well as recruitment and retention challenges in the context of the COVID-19 pandemic are discussed.

1. Introduction

The current study describes a clinical trial investigating the effectiveness of an emotion coaching augmentation to Family-Based Treatment (FBT) for adolescents with anorexia nervosa (AN) and atypical anorexia nervosa (AAN). AN has one of the highest mortality rates of any psychiatric illness [1] and atypical anorexia nervosa (AAN), a recent diagnostic category for DSM-5, can also result in significant morbidity and mortality [2]. Consequences of AN and AAN are severe such as underweight status, malnutrition, and medical complications such as bradycardia, infertility, and orthostatic abnormalities, necessitating swift and effective intervention [3]. Notably, AAN comprises approximately 30% of eating disorder clinic populations [4] but these individuals have not typically been included in clinical trials. While individuals with AAN meet the same diagnostic criteria as AN, they are not necessarily significantly underweight. However, individuals with AAN have often lost a greater percentage of body weight than those with AN, still require weight restoration to a healthy expected body weight

relative to their personal growth history, and are physically and psychologically just as impaired as individuals with AN [5,6].

FBT [7] is a well-established treatment for AN comprising three phases. In Phase I, parents assume management of weight restoring their adolescent to weight restoration; in Phase II, management of eating is shifted back to the adolescent once weight is restored; and in Phase III, goals include supporting adolescent autonomy and developing/maintaining appropriate parent-adolescent boundaries in the absence of the eating disorder. The primary interventions in FBT are behaviorally focused: setting concrete goals for caloric intake and weight gain, coaching parents on how to support each other and their child through weight restoration, and reducing other AN-related activities, such as excessive exercise. While FBT has strong empirical support as the first-line treatment for adolescents with AN, treatment non-response (i.e., failure to weight restore or normalize weight-related cognitions) still occurs in approximately 50% of patients [8,9]. Thus, identifying predictors of non-response in FBT is critical to improve outcomes and mitigate the risks described above for adolescents with

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AN. One predictor of treatment non-response that is a promising intervention target is high expressed emotion, which comprises caregivers' attitudes and behaviors towards an ill family member [10], including critical comments, hostility, and emotional overinvolvement. Low warmth is an additional caregiver attribute associated with outcomes for youth with AN [11]. These patterns of family interaction may reflect premorbid parental attitudes, and/or they may be exacerbated by the onset of AN/AAN diagnosis.

In general, parental criticism is associated with negative outcomes in adolescents in the general population including increased risk for non-suicidal self-injury and depressive symptoms [12,13]. In the adolescent developmental literature, high parental warmth is a robust protective factor against the development of a host of internalizing and externalizing disorders even into adulthood [14]. Notably, families of adolescents with AN with elevated levels of criticism and low warmth are less likely to be successful with FBT [11,15]. Specific to AN treatment, high parental critical comments explain as much as 34% of variance in weight restoration outcomes and even one critical comment during the Five-Minute Speech Sample (FMSS), a validated assessment tool used for measuring expressed emotion [16], is associated with negative treatment outcomes [11,17]. Conversely, greater parental warmth significantly predicts weight restoration and improved psychological functioning in adolescents with AN [11]. However, parental warmth is less frequently studied in AN clinical trials. Thus, both critical comments and warmth should be targeted at treatment initiation to optimize outcomes in pediatric AN/AAN. One way to target parental critical comments and warmth is to potentially increase the effectiveness of FBT via emotion coaching.

Emotion coaching interventions are designed to reduce parental critical comments toward the adolescent, facilitate effective communication between parent/adolescent, and increase parental warmth toward the adolescent [18]. These interventions focus on teaching parents skills including active listening (e.g., reflection, eye contact), emotional support (e.g., validating emotions, expressing affection, and acceptance), and emotion coaching (e.g., labeling emotions, identifying appropriate coping strategies). Existing literature suggest that emotion coaching interventions are effective augmentations to evidence-based interventions targeting childhood trauma, attention deficit hyperactivity disorder, and adolescent substance use prevention [19–21]. Emotion coaching interventions complement behavioral strategies by focusing on the child's emotional experience and behavior, such that parents' attention to and validation of their child's emotional experience supports coaching of socially appropriate emotional expression. Through improving supportive emotional communication, critical comments decrease, while parental warmth increases [22]. Notably, emotion focused interventions are not novel to the eating disorder field [23–26]. Emotion focused family therapy (EFFT) was developed as an adjunct to FBT and piloted in a 2-day parent intervention. Results were promising, with parents demonstrating improved self-efficacy, more positive beliefs about their ability to be an emotion coach, and less fears about treatment [24]. However, past studies testing emotion coaching as an adjunct to FBT were case studies [27] or pilot studies without randomization to treatment or control groups [24,25], limiting generalizability of their findings.

We expect that augmenting FBT with emotion coaching (FBT + EC) will both reduce parental critical comments and increase parental warmth, and in turn, improve outcomes in pediatric AN/AAN. In the current study, we provided augmented FBT for families with high critical comments/low warmth using an emotion coaching parent group (10 weekly group sessions, delivered separately from FBT) in a two-phase study. Phase I of the study was an open pilot (N = 4) to assess feasibility and acceptability of the FBT + EC intervention. Phase II is currently underway and is assessing the effectiveness of FBT + EC compared to FBT + support (attention control). This paper presents results of Phase I of the study as well as the 2-phase study methodology and intervention design.

2. Methods

2.1. Phase I: Open pilot

2.1.1. Open pilot participants

For the Phase I open pilot, we recruited four families with AN or AAN and their caregivers from the Eating Disorders Program at Cincinnati Children's Hospital Medical Center from September 2019–December 2019. Inclusion and exclusion criteria included: 1) adolescent between 12 and 17 years of age, 2) adolescent newly diagnosed with AN or AAN, 3) adolescent and family beginning outpatient FBT, 4) adolescent and caregiver able to read and speak English, 5) no co-morbid medical conditions affecting weight (e.g., diabetes), 6) caregiver willing to participate who spends at least 50% of time with the adolescent, 7) caregiver screens positive as either high critical comments or low warmth on the Five Minute Speech Sample [16].

For the open pilot, one adolescent participant was male while three were female. The mean age of adolescent participants was 13.8 years (± 1.5), and 3 out of 4 participants had AN with just one participant having AAN. All four caregivers were biological mothers.

2.1.2. Measures and procedures

The Five-Minute Speech Sample (FMSS), [16]. The Five-Minute Speech Sample is derived from parents' freely provided responses when prompted to discuss their thoughts and feelings about their child, and was used for the current study to determine study eligibility (i.e., high criticism and/or low warmth in FMSS content). The FMSS has demonstrated 6–8-week stability and concurrent validity with a semi-structured interview assessing affective attitudes (i.e., Camberwell Family Interview [28]). For this study, parental criticism and warmth were coded using an adapted version of the Family Affective Attitude Rating Scale (i.e., FAARS [29]), a validated coding scheme for the FMSS designed to provide global ratings of both content and tone of the recorded FMSS. We used the FAARS because ratings are made based on dimensions that are developmentally relevant for families with adolescents (as compared to the original FMSS which was designed for parents of adult children) and because the measure includes an assessment of parental warmth. On the FAARS, criticism scores range from 1 ("no evidence") to 9 ("two or more concrete, unambiguous examples"). To qualify as highly critical (i.e., study eligible), parents' comments scored at least a 5 which corresponds to "one concrete, unambiguous example;" Warmth scores ranged from 1 ("no evidence") to 9 ("two or more concrete, unambiguous examples"). To qualify as low warmth (i.e., study eligible), parents' comments scored no higher than a 3 which corresponds to "1 or more weak examples." The rating scale was consistent with the published FAARS manual but we added examples relevant to families of adolescents with AN/AAN. Specifically, in addition to the FAARS manual examples of general critical comments (e.g., "She leaves her books all over the house and I'm tired of cleaning up after her"), we added AN/AAN specific examples (e.g., "She's such an obsessive runner now and it's just to burn up all her calories").

Emotion Coaching Skills: Family Meal Debriefing Observational Assessment. During this assessment, families were asked about a recent meal or snack that was particularly difficult. We allowed parents and their adolescent 10 min for an open discussion about how they felt during and after the meal. Emotion discussions were coded for the emotion communication skills that are taught and practiced in the EC intervention. All EC domains are scored in terms of the frequency of skills used during the family meal: none, some, a lot. These skills included active listening (e.g., reflection, summarizing, positive non-verbals), emotion support (e.g., matching affect, empathy & perspective taking, normalizing, age-appropriate physical affection), and emotion coaching (e.g., labeling emotions, scaffolding, helping teens understand the causes of emotions, extending and understanding mixed emotions, coping strategies). All EC domains are scored based on the frequency that skills are used during the family meal, including "none," "some," or "a lot".

Percent expected body weight (%EBW). Adolescent weight was obtained in clinic by an assessor blind to treatment condition. The adolescent wore a hospital gown and was weighed on a regularly calibrated, balance-beam scale. Percent EBW is the current weight divided by the adolescent's %EBW based on sex, age, and height, as well as personal growth history for adolescents with AAN. Percent EBW is more valid than other metrics of weight restoration, since individuals with AAN may not be underweight in terms of body mass index, but may be underweight in terms of what is healthy for them based on their personal growth trajectory.

Feasibility and Acceptability Questionnaire. The Feasibility and Acceptability Questionnaire comprises 18 items and completed by parents and adolescents. Questions assess the usefulness of the intervention, what the parent learned as a result of the intervention (e.g., "I have become more aware of my own emotions"), and the perceived effects of the intervention on the adolescent's ED and ED treatment (e.g., "My teen better understands her emotions"). Items are rated on a 4-point scale ranging from "strongly disagree" to "strongly agree." This measure was developed specifically for this study.

Acceptability of the Intervention Measure (AIM); Intervention Appropriateness Measure (IAM); Feasibility of the Intervention Measure (FIM), [30]. The AIM, IAM, and FIM are implementation measures completed by interventionists of the EC parent group. The measures assess perceptions of the intervention's acceptability (e.g., "The EC intervention is appealing to me"), appropriateness (e.g., "The EC intervention seems fitting"), and feasibility (e.g., "The EC intervention seems possible.") Each item is rated on a 5-point scale from "completely disagree" to "completely agree." Higher scores are indicative of higher ratings of intervention acceptability, intervention appropriateness, and feasibility of the intervention. Acceptable discriminant content validity has been demonstrated for each of the three measures with alpha values ranging from 0.87 to 0.89 [30].

Eating Disorder Examination (EDE, [31]). The EDE is a structured clinical interview designed to assess eating disorder psychopathology. The EDE is comprised of four subscales: Weight Concerns, Shape Concerns, Eating Concerns, and Restraint. The four subscales are averaged to arrive at the Global EDE score. Higher scores are associated with higher levels of eating disorder symptoms. The EDE is considered the "gold standard" of eating disorder assessment and has established good reliability and convergent validity in several studies [32].

Background Information Form. This form was administered to all families at the baseline visit to gather demographic information including age, race/ethnicity.

Procedure. Four families meeting the eligibility criteria completed the baseline assessment. This included the FMSS and family meal debrief, adolescent interviews and questionnaires, and parent questionnaires. Then families began weekly outpatient FBT and the separate EC group intervention in late January 2020. Both parents in the EC group and EC interventionists completed mid-way feasibility and acceptability ratings of the intervention. Parents also completed the FMSS to see if changes to critical comments and warmth were observed midway through the intervention. Finally, all four families completed the post-assessment: FMSS, family meal debrief, adolescent interviews and questionnaires, and parent questionnaires.

2.1.3. Data safety monitoring board

The data safety monitoring board consisted of experts in treatment of anorexia nervosa, conducting randomized clinical trials with adolescents with AN, and experts in developmental psychopathology. The board met every six months to evaluate any serious adverse events, adverse events, recruitment progress, and participant safety and made recommendations to National Institute of Mental Health (NIMH) regarding continuation, modification, or termination of the study. No serious adverse events occurred during the study. Adverse events related to adolescent hospital admission secondary to their eating disorder were evaluated and determined to be unrelated to the study intervention.

2.1.4. FBT + EC intervention

In addition to FBT, the EC intervention involved 10 additional weekly parent group sessions. These sessions were 90 min in length and delivered by therapists embedded within the Cincinnati Children's Hospital Medical Center (CCHMC) Eating Disorders Program. The EC intervention adapted common aspects of emotion coaching interventions (e.g., emotional awareness, emotion labeling, emotional validation) and tailored this content through examples specific to adolescents undergoing ED treatment. Specific EC skills (see Table 2) were also chosen based on their effectiveness in past EC intervention studies in other populations [22].

The original draft of the EC intervention manual was refined based on interventionist feedback given at a 2-day training prior to the start of the open pilot. We further sought parent and interventionist feedback following the open pilot phase of the study which we used to modify the EC manual even further prior to the RCT phase of the study (see section 2.1.5). Thus, the content in the finalized EC intervention manual [33] was heavily driven by both caregiver and interventionist feedback. Each EC group session provided guidance on specific EC skills. General themes that arose during the course of FBT (e.g., adolescent attempting to negotiate about how much to eat) were discussed and ways in which parents could use each of the EC skill domains were strategized. The structure of EC parent group sessions began with review of homework as applicable, a didactic component to teach new skills, followed by role plays between parents in the group and interventionists (using video-conferencing break-out rooms upon shift to telehealth), and live coaching and feedback from the interventionist.

Between sessions, EC parents were assigned self-reflective homework assignments intended to apply session content to their own goals. Parents were also instructed to practice skills via daily 5- to 10-min debriefing with their adolescents following challenging or emotion-provoking meals or snacks. Group members had a homework sheet where they reflected on what went well and what could have gone better that they could share during the group. Because this intervention is a specific adjunct to FBT, the interventionists were particularly attuned to the therapeutic goals and modality of the FBT re-feeding process and provided tailored guidance to parents on how to maintain effective EC skills while staying on track with FBT as parents may sometimes find the goals of emotional support and behavioral compliance to be at odds. For example, parents might be conflicted by validating a child's emotion (e.g., anxiety) while not condoning a behavior (e.g., food refusal).

2.1.5. Phase I open pilot acceptability and feasibility results

Midway through the intervention (after session 5), all four families "agreed/strongly agreed" that they preferred keeping the EC group format versus changing to an individual one, valued interventionist feedback, and learned to communicate more effectively with their adolescent about their eating disorder. Notably, the COVID-19 pandemic began after the 6th session (out of 10) in this open pilot. We responded swiftly by adjusting to telehealth delivery of both FBT and EC group intervention (following expedited Institutional Review Board (IRB) approval). One participant dropped when the COVID-19 pandemic began. The remaining three participants continued with the FBT + EC group intervention using a telehealth format. At the end of the 10-session intervention, caregivers unanimously endorsed positive ratings on an acceptability and feasibility questionnaire, noting the high impact of the intervention in improving their emotion communication with their teens (100% endorsed that they "strongly agreed"). Further, 100% of participants endorsed a preference for telehealth delivery versus face-to-face format due to convenience. Parents preferred shorter session times (60 instead of 90 min), more role plays during group, and recommended less redundancy in sessions 9 and 10.

In terms of the interventionist feasibility and acceptability (n = 2 interventionists), ratings on the AIM, IAM, and FIM were assessed, with mean scores as follows: AIM: 4.9 (SD = 0.03), IAM = 4.9 (SD = 0.03), and FIM = 5.0 (SD = 0.03).

Baseline to post-intervention comparisons indicated decreased critical comments on the FMSS with scores decreasing from 7.67 (baseline) to 4.30 (post-treatment) on a scale of 1–9 (higher scores reflecting greater criticism). Parental warmth increased from 3.8 (baseline) to 5.7 (post-treatment) with higher scores indicative of greater warmth. Of our three completers, two adolescents completely restored weight ($\geq 95\%$ *expected body weight*) and one partially restored ($>90\%$ *expected body weight*). Our open pilot demonstrated high feasibility and acceptability even amid the pandemic. It also highlighted the advantage and parental preference for telehealth delivery and the need to slightly modify the EC treatment (e.g., reduced session length, increased role play) for the pilot effectiveness RCT. Following these changes to our treatment manual [33], we began our pilot RCT phase.

2.2. Phase II: Small RCT

2.2.1. RCT participants

The same inclusion/exclusion criteria were used for the RCT phase as the open pilot phase (see section 2.1.1). To date, we have recruited 41 participants in the RCT phase. Study adolescent participants were mostly white, non-Hispanic (95%), female (88%), with a mean age of 14.9 years (SD = 1.6). Most of our study adolescents were diagnosed with AN (54%) while 46% were diagnosed with AAN. Finally, most study caregivers were mothers (95%). See Table 1.

2.2.2. RCT procedures

2.2.2.1. *Baseline visit.* Adolescents and parents completed the FMSS and family meal debrief together, parent completed questionnaires, and the adolescent completed questionnaires as well as structured clinical interviews with the research assistant to assess eating disorder symptoms and general psychopathology. Research assistants conducting assessments were not blind to treatment condition. See Table 3.

2.2.2.2. *Assessments.* Assessments occurred at 1-month (halfway through the intervention), end of treatment, and 3-month follow up. At the 1-month visit, only the FMSS and family meal debrief were conducted to assess change in parent critical comments and warmth. The end of treatment and 3-month follow up assessments included the same procedures as the baseline visit. Medical chart reviews also occurred at each visit. See Table 3.

2.2.2.3. *Randomization method.* Participants scoring ≥ 5 on FMSS criticism and/or ≤ 3 on FMSS warmth were randomly assigned to treatment (FBT + EC) or control (FBT + Parent support group) based upon a randomization schedule maintained by the study biostatistician.

Table 1
Adolescent characteristics at baseline.

	N (%) or M (SD)
Age (in years)	14.9 (1.6)
Gender identity	
Cisgender Male	4 (9.8%)
Cisgender Female	36 (87.8%)
Transgender Male	1 (2.4%)
Diagnosis	
AN	22 (53.7%)
Atypical AN	19 (46.3%)
Ethnicity	
Hispanic	1 (2.4%)
Non-Hispanic	40 (97.6%)
Race	
Asian	1 (2.4%)
White	40 (97.6%)
Caregiver type	
Mother	39 (95.1%)
Father	2 (4.9%)

Table 2
Description of intervention sessions across the two groups.

Session	Parent Support Group	Emotion Coaching Parent Group
1	Introductions, group rules, session by session guide, parent resources.	Review functions of emotions, and family emotional climate; setting SMART goals
2	Medical issues associated with AN (low heart rate, abnormal labs, constipation)	Build parental self-awareness of negative emotions and coping skills
3	Understanding the various levels of care in eating disorder treatment	Build parental self-awareness of positive emotions and increasing pleasurable activities
4	Taking time off from work to support your child and self-care	Identify ways that parents can increase engagement in communication with teen.
5	Medical procedures when having an eating disorder (e.g., dental and wisdom tooth removal) and medications	Identify ways parents can show support for teen’s emotions and reduce invalidating responses
6	Amenorrhea and determining expected body weight	Identify ways parents can help teens label and understand their feelings (e.g., emotion-focused questions, emotion labeling)
7	Collaborating with the school on your child’s eating disorder	Identify and learn to support healthy coping strategies for teens in FBT
8	Navigating your child’s peer/ social media influences	Identify common emotional triggers for teens in FBT and practice emotionally supportive responses
9	How to ensure you have time for other children/demands at home	Skills practice and integration, revisit SMART goals
10	Parent Q and A/wrap up/ summary	Consolidate skills and plan for future progress

Randomization was stratified by sex and diagnosis (AN vs AAN) to ensure equal proportions of patients from each sex and each diagnostic category in each of the 2 conditions. We also stratified based on referral source (inpatient medical referral and direct outpatient referral).

2.2.2.4. *Description of interventions.* See Table 2 for EC Parent Group and Parent Support Group intervention content.

2.2.2.4.1. *FBT + EC intervention group (treatment).* See section 2.1.4

2.2.2.4.2. *Parent support group (control).* The parent support group is a 10 weekly session intervention and provides general psycho-education for parents. This group is an attention control condition with the same format as the EC parent group (e.g., interventionist-guided parent group), and parents in this condition received the same dose of intervention (e.g., 1-h per week). Thus, only the content of the parent support group differs from the parent EC group. These parent support group sessions provide information for parents including the causes and treatment of AN/AAN, supporting other family members, and practical issues that arise in the context of FBT for AN/AAN. The content for this group was chosen based on ED clinician feedback (e.g., FBT providers, adolescent medicine physicians, nurses) about common themes that arose for families undergoing FBT.

2.2.2.5. *Compensation.* Participants were compensated for their time and effort \$50 per study visit (\$25 for adolescent, \$25 for parent) and there were 4 study visits. Thus, each adolescent/parent dyad received \$200 for completing all study visits in the form of a re-loadable debit card.

2.2.2.6. *Treatment fidelity.* Treatment fidelity was assessed using audio recordings of each EC parent group session. Dr. Shaffer reviewed 100% of EC parent group sessions and met with EC interventionist weekly to ensure fidelity to the EC treatment manual. To ensure fidelity to the support group, a study staff member checked 10% of sessions to ensure they were consistent with the support group manual. Finally, all study

Table 3

Assessment measures.

Construct	Questionnaire	Respondent	When administered	# items/length of time to complete/Score Used/Psychometrics
Mechanisms				
Critical comments	Five Minute, Speech, Sample using the Family Affective Attitudes, Rating Scale [29]	P/B	1,2,3,4	1 item; Time: 5 min; Score Used: Criticism Score. Reliability: $\alpha = 0.73-0.79$
Parental warmth		P/B	1,2,3,4	1 item; Time: 5 min; Score Used: Warmth Score. Reliability: $\alpha = 0.73-0.79$.
Primary Outcome				
Weight restoration	Percent expected body weight	M	1,2,3,4	Percent expected body weight is obtained at the study visit. Current weight is taken in kilograms and then divided by the individual's expected body weight.
Acceptability and Feasibility				
EC Acceptability and Feasibility	Feasibility and Acceptability Questionnaire	P/A	2,3,4	18 items; Time: 10 min; Measures parent and adolescent satisfaction with aspects of FBT + EC intervention.
Interventionist Acceptability and Feasibility	Acceptability of the Intervention Measure; Intervention Appropriateness Measure; Feasibility of Intervention Measure [30]	I	Each week of the EC intervention	11 items; Time: 10 min; Measures degree to which interventionists agree that the EC intervention is acceptable, appropriate, and feasible.
Patient and Parent Characteristics				
Demographic variables	Background Information Form	P	1	24 items; Time: 10 min; General information about the adolescent (age, race, sex) and parent (education, age, race, sex).
Eating Disorder Symptoms	Eating Disorder Examination [31]	A/C	1,3,4	44 items; Time: 45 min (standardized clinical interview); Score Used: Global Score; Inter-rater reliability = 0.69–0.99
Therapy & Medications	Treatment Form	M/P	1,3,4	Current engagement in psychotherapy and/or pharmacotherapy for comorbidities.
Emotion coaching skill use	Family Meal Observational Assessment	A/P/B	1,2,3,4	Family meal assessment is coded at each time point to assess observed parent use of emotion coaching skill use with adolescent during a meal.

P=Parent; A=Adolescent; I=Interventionist; M=Medical Chart Review; B=Blind Coder

Note: 1 = baseline; 2 = halfway through intervention; 3 = post-intervention; 4 = 3-month follow up.

FBT therapists met for regular supervision with Dr. Le Grange to ensure fidelity to the FBT treatment manual.

2.2.3. Measures

See section 2.1.3 and Table 3.

2.2.4. Study statistical analyses

2.2.4.1. Power analysis. Although a pilot trial, Monte Carlo simulation power calculations showed that, assuming $N = 50$, power will be > 0.80 for between group difference effects of $d > 1$ for all outcomes (criticism, parental warmth, weight restoration), assuming both standardization of analysis variables and baseline covariates (criticism, parental warmth, length of illness, and %EBW (Expected Body Weight), which will explain ($R^2 = 0.35$) 35% of response variable noise variance.

2.2.4.2. Planned analyses. To assess feasibility, acceptability, and fidelity of the FBT + EC parent group in adolescents with AN and their families, we examined means and standard deviations of ratings completed by families on the EC Feasibility and Acceptability Questionnaire. To assess retention in the pilot phase we examined the percent of the 10 sessions attended by study participants. We also assessed caregiver and adolescent ratings of acceptability via the EC feasibility and acceptability questionnaire, including satisfaction regarding the length and number of intervention sessions. Ratings of >3 were considered acceptable based on a scale of 0–4. To examine interventionist fidelity to the EC intervention, all intervention sessions were audio recorded and reviewed by intervention developers to ensure fidelity to the EC treatment manual [33]. EC interventionists attended weekly supervision with intervention developer to receive feedback on fidelity to the manual and corrective feedback if required. Once all groups are completed, we will compare attrition rates between the groups (FBT + support vs. FBT + EC) using chi-square tests. We will also compare the acceptability and feasibility ratings between groups (FBT + support vs FBT + EC) using chi-square and two-sample t-tests.

To test our exploratory aim examining whether the FBT + EC parent

group intervention reduces criticism, increases parental warmth, and improves weight restoration in the RCT, all analyses will be carried out with missing data assumed to be missing at random and handled via maximum likelihood estimation with auxiliary correlates within Mplus (Version 8) on the full sample ($N = 50$). Bivariate correlations will first be calculated among criticism, parental warmth, and weight restoration (measured continuously as mean percentage of expected body weight; % EBW) at 1-month, post-treatment, and 3- months follow up. To test whether families in the FBT + EC group will have lower levels of criticism and higher parental warmth as well as greater improvements in weight restoration (H3c) than families in the FBT + support group, 3 separate ANCOVA models will be used to test our hypotheses for each outcome. Baseline measures of criticism, parental warmth, length of illness, and %EBW will be included in the models as control covariates.

3. Discussion

The study procedures described here highlight the development and preliminary acceptability and feasibility of augmenting FBT for adolescents with AN/AAN with emotion coaching, as well as planned analyses for the pilot RCT. This intervention is designed to target families at risk for poor response to FBT: those families with one or more parents who demonstrated high criticism and/or low warmth toward their adolescent. It is imperative to target poor response to FBT given that AN/AAN has the second highest mortality rate of any psychiatric condition [34]. This augmented treatment is consistent with a growing clinical literature demonstrating the utility of emotion coaching parenting interventions to reduce parental criticism and increase parental support and validation of youth experiencing challenging emotions and emotion-related behaviors [18], particularly as strategic augmentations to existing evidence-based interventions (cf. [19,20]).

Overall, we found that the FBT + EC was rated as highly acceptable by families and interventionists and feasible in the context of routine clinical care for AN/AAN. Parents in the open pilot requested shorter group sessions, more role plays, and less repetition in the final two sessions. As such, we made these changes to the EC treatment manual

before the open trial.

Notably, the methodology that we initially planned for this study had to be changed due to the onset of the COVID-19 pandemic which occurred halfway into the open pilot portion of the study. Specifically, in March 2020 (i.e., onset of the COVID-19 pandemic), we pivoted from in-person groups to a telehealth format for the EC groups and study assessments. Researchers have suggested that these necessary modifications secondary to the pandemic could compromise the internal validity of the study since we cannot assume the variations in intervention delivery are equivalent [35]. In anticipation of the RCT phase of the study, we continued to conduct all interventions and assessments via telehealth. Thus, while our open pilot participants experienced a shift in intervention delivery mid-way due to the pandemic, RCT study participants all received the same telehealth intervention and assessment delivery format throughout the length of the study enhancing internal validity.

Parent critical comments and low parental warmth in the context of FBT for AN/AAN are associated with poor response and treatment drop-out [36–38]. Even one parent critical comment (captured by the FMSS) is associated with poor outcomes for their ill adolescent [37,39] emphasizing the importance of this target mechanism. While FBT aims to “modify parent criticism” the current manualized treatment does not equip therapists with specific tools to support parents in this goal, and many families are challenged by the emotionally stressful and potentially conflictual nature of the re-feeding process in FBT. Reducing critical comments and increasing parental warmth with additional intervention can improve outcomes for typical non-responders to FBT. Our open pilot provided preliminary support for FBT + EC in reducing parent critical comments, increasing parental warmth, and increasing adolescent weight.

This augmented intervention, if effective in the proposed small RCT, will be replicated in a proposed large-scale multi-site RCT comparing FBT + EC to FBT + support. Engaging multiple sites will serve longer-term goals of enhancing dissemination and implementation in various clinical settings. If effective, FBT + EC has the potential to decrease parental critical comments, increase parental warmth, and improve weight restoration outcomes in adolescents with AN/AAN. Ultimately, providing parents with emotion communication tools and strategies has the potential to strengthen parent-adolescent relationships during a vulnerable developmental period in the eating disorder recovery process.

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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