STUDY TITLE: Emotion Coaching Skills as an Augmentation to Family Based Therapy for Adolescents with Anorexia Nervosa or Atypical Anorexia Nervosa
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CINCINNATI CHILDREN'S HOSPITAL MEDICAL CENTER

STUDY PROTOCOL

Study Title: **Emotion Coaching Skills as an Augmentation to Family Based Therapy for Adolescents with Anorexia Nervosa or Atypical Anorexia Nervosa**

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1. ABSTRACT

Pediatric anorexia nervosa (AN) affects 400,000 adolescents in the US with devastating consequences including growth delay, bone density loss, bradycardia, and the highest mortality rate of any psychiatric condition (11.5%), with half of all deaths due to suicide. Atypical anorexia nervosa (AAN) is also associated with similar poor outcomes despite patients being at a normal weight. Since AAN is a new diagnosis for DSM-5, most of the outcome studies have only included AN. Early intervention in adolescents is lifesaving, making pediatric AN treatment an important public health concern. The goal of pediatric AN treatment is to restore the adolescent back to a healthy weight and reverse the dangerous effects of malnutrition. Family based therapy (FBT) is the gold standard of treatment for pediatric AN; however, 50% of patients do not respond. The consequences of treatment non-response are dire, underscoring the importance of improving treatment via augmentations to address non-response. One barrier to treatment response in pediatric AN is expressed emotion (EE), which is defined as a family's response to an ill patient that is characterized by hostility, critical comments, and emotional overinvolvement. Several studies have highlighted that families with high EE undergoing treatment for their adolescent with AN have poorer outcomes, including higher drop-out rates, lack of weight restoration, and less improvement in eating disorder symptoms. Conversely, parental warmth, a facet of EE, is associated with good outcomes in FBT. Recent parenting interventions focused on emotion coaching (EC) to address high EE have demonstrated success as adjuncts to evidence-based treatments in other pediatric populations (e.g., PTSD, ADHD) but have not been applied to pediatric AN. Given the detrimental effects that high EE has on the re-feeding process and the benefits of parental warmth, emotion coaching has the potential to reduce high EE, increase parental warmth, and improve weight restoration in adolescents with AN. The aim of this R34 pilot effectiveness trial (1R34MH115897-01A1) is to conduct a randomized controlled clinical trial of 50 adolescents and their parents to compare FBT+EC parent group (n=25) versus FBT+support (n=25). This study would have a large impact on pediatric AN with the potential to improve weight restoration outcomes by augmenting FBT for families high in EE.

2. PURPOSE OF STUDY

The purpose of this study is to establish the feasibility, acceptability, and preliminary efficacy of an emotion coaching skills group for parents as an adjunct to FBT for anorexia nervosa or atypical anorexia nervosa in adolescents.

3. BACKGROUND

Anorexia Nervosa (AN) is associated with a host of physical and psychological problems and has the highest mortality rate of any psychiatric condition.[1] The prevalence of AN is ~1%, disproportionately affecting girls and young women, with boys and young men comprising about 10% of cases.[2] The average age of onset is 15-19 years; however, incidence is

increasing in young adolescents, making this a critical developmental period to study.[2] Mortality rates range from 5.2-11.5%, with about half of deaths caused by suicide and half to malnutrition.[3] AN is associated with severe physical health consequences affecting every major organ system in the body including cardiovascular, musculoskeletal, neurologic, dermatologic, endocrine, hematological, reproductive, and gastrointestinal.[4] AN is associated with significant psychiatric co-morbidities including depression, anxiety disorders, with risk of suicide 18.1 times higher than same-age peers.[1,3]

FBT is the most promising evidence-based treatment for pediatric AN[5-9], but 25-50% of patients do not respond to this intervention. In the course of AN, the neurobiological changes that occur secondary to malnutrition make it difficult for the adolescent to feed themselves, often rendering individual treatment ineffective. FBT applies a family systems approach and challenges the practical factors that maintain AN (e.g., allowing the adolescent to make their own food choices), focuses on reducing parental self-blame, and views parents as necessary to the success of treatment. A family meal session is utilized as an ecologically valid method to assess family behavior and interaction about eating at treatment entry. In the current project, we will conduct a family meal session at treatment entry (baseline), 1-month, 3-month, and 6-month time points. In the family meal session, the interventionist asks families to bring a typical lunch or dinner to session and observes family meal time behaviors and communication. The interventionist notes who is plating and serving the food, how and what the adolescent is eating, and how families address disordered eating at the meal (e.g., food refusal, hiding food in clothing, pushing food around plate) in order to assess family dynamics as well as food intake. Following this assessment, FBT comprises 3 phases. In Phase I, parents assume control over re-feeding their adolescent to weight restoration; in Phase II, control over eating is shifted back to the adolescent once weight is restored; Phase III goals include supporting adolescent autonomy and developing/maintaining appropriate parent-adolescent boundaries. 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 re-feeding, and reducing other AN-related activities, such as excessive exercise. The shift in family dynamics that occurs during Phase I (re-feeding) often creates significant conflict between the adolescent and parents. In some families, this conflict can instigate or exacerbate unhelpful parenting practices such as hostility and/or critical comments directed toward the adolescent. Although FBT is the most promising evidence-based treatment for pediatric AN, 25-50% of patients do not remit. One obstacle to positive treatment outcomes is that FBT does not explicitly provide parents with tools to navigate the conflict that is inherently created in the family system during FBT. Additional intervention is needed to provide parents with concrete skills so that parents and adolescents communicate effectively, weight restoration can be successful, and the cycle of AN can be broken rather than reinforced.

Expressed emotion has been identified as a significant and intervenable mechanism predicting outcomes in pediatric AN. Early and effective intervention can prevent costly residential treatment and mortality for the pediatric AN population. Although several factors have been identified as non-specific predictors for treatment success, many are non-modifiable for treatment (e.g., length of illness, prior hospitalization, age).[10] However, evidence is accumulating that expressed emotion in the family is an important factor in AN treatment. Expressed emotion (EE) is an umbrella term defined as caregivers' negative attitudes and behaviors towards an ill family member.[11] EE comprises five factors: critical comments, hostility, emotional overinvolvement, warmth, and positive remarks,[12] and these are typically coded from assessments such as the Five Minute Speech Sample (FMSS). Research on EE was originally rooted in the schizophrenia literature, where high EE, characterized by criticism, hostility, and

emotional over-involvement, is associated with higher rates of schizophrenia relapse.[13] EE is also an important mechanism negatively impacting clinical outcomes in individuals with AN. [5] High EE is operationalized as 1 or more critical comments, 1 or more emotional overinvolvement statements and/or behaviors, or both. [14]Whereas the EE literature in schizophrenia showed a relationship between 6 or more critical comments and poor outcomes, even one critical comment can have negative implications for patients with AN. [15] Eleven empirical studies and one meta-analysis demonstrate the significant role of high parental EE (e.g., criticism, hostility, emotional over-involvement) in poor treatment outcomes for pediatric AN patients, explaining as much as 34% of variance in weight restoration.[5] Further, lower parental EE (fewer critical comments, hostility, and emotional overinvolvement) at the baseline family meal session (treatment entry) is associated with early weight gain.[16]

Parental warmth, a facet of EE, is significantly negatively associated with critical comments;[17] however, it is not often assessed in treatment outcome studies. Notably, high parental warmth also predicts weight restoration and improved psychological functioning.[18,19] For purposes of the current study and consistent with Caspi and colleagues, we operationalize parental warmth by a parent's tone of voice, spontaneity, sympathy, and/or empathy for the child.[17] Thus, although we acknowledge that parental warmth is a facet of EE, given that most studies refer to high EE as criticism, hostility, and overinvolvement, we will use the term high EE to refer to these constructs and parental warmth separately from this point forward.

FBT often appears to create or exacerbate negative emotions in both parents and adolescents because parents are asked to take over control of re-feeding their adolescent, which creates significant distress and conflict in the parent-adolescent relationship. Specifically, FBT involves exposing the adolescent to anxiety-provoking stimuli during the refeeding process. In the broader family anxiety literature, parents who have difficulty responding supportively to their child's anxiety or who are overly critical can disrupt or undermine the process of exposure-based treatments.[20,21] These findings appear to extend to the treatment of AN via FBT. For example, high levels of EE, including criticism or distress about their child's negative emotions, often interferes with successful weight gain during FBT.[22] Individuals with AN generally have an anxious temperament and tendency to be overstimulated, reflecting a neurobiological sensitivity to negative stimuli, such as EE, which can impede weight gain.[23] In an RCT examining FBT versus individual therapy for pediatric AN, adolescents and their families with poor outcomes (i.e., below 15% expected body weight) had significantly higher EE at baseline than adolescents with optimal outcomes (i.e., at or above 85% expected body weight).[24] While there were no differences in initial levels of EE between the optimal and poor outcomes groups for that trial, levels of EE increased from baseline to end of treatment in the poor outcomes group regardless of treatment type (i.e., FBT versus individual). This suggests that even if FBT therapists encourage parents to support their adolescent during the weight restoration process during FBT, families high in EE lack the skills necessary to do so. Further, the current treatment does not provide extensive guidance to therapists or parents on how to reduce EE. To date, the only accommodation to address high levels of EE in families is to conduct FBT sessions via parallel individual therapy (i.e., adolescent and parents seen separately).[24] However, separate sessions are not ideal or generalizable, as parents and adolescents have to interact around meal and snack times at home during the re-feeding process.

Our own preliminary data corroborate these conclusions, showing that parents who demonstrated an increase in critical comments, one component of EE, from baseline to end of treatment, or remained high in critical comments at end of treatment, were less likely to achieve weight gain for the adolescent compared to parents with low baseline critical comments, who remained low at end of treatment.[22] Our preliminary data also show parents with higher baseline EE are less likely to have adolescents who achieve a four-pound weight gain by week four of FBT, an important early indicator of treatment response.[25] Given the strong relationship

demonstrated between early response and weight restoration at end of treatment, [25]addressing the relationship between EE and early response is critical. [25] While 11 studies have demonstrated the relationship between high EE (i.e., critical comments, hostility, and emotional overinvolvement) and weight restoration in AN, two studies did not support EE as a mechanism for weight restoration. Notably, one of these studies still highlighted that high baseline EE was associated with treatment dropout and high baseline paternal criticism predicted less improvement in eating disorder symptoms post-treatment.[26] The other study identified parental warmth, a facet of EE, as a significant mechanism of weight restoration.[18] These data underscore the need to address high EE and parental warmth as significant mechanisms, particularly during eating-related interactions, to optimize the treatment for pediatric AN.

Interventions to reduce EE and improve parental warmth show promising outcomes in the family-based treatment of other psychiatric diseases. Emotion coaching (EC) interventions are designed to reduce high EE and increase parental warmth by teaching parents to respond to their child's emotions in a way that facilitates socioemotional development and emotional security, building on developmental theory of emotion socialization. The specific skill sets that are taught to parents in EC interventions, which is the focus of the current proposal, include active listening (e.g., eye contact, reflection, helpful questions), emotional support (e.g., validating emotions, expressing affection and acceptance), and emotion coaching (e.g., labeling emotions, identifying appropriate coping strategies). EC parenting interventions have been implemented to augment evidence-based, behaviorally focused interventions targeting child trauma,[27] ADHD,[28,29] and adolescent substance use prevention.[30] Similar to FBT, these broader parenting interventions largely emphasize behavioral approaches, where the focus of treatment is on parents' responses to child behavior, utilizing reinforcement and contingency management principles. The goal of EC interventions is to complement behavioral treatment approaches, with specific focus on the child's emotional experience and emotion-related behavior, such that parents' attention to and validation of their child's emotional experience supports coaching of socially appropriate emotional expression. By improving supportive emotion communication, indicators of high EE (i.e., hostility, critical comments) would decrease, while parental warmth would increase. Notably, EC interventions have been conducted in families of adolescents with internalizing and externalizing disorders, resulting in lower rates of EE, increased warmth,[31,32] less family conflict, and less internalizing and externalizing symptoms.[33] A recent study demonstrated efficacy of a parent EC intervention in reducing internalizing symptoms (e.g., anxiety), in youth transitioning to secondary school (M_{change} = -4.24, SE = .91, 95% CI: -6.29, -2.69).[31] Since behavioral interventions, such as FBT, can be at odds with EC interventions (e.g., seeking compliance vs. supporting emotions in difficult circumstances), a feasibility trial is needed to effectively integrate these two approaches. We aim to target the mechanisms of high EE and parental warmth, through our EC-augmented FBT intervention in order to improve weight restoration in pediatric AN.

The proposed intervention aims to address a significant gap in the pediatric AN treatment outcome literature by targeting previously and largely overlooked factors associated with poor treatment outcome: High EE and parental warmth. We will select families with high EE, a primary barrier to effective FBT, and provide them with augmented treatment to facilitate weight restoration. We are focusing on the patients/families at elevated risk (i.e., high EE) at baseline so that the intervention is most likely to be effective and targets families who need it the most. This contribution is significant because high EE is a well-established mechanism of treatment not previously targeted in the treatment of pediatric AN. FBT addresses the primary task of empowering parents to restore their adolescent back to a

healthy weight. However, remission rates for FBT for pediatric AN are suboptimal at 50%. Although the FBT treatment manual does briefly review EE and emphasizes minimizing blame on the patient, it does not rigorously and extensively target reducing parental criticism, hostility, and emotional overinvolvement (high EE) that inhibit weight restoration, or increasing parental warmth that might facilitate weight restoration. Thus, the proposed augmentation aims to improve the effectiveness of FBT by explicitly targeting the important mechanisms of high EE and warmth, previously neglected areas of intervention, and optimize weight restoration outcomes in pediatric AN (see Figure 1). If successful, this augmentation to target the identified mechanisms of high EE and warmth would significantly improve weight restoration outcomes.

4. STUDY DESIGN

We will conduct a pilot RCT of 50 adolescents and their parents to compare FBT + EC parent group condition (n = 25) versus FBT + support group condition (n = 25). FBT will be identical in both the treatment and control condition (see Figure 1). The treatment group will receive 10 EC parent group sessions while the attention control group will receive 10 psychoeducation parent support group sessions (See Table 1). These EC parent group and support parent group sessions will occur separately from FBT. Participants in both conditions will receive active intervention over a 6-month period (total of 20 FBT sessions; 10 EC or parent support group sessions) and EE, parental warmth, and weight restoration will be assessed at 1, 3 and 6 months. Notably, given the recent changes to the ability to conduct face-to-face therapy sessions due to COVID-19, all FBT and EC sessions will be provided via telehealth. FBT sessions will be conducted using “Jabber” a HIPAA compliant telemedicine interface currently used by BMCP at CCHMC. EC sessions will be conducted via Zoom for Healthcare. Zoom for Healthcare allows for multiple members to be part of a group session in a HIPAA compliant setting. Going forward, if restrictions are lifted, FBT sessions will likely return to face-to-face visit types consistent with BMCP standard of care. However, for consistency, we will continue to conduct both EC groups and Support groups via Zoom for Healthcare for the entirety of the study.

Figure 1. FBT

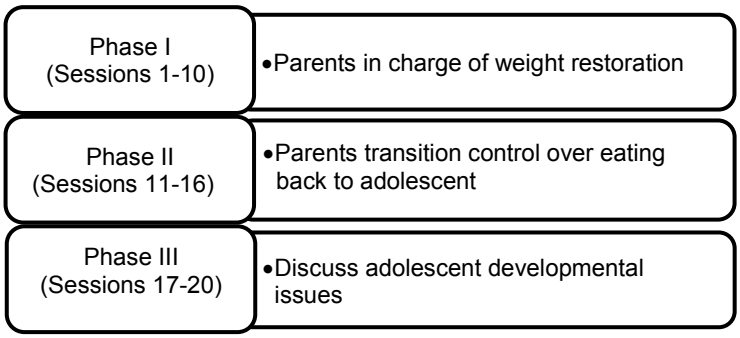


Table 1. Description of Intervention Sessions

Session	***FBT***	***Control: FBT + Parent Support Group***	***Treatment: FBT + EC Parent Group***
Phase I			
1	Introduce FBT and engage family in therapy, obtain history of how AN is affecting the family, obtain preliminary information	Medical issues (low heart rate, labs, constipation)	Review parental emotional awareness and emotion regulation, function of emotions, and family emotional climate

	about how the family functions and how this may promote or impede weight restoration		
2	Weigh teen, discuss/ support parent's efforts at weight restoration, distinguish the teen from the AN, modify family criticism of teen, review progress	Understanding the different levels of care in ED treatment	Parent emotional awareness and emotion regulation* *Core EC skills to be reviewed at the beginning of each group
3	Same as Session 2	Taking time off from work to support my child	Review parental emotional awareness and emotion regulation skills: mindfulness, adaptive coping, problem solving, relaxation
4	Same as Session 2	Medical procedures when having an eating disorder (e.g., dental and wisdom teeth removal)	Review parental emotional awareness and emotion regulation skills. Active Listening: Identify ways that parents can increase engagement in communication with teen
5	Same as Session 2	Amenorrhea and determining expected body weight	Review parental emotional awareness and emotion regulation skills. Emotion Coaching: Help the teen label and understand their feelings
6	Same as Session 2	Medications	Review parental emotional awareness and emotion regulation skills. Emotion Coaching: Ask the teen emotion-focused questions, reinforcing effective coping, extending understanding of feelings
7	Same as Session 2	Working with the school on my child's ED	Parent emotional awareness and emotion regulation
8	Same as Session 2	How do I navigate my child being influenced by peers	Review parental emotional awareness and emotion regulation skills. Emotion Support: Identify invalidating/unsupportive communication patterns
9	Same as Session 2	How to ensure I have time for other children/demands at home	Review parental emotional awareness and emotion regulation. Emotion Support: Identify and practicing validating communication
10	Same as Session 2	Parent Q and A/wrap up/summary	Review parental emotional awareness and emotion regulation. Triggers: Identify coping strategies when teen experiences tough emotions

Phase II			
11-16	Assist parents in negotiating the shift of control over eating back to the teen	*FBT components only*	FBT components only; no group
Phase III			
17-20	Discuss teen developmental issues	*FBT components only*	FBT components only; no group

Methodology

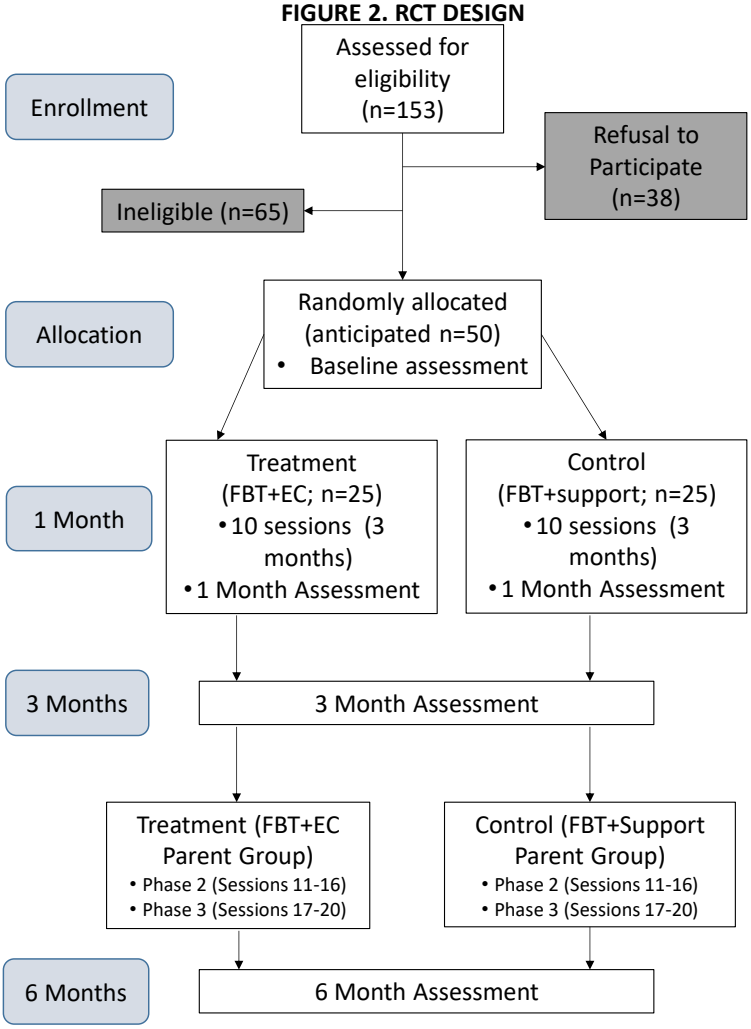
Screening for High EE Using the Five Minute Speech Sample (FMSS).[14] The FMSS is an empirically validated approach for the assessment of EE, we will screen families for baseline levels of EE. The FMSS is derived from responses audio recorded by the parent when prompted to give their thoughts and feelings about their child. The FMSS has demonstrated 6-8 week stability and concurrent validity with a semi-structured interview assessing affective attitudes (i.e., Camberwell Family Interview).[14] Since FBT is an intensive intervention for families, we anticipate that EE has the potential to increase after FBT has begun. Thus, we will offer two potential time points for participants to qualify on the FMSS for the study: at diagnosis prior to starting FBT, and again halfway through Phase I of FBT (session 5). A participant that is a screen fail at diagnosis will be asked if they would like to be contacted again in approximately one month, (after session 5 of FBT) and they will be screened again with the FMSS. Any individual who screen fails the FMSS for the second time will be removed from our recruitment list and cannot participate in the study. However, individuals who screen fail at diagnosis but pass at the 5 session mark are eligible to participate if they meet all other eligibility criteria. Individuals who pass the screening process will then be sent baseline questionnaires to complete and scheduled for an in person or online baseline assessment to complete interviews. Any questionnaires not completed prior to the baseline visit will be completed at that time. Following the baseline visit, participants will be randomized to either the treatment or control condition. The randomization calculations will be conducted by the study statistician and managed by research staff blind to study hypotheses. See Figure 2 for RCT Design.

Treatment Condition. For the treatment condition, in addition to FBT, participants will receive 10 additional, weekly, parent group sessions (each session is 90 minutes), within a 3-month time frame to account for cancellations. These sessions will be conducted via Zoom Healthcare given the COVID-19 restrictions. Groups will be conducted via Zoom for the entirety of the study. Two masters level therapists will be trained to conduct this pilot effectiveness trial. Parents can join group as they become eligible, following an introduction to the treatment module, since the skills are modular and rotate. This format is also more robust for parents who have to miss a group session. The structure of EC parent group sessions will begin with review of homework as applicable, a didactic component to teach new skills, followed by role plays between parents in the group and interventionist, and live coaching and feedback from the interventionist. In-session feedback will be guided by observational coding sheets similar to those used to code EC skills at baseline and post-assessment. Between sessions, EC parents will be instructed to practice skills via daily 5-10 minute de-briefing with their adolescent following select meals or snacks. This homework will be audio-recorded daily with provided recorders, and parents will bring in one selected example weekly for written feedback from the interventionist. Further, during homework review, parents can share their de-briefing homework with the rest of the parents in the group to get feedback and support. Because this group will be offered as a specific adjunct to FBT, the interventionists will be particularly attuned to the

therapeutic goals and modality of the FBT re-feeding process, and provide tailored guidance to parents on how to maintain effective EC skills while staying on track with the behavioral treatment, as parents may sometimes find the goals of emotional support and behavioral compliance to be at odds. In past pilot work, we have found that parents can navigate this conflict by validating a child's emotion (e.g., anxiety) while not condoning a behavior (e.g., food refusal).

Control Condition. For the control condition, participants will receive a 10-week parent support group in addition to weekly FBT. These sessions will occur via Zoom for Healthcare by two Nurse Care Coordinators. The session content is outlined in Table 1.

FIGURE 2. RCT DESIGN



5. DURATION

Participants will be in the study for a total of 6 months and an additional 6 months is required for data management and analyses.

6. SELECTION & RECRUITMENT OF PARTICIPANTS

Study Participants

Study participants will include 50 adolescents with AN and AAN between 12-17 years old and their parents. Adolescents and their parents will be recruited during their initial visit in the CCHMC Eating Disorders Program medical outpatient visit, during an in-patient stay while medically hospitalized for complications of AN of AAN on the LA4-2 inpatient Eating Disorders Unit, or during their first outpatient psychotherapy visit. Given the recent face to face restrictions due to COVID-19, we will recruit patients via phone and/or email once their physician has introduced them to the study and they are interested in participating.

Inclusion criteria

- Age 12-17 years
- Diagnosis of AN or AAN
- Have 1 or more critical comments on the Five-Minute Speech Sample (FMSS)
- Primary caregiver consent and adolescent assent to participate in study
- Primary caregiver must have at least 50% of meals with participant for FBT

Exclusion criteria

- No critical comments on the FMSS
- Diagnosis of significant developmental disorder (e.g. Autism)

- Inability to read and speak English due to the questionnaires and intervention only been developed in English
- significant medical co-morbidity affecting their weight including Crohn's Disease or Cystic Fibrosis

Recruitment Procedures

Potential participants and their caregivers meeting eligibility criteria will be identified by a trained research assistant in collaboration with the members of the Eating Disorders Team. We will be requesting a review of health information to identify potential participants via EPIC clinic schedules. The research staff will review clinic schedules of medical attendings within the division of Adolescent Medicine to identify patients who are most likely to be eligible for the study based on known inclusion/exclusion criteria (e.g., age and diagnosis). This will reduce participant burden as we will not approach non-eligible patients. Once the physician gives approval, a recruitment letter will be sent to potential research participants notifying them of the study within 2 weeks of their upcoming appointment. If potential participants who meet eligibility criteria are interested in participating, a trained research assistant with significant experience recruiting families with adolescents with AN and AAN will contact families within 24 hours of their initial visit in the CCHMC Eating Disorders Program medical outpatient visit, via Jabber during an in-patient stay while medically hospitalized for complications of AN of AAN on the LA4-2 inpatient Eating Disorders Unit, or within 24 hours of their first outpatient psychotherapy visit. Given recent face to face restrictions due to COVID-19, we will recruit initially via phone after eligible participants have been seen in adolescent medicine clinic. Once face-to-face restrictions have lifted, we will return to face-to-face recruitment. A thorough overview of the study will be provided, including study procedures, benefits, and risks. All questions will be addressed, and an information sheet will be given. In order to determine eligibility, the Five-Minute Speech Sample (FMSS) will be administered with a plan that the research coordinator will inform families of their eligibility within 2 days of the FMSS. **Adolescents and their families who do not meet eligibility criterion based on the FMSS screening instrument will not be eligible to participate and no baseline visit will be set up. However, if families are willing to be contacted again, they have an opportunity to be screen again after session 5 of FBT (approximately one month later).** If eligible, the research coordinator will speak with the family over the phone to schedule a baseline visit, complete e- consent from the caregiver or guardian, and e-assent from adolescents. Copies of informed consent/assent forms will be emailed to participants.

Table 2. Type of Measure and Informant		**Screening**	**Baseline**	**Session 1-20**	**1-Month**	**3-Month**	**6-Month**
Information Sheet	Information for families before eligibility is determined	P,A					
Five Minute Speech Sample[34] (*Primary Outcome Measure)*	Research staff reads a brief prompt and then audio records a parent describing their child for 5 minutes. The researcher does not prompt or guide the caregiver during the task. Recordings are then transcribed and scored	I,P, TD			I,P, TD	I,P, TD	I,P, TD
Treatment Fidelity	Session checklist created for study (Fidelity ≥ 90% of elements delivered, based on video coding			TD			
EC Acceptability and Feasibility Questionnaire	Measures parent and adolescent satisfaction with aspects of treatment			P,A *	P,A	P,A	P,A
Treatment Adherence: Attendance	Total number of sessions attended (adherence>4 sessions)			I			

Treatment Adherence: Homework Completion	Full, partial, and no completion rated (adherence ≥ 90% homework completed)			I			
Eating Disorder Examination[35]	Structured clinical interview of adolescent eating disorder symptoms		A		A	A	A
Schedule for Affective Disorders and Schizophrenia for School Aged Children (6-18 years)[36]	Structured diagnostic interview to assess current and past psychopathology in adolescents		A		A	A	A
Strengths and Difficulties Questionnaire[37]	Adolescent report of anxiety and depressive symptoms		A		A	A	A
Muscularity-Oriented Eating Test	Adolescent report of muscularity-oriented food intake		A		A	A	A
Strengths and Difficulties Questionnaire- Parent Report[37]	Parent report of adolescent problem behaviors, anxiety, and depression		P		P	P	P
Brief Symptom Inventory[38]	Parent-report of symptoms of psychopathology and distress		P		P	P	P
Emotion Regulation Questionnaire (ERQ)[39]	Parent-report of problems with emotion regulation		P,A		P,A	P,A	P,A
The Distress Tolerance Scale[40]	Parent-report of their ability to tolerate distress		P		P	P	P
Eating Disorder Symptom Impact Scale[41]	Parent-report of caregiving burden of eating disorders with 4 subscales: nutrition, guilt, dysregulated behavior, and social isolation		P		P	P	P
Parent Vs. Anorexia Scale[42]	Parent-report of their level of self-efficacy in the context of FBT treatment for AN		P		P	P	P
Emotions as a Child Scale[43]	Adolescents report on their parent's typical responses to adolescent emotions, including unsupportive and supportive reactions		A		A	A	A
Family Meal Observational Assessment	Parents and adolescents engage in a video recorded family meal session involving conversation about the present meal and meals in the last week involving happiness, sadness, anger, and fear. Recordings coded for parent coaching of adolescent emotions in response to meals.		I,A,BC,P		I,A, BC, P	I,A, BC, P	I,A, BC, P
Weekly Homework Task	Parents are asked to practice their EC skills daily by having a 5-10 minute "de-briefing" of following select meals. Recordings coded for parent coaching of adolescent emotions in response to meals			BC			
Encouragement of Behavioral Freedom[44]	Adolescent report of parental encouragement of behavioral freedom		A		A	A	A
Multidimensional Assessment of Parenting Scale[45]	Parent report of parenting behaviors including proactive parenting, positive reinforcement, warmth, supportiveness, hostility, lax control, and physical control.		P		P	P	P
Background Questionnaire	Parent report of family demographics		P		P	P	P
Acceptability of Intervention Measure	Interventionist report of acceptability		I	I*	I	I	I
Intervention Appropriateness Measure	Interventionist ratings of intervention appropriateness		I	I*	I	I	I
Feasibility of Intervention Measure	Interventionist rating of feasibility of intervention		I	I*	I	I	I
Note. A = Adolescent, P = Parent	**I = Interventionist, BC = Blind Coder, TD = Treatment development team, *only administered after session 5 of EC intervention**						

Families will then be instructed to complete baseline assessment questionnaires online through RedCap. The baseline visit will be conducted via Zoom for Healthcare. Families will complete a family meal which will be recorded and later coded, and interviews. All families will be mailed an audio recorder to record future EC intervention homework at this time. Families will opt in for text message appointment reminders.

7. PROCESS OF OBTAINING CONSENT

Prior to study enrollment, permission from the attending adolescent medicine physicians of each eligible participant will be obtained in clinic. As noted above, once participants are identified as study eligible, they will be contact within 24 hours of an initial visit in the CCHMC Eating Disorders Program, during an in-patient stay via Jabber, or within 24 hours of their first therapy visit and provided a description of the study, including study procedures, benefits, and risks, by the trained study coordinator included on the approved IRB protocol. Due to face-to-face restrictions due to COVID-19, we will initially approach potential participants via phone after receiving permission from their physician and sending them a recruitment letter. They will be given an information sheet and asked to complete the FMSS over the phone. We are asking for waiver of documentation of consent to perform the FMSS as this is an eligibility criterion. The research coordinator will inform families of their eligibility within 2 days of the FMSS over the phone. At this time, informed e-consent and assent will be obtained from caregivers and adolescents and all questions asked by participants will be addressed. Adolescents will be explained the study in teen-friendly terms, so they understand study procedures. Participants will be explicitly informed that their care at CCHMC will not be affected whether they choose to participate in the study or decline participation.

8. STUDY PROCEDURES

This is a 6-month study of adolescents with AN and AAN and their caregivers. Study participants will complete assessment questionnaires at baseline, 1-month, 3-months, and 6-months. Participants will be randomized to either treatment or control conditions. They will engage in either 10 parent EC group sessions or 10 parent support sessions over a 3-month period followed by a post-treatment assessment (see Table 2).

Measures: At each time point, caregivers will complete self-report measures of satisfaction with the intervention, parenting behaviors, psychological functioning, levels of EE, levels of warmth, and strategies for managing adolescent negative emotions (60 minutes to complete; see Table 2). Adolescents will be assessed for their level of AN or AAN symptoms using the gold standard for AN assessment; the EDE. Adolescents will also report on parenting behaviors and their own psychological functioning. These questionnaires best assess the constructs of interest and have good reliability and validity in pediatric AN population. The mechanisms of treatment outcome that we are testing are high EE and parental warmth, which will be assessed by the FMSS and family meal at each time point. Our outcome is adolescent weight restoration (≥ 95% expected body weight [EBW]). Based on prior literature, demographic, medical, and behavioral covariates including socioeconomic status, adolescent behavioral functioning, caregiver burden, and caregiver psychological and emotional functioning will be assessed in the current proposal.

9. DATA ANALYSIS / METHODS

Exploratory Aim: Examine whether the FBT+EC parent group intervention reduces EE, increases parental warmth, and improves weight restoration in the RCT. H1a. We will have preliminary evidence that families in the FBT+EC group will have lower levels of EE and higher parental warmth than families in the FBT+support group at 1 month which will be sustained at 3 and 6 months. H1b. We will have preliminary evidence that EE and parental warmth are correlated with weight restoration at 1, 3, and 6 months. H1c: We will have preliminary evidence that adolescents in the FBT+EC group will demonstrate improvements in weight restoration compared to children in the FBT+ parent support group at 1, 3, and 6 months.

Exploratory Analyses: All analyses will be carried out with missing data assumed to be missing at random and handled via maximum likelihood estimation with auxiliary correlates[68] within Mplus (Version 8) on the full sample (N=50). Bivariate correlations will first be calculated among EE, parental warmth, and weight restoration (measured continuously as mean percentage of EBW) at 1, 3, and 6 months (H1b). To test whether families in the FBT+EC group will have lower levels of EE and higher parental warmth (H1a) as well as greater improvements in weight restoration (H1c) than families in the FBT+support group, 3 separate ANCOVA models will be used to test our hypotheses for each outcome. Baseline measures of EE, parental warmth, parental psychopathology, length of illness, and %EBW will be included in the models as control covariates.

Power: Although a pilot trial, Monte Carlo simulation power calculations showed that, assuming N=50, power will be $\geq$.80 for between group difference effects of $d \geq 1$ for all outcomes (EE, parental warmth, weight restoration), assuming both standardization of analysis variables and baseline covariates (EE, parental warmth, parental psychopathology, length of illness, and %EBW), which will explain (R^2 = .35) 35% of response variable noise variance.

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10. FACILITIES AND PERFORMANCE SITES

Recruitment and all study assessments will be conducted at CCHMC. Due to face-to-face restrictions related to COVID-19, our initial efforts of study recruitment and study visits will be conducted over the phone and/or via Zoom for Healthcare which is HIPAA compliant. Data management will occur at CCHMC. Slack will be used as a data management tool between investigators at CCHMC and UGA. No protected health information will be shared over Slack. All study videos will be coded by Co-Investigator Anne Shaffer at University of Georgia. Video recorded sessions will be transferred onto OneDrive, a secure drive on the CCHMC network. Dr. Shaffer's laboratory at UGA has the capacity to transfer digital video and audio to secure computers and DVD burners for secure physical storage of video data, supported by departmental and college IT services. Secure wireless connectivity is available. A dedicated electronics shop is provided by the University to perform routine computer repairs and software support is available from a full time information technology (IT) support person dedicated to this department. The combination of these information technologies contributes to the potential for success by assuring both efficient data handling and optimal communication among the research team.

11. POTENTIAL BENEFITS

Participants in this study may benefit from improved family communication and eating disorder symptoms. The study is anticipated to support preliminary efficacy of an EC parent skills group as an adjunct to FBT. This could lead to improvements in several outcomes for patients who receive the EC intervention, including reductions in expressed emotion, and improvements in weight restoration. These data could support continued research to refine and adapt EC interventions for adolescents with AN and AAN and their families.

12. POTENTIAL RISKS, DISCOMFORTS, INCONVENIENCES, & PRECAUTIONS

This is a minimal risk study, a risk that is no greater than that encountered in routine behavioral assessment and clinical care. There are no medical risks to study participation. All the questionnaires, measures, and interviews have been used in research, including our own, without any reported negative effects; however, it is possible that a small group may feel uncomfortable responding to questions or being observed during a family meal interaction.

Several precautions will be taken to minimize the risk, discomforts and inconveniences associated with this study protocol. In the unlikely event that adolescents and their families feel uncomfortable answering questions, they are free to skip questions or questionnaires. Families may prefer to not be videotaped for their assessments and they are free to opt out of recording. Since the EC intervention is a group, all efforts to maintain confidentiality will be made but cannot be guaranteed in a group setting. All participants will learn about the group and the importance of maintaining confidential information inside of the group setting. Outside relationships will be discouraged. Families may also be inconvenienced by scheduling and attending intervention sessions. If the adolescent or caregiver is particularly distressed, appropriate treatment and or referrals can be made by the PI, who is a licensed clinical psychologist. Notably, because a trained therapist will be interacting with participants, there is the possibility that confidential information will be discussed. All sessions will be audio recorded to ensure treatment fidelity and will be erased after review by the Research Team. See section 14 and 15 regarding how this will be handled.

If any adverse reactions or complications occur as a result of this study, we will report them per CCHMC policy.

13. RISK/BENEFIT ANALYSIS

There is minimal risk associated with study participation. Knowledge gained in this study has the potential to improve the treatment of pediatric AN and AAN by increasing parent emotion coaching skills and decreasing expressed emotion, which would improve weight restoration outcomes in this population.

14. DATA SAFETY AND MONITORING

We expect this study to be no more than minimal risk to participants. The research team will monitor for safety and adverse events at each study visit. Specifically, intervention session content will be discussed in weekly supervision by the interventionist with Dr. Shaffer, study Co-I. The interventionist and research study coordinator will also complete protocol checklists for treatment integrity and fidelity. The research study coordinator will review questionnaires for completion and review of items related to significant distress or suicidal ideation. We have procedures in place to ensure that the research coordinator checks these items immediately after completion of the measure and if the items indicate risk, a clinical psychologist either with the eating disorder team or the PI are notified immediately to assess for further risk.

If desired, administration of the assessment measures and participation will be discontinued at parent or patient request. The study team will provide referrals as appropriate for treatment needs resulting from significant adverse events or psychological issues that exceed the scope and/or intensity of the intervention. Adverse events will be reported to the CCHMC Institutional Review Board (IRB) during continuing review, while serious adverse events will be reported to the IRB within 24 hours.

15. PRIVACY AND CONFIDENTIALITY

We will also monitor adolescents for any adverse events per our Institutional Review Board (IRB) procedures and guidelines. Raw hard data will be stored in locked areas in the Division of Behavioral Medicine and Clinical Psychology and only authorized staff will have access to the computer files. Access to original data and study materials will be limited to the investigative team. All raw data, including questionnaires and computer files containing data will have confidentiality protected with the use of unique assigned study identifier codes; computer files will be password protected. A master file linking the identifying patient information with the study ID code will be secured in a password protected file. This master file will be destroyed upon

completion of the study. Data will be retained until final data analyses are completed; all de-identified data will then be shredded and destroyed. Neither names nor identifying information will appear in any publication based on this research. All audio files will be password protected and then deleted after they have been reviewed by the PI for treatment fidelity.

Confidentiality will be retained throughout the study related to intervention content, with one exception. If the participant provides information about something that might put the participant or another person in danger, we are obligated to report this as mandated reporters. This will be shared in the consent/assent form.

All study personnel have been trained in data safety and monitoring, privacy and confidentiality, minimizing risks related to loss of privacy and confidentiality. We will closely monitor performance of our research personnel to ensure the strictest standards. Study personnel will screen questionnaires for completeness and participants will be encouraged to complete missing items. If there are any elevations on risk-items, the PI will be immediately notified and will ensure that risk is assessed by either a licensed psychologist or a master's level licensed therapist. Data from each questionnaire will be entered into a Redcap database and then analyzed with SAS, Mplus, or SPSS.

Because this research study involves payment for participation, we are required by Internal Revenue Service (IRS) rules to collect and use participant's social security number (SSN) or taxpayer identification number (TIN) in order to track the amount of money that we pay them. Unless they have given specific permission for another use of their SSN or TIN related to this research study, we will only use their SSN or TIN to keep track of how much money we pay them and their SSN or TIN will not be used as part of this research study.

16. COST OF PARTICIPATION

There are no costs for participation in this research study. Participants will be responsible for the usual costs of medical care.

17. PAYMENT FOR PARTICIPATION

Participants will complete 10 EC group sessions, baseline assessments, and post-treatment assessments. Adolescents can earn $100 and caregivers $100 for their participation ($25 at each of the 4-assessments). Families can choose to have separate ClinCards or can be paid on one ClinCard together. If they miss one of the 4 assessments, they will not be paid for the one they miss.

We will give participants their payment in the form of a reloadable debit card (ClinCard) and they will receive a handout that will explain how to use this card. We will provide them with a card, and we will load money onto their card after completion of the baseline visit and after completion of the post treatment visit.

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