CME

# Intensive, Manual-based Intervention for Pediatric Feeding Disorders: Results From a Randomized Pilot Trial

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## ABSTRACT

**Objectives:** The aim of this pilot study was to investigate feasibility and preliminary efficacy of an intensive, manual-based behavioral feeding intervention for children with chronic food refusal and dependence on enteral feeding or oral nutritional formula supplementation.

**Methods:** Twenty children ages 13 to 72 months (12 boys and 8 girls) meeting criteria for avoidant/restrictive food intake disorder were randomly assigned to receive treatment for 5 consecutive days in a day treatment program (n = 10) or waitlist (n = 10). A team of trained therapists implemented treatment under the guidance of a multidisciplinary team. Parent training was delivered to support generalization of treatment gains. We tracked parental attrition and attendance, as well as therapist fidelity. Primary outcome measures were bite acceptance, disruptions, and grams consumed during meals.

**Results:** Caregivers reported high satisfaction and acceptability of the intervention. Three participants (1 intervention; 2 waitlist) dropped out of the study before endpoint. Of the expected 140 treatment meals for the intervention group, 137 (97.8%) were actually attended. The intervention group showed significantly greater improvements ($P < 0.05$) on all primary outcome measures ($d = 1.03–2.11$) compared with waitlist ($d = -1.13–0.24$). A 1-month follow-up suggested stability in treatment gains.

**Conclusions:** Results from this pilot study corroborate evidence from single-subject and nonrandomized studies on the positive effects of behavioral intervention. Findings support the feasibility and preliminary efficacy of this manual-based approach to intervention. These results warrant a large-scale randomized trial to test the safety and efficacy of this intervention.

**What Is Known**

- Behavioral intervention is a widely recommended treatment and has some support for treating pediatric feeding disorders.
- Available evidence is primarily based on case studies and nonrandomized studies at multidisciplinary day programs or inpatient hospital settings.
- No randomized controlled trials have tested the safety and efficacy.
- Lack of intervention manuals is a barrier to randomized controlled trials in this area.

**What Is New**

- This is the first randomized controlled trial examining intensive behavioral feeding intervention for chronic, severe food refusal in a day treatment setting.
- Results demonstrate the feasibility of a structured behavioral intervention for severe feeding problems in children.
- Results also provide preliminary efficacy of the structured intervention and sets the stage for a large-scale randomized controlled trial.

**Key Words:** behavioral intervention, feeding, gastroenterology, nutrition, randomized controlled trial

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Pediatric feeding disorders are characterized by persistent restrictions in consumption that exceed ordinary variations in hunger and/or food preference (1). In the Diagnostic and Statistical Manual of Mental Disorders - Fifth Edition, feeding problems of this magnitude are classified under avoidant/restrictive food intake disorder (ARFID), which requires failure to meet nutrition and/or energy needs due to restricted food intake (2). ARFID may manifest as faltering growth, significant nutritional deficiencies, dependence on enteral feeding or oral nutritional supplementations, or marked interference with psychosocial functioning. Available estimates suggest ARFID affects as many as 5%

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of children and is among the most frequent concerns in pediatric settings (3). Possible sequelae of feeding disorders include impaired cognitive development, medical problems such as placement of a feeding tube, and high levels of caregiver stress and childrearing burden (4,5). Children with complex medical histories (eg, congenital or acquired respiratory, cardiac, and gastrointestinal problems) are at increased risk for feeding disorders (6,7). Indeed, more than 70% of cases referred for intensive behavioral intervention involve medical conditions such as gastroesophageal reflux disease, food allergy, and/or gastroenteritis (5,8).

The potential for detrimental health outcomes from feeding disorders combined with high prevalence underscores the need to develop and test replicable treatments. At this time, behavioral intervention is the only an empirically supported treatment for pediatric feeding disorders (1,3,4,9). Treatment, however, can be costly with limited availability at a handful of specialty centers (1,5). In addition, methodological limitations in the extant literature have been identified (3). Notably, available evidence has been established through single-subject research and nonrandomized studies, and there are few randomized controlled trials (RCTs). Sharp et al (1) conducted a meta-analysis of 48 single-subject studies published between 1970 and 2010. Lukens and Silverman (3) completed a systematic review focusing exclusively studies with group designs, identifying 13 published studies (11 nonrandomized studies and 2 RCTs) during a 15-year period (1998–2013). Results of these reviews support the positive effects for behavioral intervention to treat chronic feeding problems. The findings also suggest that intensive intervention is the standard of care for children with complex feeding disorders, with a majority of studies conducted in multidisciplinary inpatient or day treatment programs. No RCTs, however, have been conducted in these settings.

Although there is general agreement on measurement of outcomes and core behavioral techniques during intensive treatment (1,3), there are also no examples of manual-driven interventions. Treatment manuals provide structure for the intervention and permit replication. A necessary prerequisite for testing the efficacy of a treatment manual is to show that is acceptable to affected children and parents and that it can be reliably delivered by trained therapists. The purpose of this pilot study was to examine the feasibility and preliminary efficacy of a manual-based, technology-supported intervention for young children with chronic and severe food refusal in a day treatment program.

# METHODS

## Design

The study was conducted between April 2014 and September 2014. Participants were randomly assigned to the 5-day intervention or waitlist in a 1:1 ratio using permuted blocks. Emory University institutional review board approved the study protocol and parents provided written informed consent before the collection of study data. All of the participants completed the baseline assessment on a Monday. Families were informed of the child's group assignment following this assessment. Outcome assessments were conducted at postintervention (day 5) and 1-month following the treatment. This study was registered in clinicaltrials.gov identifier (NCT02119910).

## Study Participants

To be eligible, boy and girl participants had to be between 12 months and 6 years age, deemed appropriate for behavioral feeding intervention based on active and persistent food refusal (eg, severe tantrums, disruptions), and meet diagnostic criteria for ARFID as evidenced by dependence on enteral feeding or oral nutritional formula supplementation (2). Exclusion criteria were the following: a feeding concern regarding dietary variety (food selectivity) versus volume; non-English speaking; unstable, active acute or chronic digestive disease; anatomical or active medical problems prohibiting safe oral intake (eg, oral feeding aspiration, upper airway obstruction); present or previous enrollment in behavioral feeding therapy; or serious behavioral problems (eg, self-injury, aggression, elopement) that would require a different treatment. Eligibility criteria remained static for duration of the study. Participants in the intervention group were enrolled in treatment for 5 consecutive days immediately following baseline. Children on the waitlist were offered treatment following the assessment at day 5.

## Setting

The study occurred at a multidisciplinary day treatment program in the Southeast United States specializing in the assessment and treatment of pediatric feeding disorders. In addition to behavioral psychologists, the multidisciplinary program includes registered dieticians, a speech language pathologist, an occupational therapist, a social worker, nurses, and a pediatric gastroenterologist. For the present study, the contribution of other disciplines was standardized as follows: the registered dietitian developed a menu of 8 foods with low probability for food allergies or cultural/parental dietary restrictions and provided a sliding scale for formula weaning to account for increased oral intake; the speech language pathologist and occupational therapist team monitored meal sessions for swallow safety and outlined any special accommodations (eg, seating, recline, supportive padding) for use during meals; nurses screened for any medical concerns during intervention with consultation from the pediatric gastroenterologist; and the social worker helped families secure accommodations and transportation.

Treatment involved 14, 40-minute meal blocks delivered across 5 consecutive days (Monday–Friday). This time period was deemed sufficient to demonstrate feasibility and preliminary efficacy of the manual-based approach; however, it was not considered equal to our 8-week standard of care. A team of 4 trained bachelor level therapists conducted meal sessions using the treatment manual under the supervision of a licensed psychologist. Meals 12 and 13 involved structured parent training to promote transition of treatment into the home setting (Sharp et al (10)). By meal 14, parents fed the child in the room on their own with feedback from the therapist as needed.

## Behavioral Feeding Intervention

To address the complexity of treating pediatric feeding disorders, we developed a manual-based and technology-supported behavioral feeding intervention called integrated eating aversion treatment (iEAT). The iEAT program combines a touch screen data collection system to capture mealtime performance (eg, bite acceptance, crying, disruptions) using commercially available technology (ie, iPADs); automatic aggregation and statistical analysis of data using a Health Insurance Portability and Accountability Act (HIPAA)-compliant relational data base; and a behavioral treatment manual involving escape extinction, reinforcement procedures, and formalized meal structure (ie, scripted instructions, reduced bite volume, pureed food texture). The sequencing of techniques in the manual was based on our clinical practice and review of extant literature (1). Treatment meals involved a standard menu of 8 food items, 2 from each food group (ie, protein, starch, fruit, vegetable). During each meal, the feeder (ie, therapist or parent) presented 1

item from each group using a standardized schedule (4 total foods per meal). Bites involved a small volume of a pureed food (0.5 $cm^3$). If a child accepted and swallowed the presented food at high and stable rates, the bite volume was gradually increased. The maximum bite volume for the study was 2.0 $cm^3$.

## MEASURES

### Growth Parameters and Demographic/Personal History Form

At the initial assessment, the child's height and weight were obtained to calculate body mass index [BMI]-for-age percentile based on growth charts from the Centers for Disease Control and Prevention (11). Height and weight were also collected at day 5 and 1-month post-treatment for intervention group. Caregivers completed a questionnaire that included demographic information, present- and past-feeding concerns, and previously diagnosed medical, developmental, or mental health problems.

### Meal Observation

A parent served as the feeder during pre-/post-treatment structured meal observations. During the meal, parents were instructed to seat the child in a highchair with a tray, present at least 1 bite to the child's lips, and persist with the meal as they would in the home setting. The maximum duration of the observation was 10 minutes; however, parents were informed that they could discontinue the meal at any time after presenting 1 bite. Participants randomized to the iEAT condition completed the post-treatment assessment on day 5. Participants in the waitlist condition returned for the second evaluation an average of 5.4 days following the initial assessment (range 5–7 days). Parents and children who completed iEAT were asked to return in 1 month to assess maintenance of treatment gains.

The primary outcome measures collected during the meal observations were acceptance, disruptions, and grams consumed, which are commonly used in pediatric feeding disorder studies (1). Acceptance was scored when at least half of the spoon bowl entered the child's mouth. Disruptions were defined as turning the head away from the spoon and/or pushing away the spoon or feeder's hand during bite presentation. We converted each variable into percentages: counts of a target behavior during a meal divided by the total number of bites presented per meal. All of the meals were digitally recorded. A second, blinded observer rated 100% of recorded meals to evaluate interobserver agreement. The mean coder agreement for bites presented was 85% for acceptance (range 66%–99%) and 80% for disruptions (range 62%–92%). The psychologist conducting the assessment recorded data on grams consumed by using a digital scale (premeal food minus postmeal food). A second psychologist attended 25% of live observations and independently measured grams consumed. Interclass correlation for grams consumed was 0.97.

### Treatment Satisfaction

Parents in the intervention group were asked to complete a satisfaction questionnaire at the 1-month follow-up appointment. The questionnaire included 5 items on general satisfaction and acceptability of the program (eg, ''overall, how satisfied were you with the feeding intervention?'') and 4 items on impact of the feeding intervention (eg, ''in general, how effective was the behavioral treatment in improving your child's mealtime behavior?''). Items were rated on 5-point Likert-type scale (1 = quite dissatisfied/totally disagree/not at all effective to 5 = extremely satisfied/totally agree/extremely effective). Higher scores reflect greater levels of satisfaction, acceptance, and perceived improvement.

### Treatment Fidelity

We used a fidelity checklist focusing on key aspects of treatment protocols in 3 areas: bite presentation, including instructions, time between bites (~30 s), and bite persistence; prompts, including mouth-clean checks and reminders to accept or swallow a bite; and consequences, including praise for target behaviors, ignoring problem behaviors and providing access to preferred items. The therapist was rated on correct implementation on a bite-by-bite basis (0 = component absent; 1 = component present). Therapist fidelity to the treatment protocol was then calculated in percentages (eg, if 8 of 10 presentations received a score of 1, the therapist received a score of 80%).

### Data Analysis

Feasibility analyses focused on attrition, participant attendance, therapist's treatment fidelity, and caregivers' rating of treatment acceptance. Statistical analyses for efficacy outcomes were carried out using SAS version 9.3 (SAS Institute Inc, Cary, NC) with significance at the 0.05 level. For all outcomes, before analysis, the change from pre- to post-treatment was calculated for each study participant. A Mann-Whitney $U$ test was used to compare the distribution of change scores between study groups (iEAT vs waitlist control) for each outcome of interest. In instances of heteroscedasticity, a 2-sample Kolmogorov-Smirnov test was used in place of the Mann-Whitney $U$ test. Within group, effect sizes were calculated using the formula $\frac{(\mu_{post}-\mu_{pre})}{\sigma\sqrt{2(1-\rho)}}$, where $\sigma$ is the pooled within-group standard deviation, and $\rho$ is the correlation between pre- and post-measurements (12).

## RESULTS

### Study Population

Sixty-nine potential participants were assessed for eligibility via chart review and/or phone screening by study staff (Fig. 1). Parents of 20 children consented, completed the initial assessment, and were randomized to the iEAT condition or waitlist control. There were no significant group differences on sex, age, weight, height, BMI-for-age percentile or race, or outcome measures at baseline. Using weight and height obtained during the initial assessment, the average BMI-for-age percentile of the sample fell within the healthy weight range. Nine children were reliant on tube feedings; 11 children met their nutritional needs through formula via bottle or sippy cup. Most children (90%) presented with complex medical histories and developmental delays. Gastroesophageal reflux disease was the most frequent medical diagnosis, reported in 60% of cases. Two children without a history of a medical condition were diagnosed with ''sensory integration disorder.'' A detailed summary of study participants is available at *http://links.lww.com/MPG/A583*.

Eight of 10 participants on the waitlist completed the study. One family discontinued because of transportation difficulties; the second family decided to wait for standard clinical care in our program. One participant randomized to the iEAT condition was excluded from participation on day 4, after 11 meals, because silent aspiration was detected after an unexplained fever and subsequent diagnosis of pneumonia. This adverse event occurred after consumption was established at high and stable rates and no outward signs of swallowing difficulty throughout treatment (eg, coughing before or after swallowing). This participant was included in analysis of feasibility data. Lack of postrandomization outcome data, however, prohibited inclusion in pre- to post-treatment analyses on efficacy measures. All of the other participants assigned to the iEAT condition received the full intervention (14 meals) and completed the post-treatment assessment.

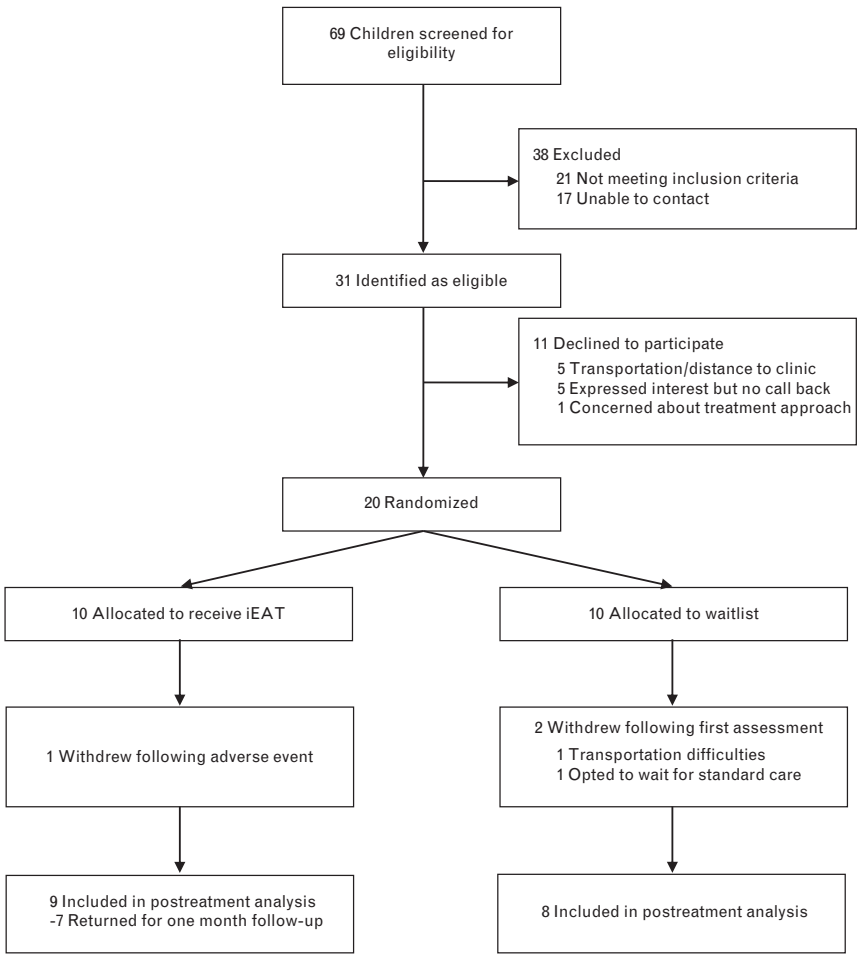


**FIGURE 1.** CONSORT flow diagram of patients through trial. CONSORT = Consolidated Standards of Reporting Trials.

## Attendance, Therapist Fidelity, and Final Treatment Protocols

Treatment was delivered for 137 of 140 (97.8%) planned meals. Therapist fidelity to the manual was >95% based on independent review in 34% of randomly selected intervention meals. All of the final treatment protocols involved operant conditioning procedures (eg, escape extinction, differential reinforcement) commonly identified during intervention for severe feeding disorders (1,4,9). Six of the 9 participants achieved required levels of stability in mealtime behaviors allowing systematic increase of the bite volume to a level spoon (2.0 $cm^3$) by meal 14.

## Efficacy Outcomes

Because primary outcome measures did not show a normal distribution, median and 25th to 75th percentile ranges are presented as descriptive statistics (Table 1). Analyses of change scores between study groups were significant across all measures, all favoring the iEAT group. Children assigned to iEAT showed a significantly greater increase in bites accepted pre- to post-treatment compared with the waitlist group (88.9% vs 5.6%, respectively) and significantly greater reductions in disruptions compared with children in the waitlist group (55.6% vs 9.2%). Behavioral improvements coincided with a significant increase in the volume of food consumed by children in the iEAT group following treatment (31 net grams in the 10 minute observation). The magnitude of the observed effects for iEAT ($d = 1.03–2.11$) fell in the large range by conventional standards. We also analyzed BMI-for-age percentile before and after treatment for both the groups. Overall, growth status was stable following intervention, with a slight increase in BMI-for-age percentile observed in children in the iEAT group.

## Post-treatment Follow-up and Treatment Acceptance

Seven of the 9 participants in iEAT (78%) returned to clinic for post-treatment follow-up at 36 days (range 31–60 days). One participant cited distance from clinic as prohibiting continued participation; the second participant could not be contacted. Mealtime behaviors for the 7 remaining participants were relatively unchanged from study endpoint and significantly better compared with baseline. Median bites accepted were 100% (range 50–100) and disruptions were 13% (range 0–100). There was a significant increase in grams consumed at follow-up (median: 71; interquartile range (IQR): 12–140) compared with postintervention (median 34; IQR: 18–39; $P = 0.031$). Post-treatment satisfaction questionnaires were available for the 7 iEAT families who returned for follow-up (Table 2). All of the caregivers reported high levels of overall satisfaction with treatment, perceived improvement in mealtime behaviors, and endorsement of the treatment approach as acceptable for addressing their child's feeding difficulties.

TABLE 1. Pre-/postcomparison of differences between groups feeding behaviors, grams consumed, and weight status

| Outcome | iEAT (N = 9) | Waitlist control (N = 8) | *P* |
|---|---|---|---|
| Acceptance, %; median (25th to 75th) | | | |
| Pre | 11.1% (0% to 40.7%) | 5.6% (0% to 24.7%) | |
| Post | 100% (94% to 100%) | 17.1% (6.3% to 30.6%) | |
| Change | 88.9% (30.7% to 94.4%) | 5.6% (−7.6% to 15.7%) | 0.008 |
| Effect size *d* | 2.11 | 0.24 | |
| Disruptions, %; median (25th to 75th) | | | |
| Pre | 81.3% (80% to 100%) | 83.3% (72.8% to 96%) | |
| Post | 30% (0% to 55.6%) | 86.6% (67.7% to 95%) | |
| Change | 55.6% (13.8% to 80%) | 9.2% (−13.1% to 11.8%) | 0.038 |
| Effect size *d*[*] | 1.03 | 0.13 | |
| Grams consumed, g; median (25th to 75th) | | | |
| Pre | 4 (3 to 8) | 2.5 (1 to 8) | |
| Post | 34 (18 to 39) | 0.5 (0 to 4.5) | |
| Change | 31 (5.5 to 43) | −1.0 (−6.0 to 0) | 0.022 |
| Effect size *d* | 1.16 | −1.13 | |
| BMI/age percentile, median (25th to 75th) | | | |
| Pre | 31.7% (9.5% to 64.4%) | 66.1% (25.6% to 95.8%) | |
| Post | 57.5% (15.6% to 90.1%) | 66.1% (25.6% to 95.8%) | |
| Change | 6.7% (0.8% to 8.6%) | −1.6% (−4.2% to 1.1%) | 0.112 |
| Effect size *d* | 0.52 | −0.19 | |

BMI = body mass index; iEAT = integrated eating aversion treatment.
[*]Both *d* values reflect negative reductions; however, sign changed to reflect hypothesized direction of improvement.

## DISCUSSION

This pilot study is the first RCT examining intensive behavioral feeding intervention for chronic, severe food refusal in a day treatment setting. Children in this study required artificial supports (eg, tube or formula dependence) to meet basic nutritional requirements. In 90% of cases, the clinical picture was complicated by medical conditions and/or developmental concerns. Treatment attendance in iEAT was high, the treatment approach was acceptable to parents, and therapists implemented the intervention with high fidelity. The preliminary efficacy results are consistent with positive findings from single-subject studies and nonrandomized trials of intensive behavioral intervention for severe feeding problems in children (1,3). Although the sample size was small, the results at 1-month post-treatment support the possibility of enduring benefit. Consistent with present standards of care, the study occurred at a multidisciplinary day treatment program specializing in the assessment and treatment of pediatric feeding disorders (3). The multidisciplinary approach is recommended because feeding disorders commonly involve problems across areas of expertise (4). In this study, for example, 1 participant assigned to iEAT silently aspirated during intervention. This adverse event underscores the need to conduct behavioral interventions with multidisciplinary support.

Several limitations of this study warrant comment. The sample size was small. The design also involved an active intervention versus waitlist control. Future trials may consider use of an active comparison condition to control for attention and time. Potential control conditions include appetite manipulation (13), medication intervention (14), and sensory/oral motor therapies (15). This feasibility study was only 5 days in duration. As in our day treatment program, standard treatment for children with severe ARFID is often 8 weeks in duration focused on elimination of enteral or formula feedings. In this pilot, manual-based intervention study, we could only show that children were progressing in the right direction. In future studies, we can evaluate whether the short-term treatment gains of decreased refusal and increased oral intake are prerequisites for distal reductions in supplemental feedings. The study did not include long-term assessment of outcomes to confirm the durability of treatment. In addition, the format of the

TABLE 2. Average caregiver ratings of treatment satisfaction

| Item[*] | Treatment n = 7 |
|---|---|
| Overall how satisfied are you with the ''feeding intervention''? | 4.7 |
| In general, how effective was the behavioral treatment in improving your child's mealtime behavior? | 4.9 |
| In general, how effective was parent training in teaching the skills necessary to implement the behavioral treatment at home? | 4.3 |
| At home, my family will continue to use the behavioral treatment from this program. | 4.7 |
| Compared with when we started the program, my child's feeding/behavior is much improved. | 4.9 |
| If a friend was in need of similar help, would you recommend the ''feeding intervention'' to him/her? | 4.7 |
| This is an acceptable intervention for my child's eating behavior. | 4.9 |
| The program improved my child's eating/target behavior so it is not much different from others. | 3.6 |
| At a restaurant, we plan to use the behavioral treatment program. | |

[*]Questionnaire involved 5-point Likert-type scale: 1 = quite dissatisfied/totally disagree/not at all effective to 5 = extremely satisfied/totally agree/extremely effective.

meal observation (ie, clinic-based and limited to 10 minutes) did not permit evaluation of consumption in a more naturalistic manner, potentially involving longer meal duration. Future research could involve more systematic evaluation of treatment outcomes in the home. Finally, a larger trial would permit a more rigorous evaluation of weight status, with present data suggesting intervention may improve growth and/or protect children from a possible decline in BMI-for-age percentile.

## CONCLUSIONS

In this pilot study, we showed that a manual-based, technology-supported treatment is acceptable to families, families agreed to engage in a randomized clinical trial involving a structured feeding treatment, and intervention can be reliably delivered by therapists (16). Although we recognize that efficacy analyses in pilot trials are preliminary, the results are encouraging. Feasibility and preliminary efficacy results suggest that a larger, randomized trial of the iEAT manual is warranted.

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