# Confirming the Efficacy/Mechanism of Family Therapy for Children with Low Weight Avoidant/Restrictive Food Intake Disorder (ARFID)

**Study Protocol**

**NCT04450771**

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The overarching purpose of this research is to study a fully manualized protocol of FBT-ARFID using an RCT. The study intends to evaluate the effects of this intervention on the age- and sex-appropriate EBW% of children 6-12 years old with ARFID. To this end, the proposed study will address the following specific aims:

Aim 1: To conduct an RCT involving children and adolescents between the ages of 6 and 12 years of age with DSM 5 ARFID and weight below 88% of EBW comparing FBT-ARFID with medical management to manualized Non-Specific Care (NSC) with medical management.

Aim 2: To examine treatment acceptance by parents.

Aim 3: To explore moderators of treatment outcome. We will examine all baseline variables as potential predictors and/or moderators of outcome.

Participants will be recruited through pediatricians, mental health experts, clinics treating EDs, and local parents' groups. Potential participants who are interested will be given contact information (or obtain it from flyers or advertising) for the research coordinator to complete a telephone screen.

Inclusion criteria for this study are: 1) children meeting DSM-V criteria for ARFID; 2) children between the ages of 6 to 12 years old 2) medically stable for outpatient treatment according to the recommended thresholds of the American Academy of Pediatrics and the Society of Adolescent Medicine; 3) Not engaging in another individual or family based psychotherapy trial during the duration of treatment sessions in the study; 4) No prior FBT; 5) If taking medication for co-morbid disorders, participants must be on a stable dose of medication for 8 weeks (2 months) before participating. If the participant is on a new medication at baseline, but is discontinuing the medication in order to start the study, they must have discontinued the medication before beginning treatment; 6) IBW between 75% and 88%; 7) Able to fluently speak and read English

Those eligible for the program will be invited to read and sign informed consent forms and complete the baseline assessment. A total of 100 children (ages 6 years to 12 years, 11 months old) diagnosed with ARFID and their families will be recruited and randomized to FBT-ARFID with medical management for 14 sessions provided over 4 months
or manualized Non-Specific Care (NSC) with medical management for 14 sessions over 4 months.

1) Family-based Treatment for ARFID (FBT-ARFID): FBT-ARFID is a manualized treatment based on the model of FBT that employs the same interventions as standard FBT for AN and BN: externalization, agnosticism, parental empowerment, a behavioral focus on changing eating behavior. Early sessions focus on inciting parents to make changes and includes a family meal that allows therapists to observe and consult directly to mealtime behaviors. Treatment consists of a total of 14 sessions that are about an hour long over about a 4-month period.

2) Psychoeducational Motivational Therapy (PMT): This treatment is a manualized non-specific psycho-educational and motivational enhancement approach that is based on a supportive non-directive psychotherapy model that has been used in other RCTs with eating disorders as a comparison. PMT consists of sessions with the child alone and 5

parent only meetings. There are a total of 14 sessions that are about an hour long over about a 4-month period. The focus of PMT is psychoeducation about health and social impacts of restrictive eating and supporting parent and child exploration of motivation to change eating patterns and choices they make about changes to eating. However, the therapist does not initiate behavioral or cognitive interventions. Feelings about eating and making changes are explored in both the child and parent sessions.

There will be five major assessment points (BL, 1 month, 2 months, End-of-Treatment, and 6 month Follow-up). Both the child and the parent will complete measures at these time points. In addition, patients and parents will participate in short bi-weekly survey assessments for the first 2 months of treatment to ensure early detection of possible mediators.

Participants and Families will complete the following measures/assessments:

**PRIMARY OUTCOMES:**
*1) Expected Body Weight (EBW*) for child participant will be calculated based on the Center for Disease Control Growth Charts with weight adjusted for age, sex, and height. This will be measured at the major assessment timepoints. Additionally, therapists will collect the child's height and weight information at each of the 14 treatment sessions.

*2) Parents versus Avoidant Restrictive Food Intake Disorder (ARFID)* is a modification of the Parents versus Anorexia Nervosa (AN) Scale, a measure of parental self-efficacy at changing eating behaviors. The modifications to the scale are minor and consisted of changing the name of the disorder named in the scale's questions from AN to ARFID.

*3) Parental Feeding Behavior Assessment:* One mechanism that we are exploring in this study is whether specific changes in parental mealtime feeding behaviors are a possible mechanism of FBT-ARFID. We will record a meal session at baseline and week 6 in all participants. These meals will be coded for behaviors associated with successful re-feeding using a procedure developed for FBT.

**SECONDARY OUTCOMES:**
*1) The Pica, ARFID, Rumination Disorder Interview (PARDI)*: The PARDI is a new measure designed to diagnose and evaluate symptom severity of ARFID putative subtypes. Data demonstrate the measure's validity and ability to distinguish ARFID patients from other clinical groups. Parents will be assessed using the PARDI at all major assessment timepoints.

*2) Therapy Suitability and Patient Expectancy (TSPE):* The TSPE measures perceptions of the suitability and expectancy of the treatment provided will be rated on a visual analogue scale (0-10) by parents.

*3) Parenting Style Questionnaire (PSQ):* This questionnaire is a validated measure of parenting style related to authoritative and permissive style. This questionnaire will be completed parents.

*4) Center for Epidemiological Studies Depression Scale for Children (CES-DC):* This is a validated measure of child depression and will be completed by children.

*5) Revised Children's Manifest Anxiety Scale (RCMAS):* This is a validated measure of childhood anxiety and will be completed by children.

*6) Helping Relationship Questionnaire (HRQ): The HRQ* is an 11-item questionnaire measures the quality of the therapist-patient relationship. The HRQ will be completed by parents.

*7) Schedule for Affective Disorders and Schizophrenia for School-Aged Children (6-18 years) (K-SADS):* The K-SADS-PL is a widely used interview for detecting psychiatric disorders in children and adolescents. Only parents will be interviewed. The presence or absence of other psychiatric co-morbidity prior to treatment is one of the predictor or moderator variables.

*8) Strengths and Difficulties Questionnaire (SDQ):* The 25 items in the SDQ designed assess conduct, social, and peer behaviors. This is to be taken by parents.

*9) Beck Depression Inventory (BDI):* Instrument designed to measure depression. In this case, it will measure parental depression.

*10) Beck Anxiety Inventory (BAI):* Instrument designed to measure anxiety. It will measure parental anxiety in this study.

*11) 36-Item Short Form (SF-36):* A general measure of physical and mental health functioning. This assessment will be taken by the parents.

*12) Bandura's General Self-Efficacy Scale (GSES):* Measure of parental self-efficacy.

*13) Parental Sense of Competency Scale (PSOC):* Measure of parental self-efficacy.

Medical Oversight: Initial and ongoing medical oversight of patients will be required of subjects in the study to ensure they are medically stable for outpatient treatment and will be provided at each site by a pediatrician with expertise in the treatment of eating disorders. This study pediatrician will be blind to patient assignment as has been the standard practice in our previous studies of adolescent AN and ARFID. Thus, similar to our previous studies, all subjects will be required to have medical insurance that covers pediatric care and hospitalization for medical problems associated with ARFID. In addition, the study will fund a pediatrician with expertise in adolescent eating disorders to consult with medical providers on management and adherence to the medical monitoring and hospitalization requirements of the study. The criteria for medical stability of adolescents with eating disorders at our centers are published. The decision to hospitalize patients will be made on standard criteria by the site-specific study pediatrician.