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The Autism MEAL Plan vs Parent Education: A Randomized Clinical Trial

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Abstract

Objective: To assess the feasibility and initial efficacy of a structured parent training program for children with autism spectrum disorder (ASD) and moderate food selectivity.

Study design: This 16-week randomized trial compared *Managing Eating Aversions and Limited* variety (MEAL) Plan to parent education. MEAL Plan (10 core and 3 booster sessions) provided parents with nutrition education and strategies to structure meals and expand the child's diet. Parent education (10 sessions) provided information about autism without guidance on nutrition, meal structure or diet. In addition to feasibility outcomes, primary efficacy outcomes included the Clinical Global Impression - Improvement scale (CGI-I) and the Brief Autism Mealtime Behaviors Inventory (BAMBI). Grams consumed during a meal observation served as a secondary outcome.

Results: Eligible children (N=38; 19 per group, 32 males. For MEAL Plan, attrition was <10% and attendance > 80%. Therapists achieved > 90% fidelity. At Week 16, positive response rates on the CGI-I were 47.4% for MEAL Plan; 5.3% for parent education ($p < 0.05$). The adjusted mean difference (SE) on BAMBI at Week 16 was 7.04 (2.71) points ($p = 0.01$) in favor of MEAL Plan. For grams consumed, the adjusted standard mean difference (SE) was 30.76 (6.75) also in favor of MEAL Plan ($P = .001$).

Conclusions: MEAL Plan appears feasible, and preliminary efficacy results are encouraging. If further study replicates these results, MEAL Plan could expand treatment options for children with ASD and moderate food selectivity.

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Trial registration Clinicaltrials.gov:

Keywords

Autism; Avoidant/Restrictive Food Intake Disorder; behavioral intervention; feeding; food selectivity; nutrition; pediatric feeding disorders

Autism spectrum disorder (ASD) is often complicated by food selectivity (i.e., eating a narrow variety of foods and/or rejecting one or more food groups) (1, 2). Across a range from mild to severe, food selectivity affects as many as 95% of children with ASD (1, 3). Children with mild food selectivity may not require treatment. Children with moderate or severe food selectivity, however, will require intervention to promote dietary diversity and decrease the risk of nutritional deficiencies, loss of bone density, and constipation (1, 4, 5, 6). Diets overly reliant on complex carbohydrates or fats may portend obesity, diabetes, and cardiovascular disease later in life (7). Food selectivity also increases the challenges of raising a child with ASD (8–11). Parental attempts to expand the child's diet may elicit crying, aggression, self-injury, throwing objects, spitting, and pushing food away in protest (8, 10, 12). These disruptive behaviors may occur at the sight or smell of non-preferred foods. Parents may also worry that persisting with introduction of new foods could lead to further dietary restriction by the child (11).

Combined behavioral and medical intervention in highly structured inpatient units or day treatment programs is well-supported for children with ASD and severe food selectivity (3, 13, 14, 15). These intensive programs, however, are expensive and not available in all communities (13, 16). Moreover, children with ASD and moderate food selectivity may not require this level of treatment. Parent training is emerging as useful for moderate food selectivity in children with ASD (17–20). The high prevalence of food selectivity in ASD and associated health risks underscore the need to develop and test treatments in line with the severity of the condition. The aims of the current study were to evaluate the feasibility and preliminary efficacy of a structured multidisciplinary intervention in children with ASD and moderate food selectivity.

Methods

Children were randomly assigned in a 1:1 ratio to *Managing Eating Aversions and Limited* variety (MEAL) Plan or the structured Parent Education Program (PEP) (17) for 16 weeks. At Week 16, parents of children randomly assigned to PEP were invited to participate in MEAL Plan. Parents of children randomly assigned to MEAL Plan were asked to return at Week 20 for a post-treatment follow-up. The study treatments were delivered in a group format. To ensure consistent baseline measurements across groups, recruitment was conducted in five waves over a 10-month time period. Our goal for this feasibility and preliminary efficacy trial was to enroll eight participants per wave (four per treatment condition). The selection of 4 per group was intended to ensure sufficient individual attention during treatment sessions. The institutional review board at Emory University approved the study protocol and parents provided written informed consent prior to study data collection. Parents received compensation for each assessment visit to cover travel costs. An un-blinded statistician monitored enrollment, attrition, adverse events, and collection of study results every 6 months during the trial.

Participants and Setting

The study was conducted at a multidisciplinary feeding disorders program located in the southeastern United States. The diagnosis of ASD was based on clinical assessment supported by the Autism Diagnostic Observation Schedule (ADOS) (21) and the Social Communication Questionnaire (SCQ) – Lifetime (22). Prior to treatment, we also collected height and weight to calculated body mass index. To characterize the sample and to facilitate comparison with other studies, we administered the Vineland Adaptive Behavior Scales, 2nd edition (23) and the Aberrant Behavior Checklist (24). Eligible participants were males or females between three and eight years of age with a diagnosis of ASD who lived in a household with at least one parent or primary caretaker able to read and speak English. To be included, children had to exhibit moderate food selectivity defined as a diet involving the following: at least 6 total food items; at least one fruit or vegetable, as well as at least one item from the other food categories (ie, protein, grain, and dairy); and 2 or fewer food items in at least one food category (i.e., fruit, vegetable, protein, grain, or dairy). This definition was devised to delineate mild, moderate and severe food selectivity (25). In this model, severe food selectivity is defined as complete rejection of one or more food groups. To evaluate food variety, parents were asked to complete a three-day food record; study staff reviewed the food record with caregivers using a semi-structured interview to confirm moderate food selectivity (i.e., eligibility). Eligibility also required parental report of food selectivity accompanied by persistent refusal behaviors when presented with non-preferred foods as a primary clinical concern. Children with severe food selectivity, those currently participating in behavioral intervention for feeding, or children with serious behavioral problems above and beyond mealtimes were excluded. The presence of a medical condition requiring a specialized diet (e.g., cystic fibrosis or diabetes) and medical problems such as aspiration or upper airway obstruction were also exclusionary. These eligibility criteria remained fixed throughout the study.

Treatments

Autism MEAL Plan—The 16-week randomized controlled trial (RCT) of MEAL Plan included ten 90-minute group sessions delivered over 12 weeks. The 12-week span provided scheduling flexibility to allow for holidays or unanticipated events (e.g., inclement weather) – and promoted subjects receiving the full dose of MEAL Plan. A booster session (telephone or in-person) was offered at approximately Weeks 14 and 16 (endpoint in randomized phase) and four weeks post-treatment (Week 20).

To promote treatment fidelity, the MEAL Plan manual included therapist scripts for behavioral and nutritional components. Initial sessions covered introduction to feeding difficulties in ASD, monitoring mealtime behavior, nutrition planning, structuring meals, and methods to promote appropriate mealtime behavior. Sessions 4 through 7 provided strategies for introducing food, modifying mealtime interactions, implementing the feeding intervention, and incorporating new foods in the future. The last few sessions focused on generalization of treatment gains, when to introduce new food items, program review, and summary of key elements. Treatment materials included a parent workbook with summaries of session topics and worksheets to promote parental understanding and assist with homework implementation. Role plays incorporated visuals and hands-on activities to

encourage parents to practice skills taught during sessions (e.g. collecting data on child mealtime behaviors, modifying bite sizes).

A psychologist led all sessions, assisted by a master's level psychology graduate student. A dietitian co-led sessions 2 and 7. The first 10–15 minutes of each session reviewed the homework assignment to assess completion and provide opportunities to address questions as needed. The first four sessions included only parents to build the foundation of the feeding intervention. Beginning with session 5, the last 30 minutes of each session incorporated parent-child meal demonstrations to practice application of treatment elements. Each parent-child dyad took a turn with the meal demonstration, while other parents watched from an observation room equipped with one-way mirrors. The meal demonstration also included in-vivo coaching from the therapist (either in room or live communication using an earpiece, i.e. bug-in-ear, from the observation room). Coaching sessions provided opportunities for immediate treatment implementation feedback and allowed opportunities for group members to learn from one another.

Although MEAL Plan presented behavioral and nutritional principles with examples in a group format, the curriculum also included time for child-specific guidance. For example, homework assignments were used to tailor home-based intervention for each child. For each child, a designated caretaker attended all sessions and completed assessments; other caregivers (e.g., spouse, grandparent) could attend as many sessions as possible. Childcare was provided when children were not involved in sessions.

Parent Education Program—The parent education program (PEP) is a structured curriculum that has been used as a control condition in prior parent training clinical trials with children with ASD and disruptive behavior (17). In the current study, PEP was modified for the 10-session (90 min), group format and was delivered to parents only. Children were not involved in PEP sessions. Topics covered useful information on young children with ASD including developmental expectations, education planning, advocacy, and current treatment options. PEP was an active comparator that controlled for attention and allowed us to examine the extent to which information alone would reduce mealtime behavioral problems and improve dietary variety. The PEP manual also included a session by session therapist script and parent handouts. PEP group sessions were delivered by a psychologist trained to reliability.

Randomization and Blinding

Eligible children were randomly assigned by a statistician to MEAL Plan or PEP using permuted blocks of 2 or 4 with allocation pattern concealed to investigators. Parents and therapists were aware of the assigned treatment condition. Independent evaluators were blinded to treatment assignment. To protect the treatment blind, we maintained separate study binders for therapists and independent evaluators. Parents were instructed to avoid discussing the treatment during assessments with independent evaluators. The independent evaluator remained blinded to treatment condition during the post-treatment follow-up at Week 20 for the MEAL Plan group.

Procedures and Outcomes Measures

Feasibility outcomes included recruitment, attrition, session attendance, and successful collection of baseline and outcome data in the group format. Efficacy assessments occurred at baseline (pre-treatment), Week 12 and Week 16 (endpoint) for parents and child participants in both treatment conditions. As noted, parents of children in MEAL Plan were invited to return for a follow up visit at Week 20 to evaluate the durability of treatment effect(s). The Clinical Global Impression - Improvement Scale (CGI-I) served as the first primary outcome measure (17); the Brief Autism Mealtime Behaviors Inventory (BAMBI) served as a co-primary outcome measure (12; 26).

The CGI-I (19; 27) is a 7-point scale designed to measure overall improvement from baseline. This measure has been used in several clinical trials in ASD. Scores range from 1 (very much improved) through 4 (unchanged) to 7 (very much worse). Scores of much improved or very much improved (i.e., 2 or 1) were used to define positive response; all other scores indicated negative response. The independent evaluator, blinded to treatment assignment, rated the CGI-I at Weeks 12 and 16 during the randomized trial for children in both treatment conditions. The CGI-I rating made use of all available information including the parent-nominated top two problems for each child. To obtain a full picture of each problem at baseline, the independent evaluator asked parents to describe the frequency and duration of the behavior (e.g., disruptive mealtime during meals), as well as the impact on the family (e.g., need to make separate meals; can't eat together as a family). Although the study focused on feeding problems, parental complaints were not limited to feeding problems. In all cases, however, parents nominated feeding/mealtime difficulties as one of the top two concerns. Each problem was documented in a brief narrative. This baseline narrative was reviewed and revised to capture change at subsequent visits. The new narrative and all other available information (e.g., BAMBI, mealtime behavior observation data) was used to score the CGI-I.

The revised BAMBI is a 15-item caregiver questionnaire designed to evaluate mealtime behavior in children with ASD (12, 26). The 15-item BAMBI includes four factors (Food Selectivity, Disruptive Mealtime Behaviors, Food Refusal, and Mealtime Rigidity). The Food Selectivity subscale measures the child's response to the presentation of different foods during meals; the Disruptive Mealtime Behaviors subscale focuses on maladaptive mealtime behaviors (e.g. crying/screaming, remaining in seat); Food Refusal measures the child's behaviors to avoid consuming non-preferred or new foods (e.g., expelling bites, closing mouth tightly); and Mealtime Rigidity subscale captures the child's flexibility with feeding and mealtime routines, including food preparation and presentation. Each item is scored from 1 (never occurs) to 5 (always occurs) during meals. Reverse scoring is used for four items reflecting positive mealtime behaviors. The measure yields a total score (sum of 15 items), as well as scores for each factor. Higher scores reflect more mealtime behavior problems. The modified BAMBI total score and 4-factor model demonstrated good reliability and sensitivity. By convention, a total score ≥ 34 is considered clinically meaningful (26).

Grams consumed during a meal 10-minute meal observation served as a secondary outcome measure (pre-meal food volume minus post-meal volume). At baseline, caregivers brought 2

food items historically rejected by the child (i.e., non-preferred food items), which were then presented to the child in the meal assessment. Similar instructions regarding presenting historically rejected food items were provided to caregivers at each assessment point (baseline, Weeks 12 and 16). A script guided the structure of the meal observation, including selection of seating (e.g., booster seat), bite presentations, and guidelines for discontinuation (due to disruptive behavior).

Parental satisfaction and parent perception of effectiveness.

A 10-item post-treatment questionnaire was developed to assess (a) satisfaction and acceptability of the program and the group format (e.g., "I am satisfied with the Parent Group"); (b) planned adoption of techniques learned in the home setting (e.g., "My family will continue to use the behavioral recommendations from this program."); and (c) perceived effectiveness of the intervention (e.g. "The behavioral recommendations were effective in improving my child's mealtime behaviors."). Items were rated on a 6-point scale (1 = Strongly Disagree; 6 = Strongly Agree), with higher scores reflecting greater levels of satisfaction, perceived effectiveness, and planned adoption. Scale items and outcomes are presented in Table 3 (available at www.jpeds.com).

Adverse Events

We adopted the Adverse Event (AE) Review that has been used in previous parent training trials to track adverse events (17). At each assessment visit, the independent evaluator asked whether the child had any recent illnesses, physical complaints, medical visits or medication changes. The form also covers any change in the child's daily activities such as sleep, appetite, and bowel habits. New events or change in previously reported events were rated mild (present, but not a problem), moderate (present, posing a problem or intervention required to prevent a problem), severe (present, posing a problem and needing intervention) or serious (e.g., need for hospitalization). Adverse events were documented whether considered related the study interventions or not.

Statistical Analyses

Feasibility analyses included calculation of rates on several pre-specified benchmarks: enrollment, attrition, attendance, and success of data collection. For example, the rate of enrollment was the number of children randomized divided by the number who appeared eligible but declined to enter multiplied by 100. Feasibility outcomes also included evaluation of therapist fidelity and parent satisfaction.

Descriptive statistics were calculated for all variables of interest, including means and standard deviations, and either medians and ranges or counts and percentages, as appropriate. To test efficacy, chi-square was used to compare the proportion of participants rated *much improved* or *very much improved* at Week 16 on the CG-I. Participants who dropped out or were lost to follow-up were classified as having a negative treatment response. To estimate the MEAL Plan treatment effect at Weeks 12 and 16 on the co-primary outcome (BAMBI) and secondary outcome (grams consumed during meal observation), we constructed linear mixed models using baseline and all Week 12 and 16 measurements. Models were conditioned on baseline measurements to adjust for possible difference

between intervention groups at baseline. This modeling procedure was chosen because it is more tolerant of missing data compared with Analysis of Covariance (28). Results from these models are presented as differences in least square means at Weeks 12 and 16 with associated 95% confidence intervals. All mixed models used an unstructured covariance matrix and the Kenward-Roger method for estimating degrees of freedom. Effect sizes were calculated by taking least square mean treatment differences and dividing by the pooled standard deviation at baseline. AEs were tabulated by group. AEs occurring more than once in the same child were counted once and recorded at the maximum severity level. All analyses were conducted using the intention to treat dataset, and all statistical tests were two-sided. Significance was assessed at the 0.05 level, unless otherwise noted, and analyses were conducting using SAS v. 9.4 (SAS Institute Inc, Cary, NC) (29).

Results

Enrollment began in January 2017 and ended in October 2017. Of the 111 children screened, 50 were ineligible; parents of 23 presumably eligible children declined participation (Figure 1; available at www.jpeds.com); 38 children were randomly assigned to 16 weeks of MEAL Plan or PEP. Participants (32 boys, 6 girls) ranged in age from 38 months – 88 months (mean 58.7± 13.8 months). The study groups appeared similar at baseline except for BMI weight category status (Table 1).

Feasibility and Parental Satisfaction

The rate of enrollment was 62.3% (38/61). Attrition for both groups was 16%; 32 of 38 of families completed the Week 16 assessment. Parents attended 87% (165 of 190 of MEAL Plan sessions) compared with 67% (128/190) in PEP. We successfully collected 88% of baseline and outcome data points. Parents completed 87% of assigned homework activities, including assigned meal sessions. Video recordings on a 10% randomly selected sample of MEAL Plan sessions showed excellent therapist treatment fidelity (>90%).

Sixteen of the 19 parents (84%) in MEAL Plan provided feedback on program satisfaction, treatment gains, and social acceptability (Table 3). Ratings from these parents suggest a high degree of satisfaction with MEAL Plan, with an overall rating of 5.66 (of possible 6.0) for the group. All caregiver respondents indicated *agree* or *strongly agree* that the content was appropriate and that they would recommend the intervention to others. All respondents also reported that they planned to continue to use the behavioral techniques from this program; 94% indicated that the treatment improved their child's mealtime behaviors.

Preliminary Efficacy

In the MEAL Plan group at Weeks 12 and 16, 42.1% (8/19) and 47.4% (11/19), respectively, were rated much improved or very much improved compared with 5.3% (1/19) at both time points in PEP ($p<0.05$) (Figure 2). Compared with PEP, children in MEAL Plan showed a significantly lower BAMBI total score, with an adjusted standard mean difference (SE) of −6.15 (2.25) ($p = 0.01$) at Week 12 and −7.04 (2.71) ($p = 0.01$) at Week 16 (Table 2). Differences between treatment conditions at Week 16 were observed in three of the four BAMBI subscales. Grams consumed during the meal observation increased at both time

points in MEAL Plan, with an adjusted standard mean (SE) difference of 30.76 (6.75) more grams consumed by MEAL Plan participants at Week 16 (p =0.001). By contrast, grams consumed declined at each time point in PEP.

Adverse Events

There were 67 adverse events reported during the 16-week trial, of which 66 were mild (55, 82.1%) or moderate (11, 16.4%). There was one serious adverse event. A child in MEAL Plan was hospitalized for an infection due to excessive skin picking. The serious adverse event was classified as unrelated to the study. In the study sample as a whole, the most common adverse events were vomiting, skin rash, fever, difficulty falling asleep, daytime fatigue (each at 10.5%), constipation and cough (each at 15.8%), and rhinitis (34.2%). There was no difference in the frequency of adverse events by treatment condition.

Week 20 Follow-up

Fifteen of 19 (79%) participants in MEAL Plan returned for the Week 20 follow up. CGII score remained unchanged from Week 16 levels for 12 participants (80%). Two subjects, rated as *minimally improved* at Week 16, continued to make gains and were rated as *much improved* at Week 20 by the blinded independent evaluator. For one participant, the CGI-I scores shifted from *much improved* to *minimally worse* compared with baseline.

Discussion

This study tested the feasibility and preliminary efficacy of the Autism MEAL Plan vs. parent education (an active comparator) in 38 children with ASD and moderate food selectivity. Feasibility metrics indicated the MEAL Plan curriculum was acceptable to parents. Nearly two thirds of apparently eligible participants actually enrolled in the group-based randomized trial. Attrition was < 20%. We successfully collected 88% of study data. Parents in MEAL Plan expressed high satisfaction with the program. Finally, therapists delivered MEAL Plan with high reliability. These results support the feasibility of recruiting in waves of 8 children for a randomized group-based MEAL Plan intervention. The encouraging preliminary efficacy results suggest that MEAL Plan may improve mealtime maladaptive behaviors and promote dietary expansion in children with ASD and moderate food selectivity. Potential benefits were observed on the CGI-I rated by a blinded independent evaluator, on the parent-rated BAMBI, and on grams consumed during a meal observation. Although the sample size was small, post-treatment follow-up results at 1-month support the possibility of enduring benefits.

MEAL Plan was specifically designed for children with ASD and moderate food selectivity (25). We adopted this organizing principle to match treatment intensity with condition severity. By contrast, many other parent training treatment studies in children with ASD apply a more general screening for mealtime difficulties (e.g., requiring a certain threshold score on the BAMBI (20)), without differentiating food selectivity severity by dietary patterns. This includes our prior evaluation of the MEAL plan (18), which included a sample of children with ASD and co-occurring feeding problems regardless of severity. Matching symptom severity to intervention based on a specified criterion – such as the degree of

dietary restriction - corresponds with calls for designing evidence-based practices with consideration to patient-specific characteristics. This is especially relevant to patients with multimorbidity (30) – which is often a hallmark of ASD.

Another key component of the MEAL Plan curriculum is the multidisciplinary model of care that combines behavioral intervention and nutrition education. In MEAL Plan, the dietitian evaluates each child's growth measures and nutritional needs and contributes to the selection of foods to expand food diversity. The dietitian also provides child-specific information to promote a well-balanced diet and to reduce the risk of nutritional deficiencies due to food selectivity (e.g., by introducing multiple fruits and vegetables into a child's daily intake). MEAL Plan is also designed to improve mealtime behavior. Parents are taught to structure mealtimes (e.g., having the child remain seated at a table; using praise/caregiver attention to shape target mealtime behaviors). The combination of behavior management strategies plus nutrition education is designed to establish a well-balanced diet. Thus, MEAL Plan can be viewed as a health promotion program.

The MEAL Plan is a structured intervention that is ready for large-scale study and replication. As shown in other areas of parent training in ASD (17; 27), a successful line of treatment research begins with manual development and pilot feasibility studies to set the stage for large-scale randomized trials to test efficacy. The high prevalence of food selectivity across a range of severity in children with ASD presents a glaring need to develop and test treatments that are exportable and match the level of severity. If our preliminary results are supported by a large-scale randomized trial to test efficacy and generalizability, MEAL Plan may expand the availability of empirically-supported beyond specialty clinics.

The current study evaluated MEAL Plan in a randomized group-based format. The group format presented several logistical challenges. Our target enrollment of 40 participants in 5 waves (8 per wave) required simultaneous recruitment, screening, and randomization of 8 eligible children per wave to ensure uniform baseline measurements for each wave. By necessity, each wave of participants and parents had to identify a mutually acceptable time and day of the week to attend sessions. Although not common, some participants and families were unable to participate due to scheduling conflicts with preferred times for others in the recruitment wave. We proposed group-based intervention could lower cost and increase access (i.e., 4 children vs 1 child receiving intervention at the same time). However, high quality group treatment required a team effort to manage the complexities of recruitment and scheduling. Thus, for future trials of MEAL Plan, individually-delivered intervention warrants careful consideration.

A limitation of this study, shared by many psychosocial interventions, is the reliance on parents – who were not blind to treatment assignment – to complete the BAMBI. However, the CGI-I was rated by a blinded clinician and included child-specific parent-nominated problems. Direct observation of grams consumed in a mealtime observation also offered an additional safeguard against a systematic bias in favor of MEAL Plan. Although the results are promising, the small sample size precludes drawing any definitive conclusions about efficacy. Another limitation is that we did not collect a standardized measure of dietary variety or biomarkers as predictors of response or as surrogate outcomes. Future studies

could include validated nutritional indices (e.g., the Block Food Frequency Questionnaire (31)) or microbiome sample before and after treatment. Although we used a three-day food diary and a semi-structured interview to identify moderate food selectivity and study eligibility, we did not repeat the semi-structured interview at endpoint to assess change in severity. In keeping with prior studies in parent training, we relied on the CGI-I to measure improvement (17). Future research could assess whether our semi-structured interview could be useful to capture change in the category of severity (e.g. movement from moderate to mild food selectivity). Finally, based on our clinical experience, we propose an interaction between the insistence on sameness, food selectivity and disruptive behavior in this population. This interaction presents an extraordinary challenge for parents, who may be at a loss to manage disruptive mealtime behavior. Thus, reduction in disruptive behavior appears to be a prerequisite to overcome food selectivity. Future studies should explore the role of parental engagement and disruptive behavior as possible mechanism(s) of action for MEAL Plan. The positive feasibility outcomes and encouraging preliminary efficacy results in this study support further study of MEAL Plan. In addition to demonstrating efficacy in a large-scale randomized trial, future study can also explore moderators and mechanisms of positive change.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Abbreviations:

AE	adverse event
ARFID	avoidant/restrictive intake disorder
ASD	autism spectrum disorder
BAMBI	Brief Autism Mealtime Behaviors Inventory
CGI-I	Clinical Global Impression - Improvement Scale
MEAL	Managing Eating Aversions and Limited variety
PEP	parent education program
PSI-SF	Parenting Stress Index- Short Form
RCT	randomized controlled trial

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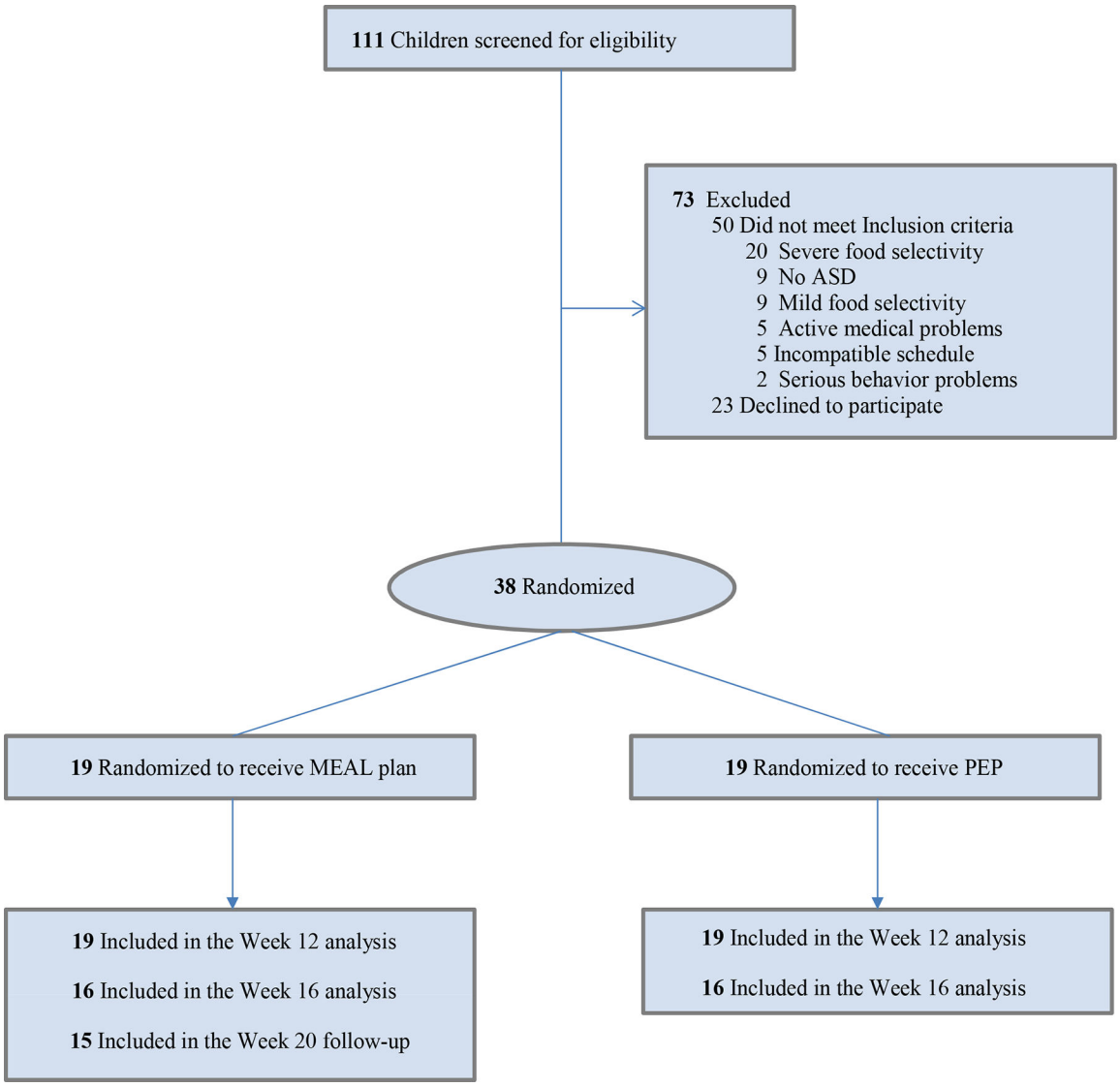

Figure 1.
Study flow chart.

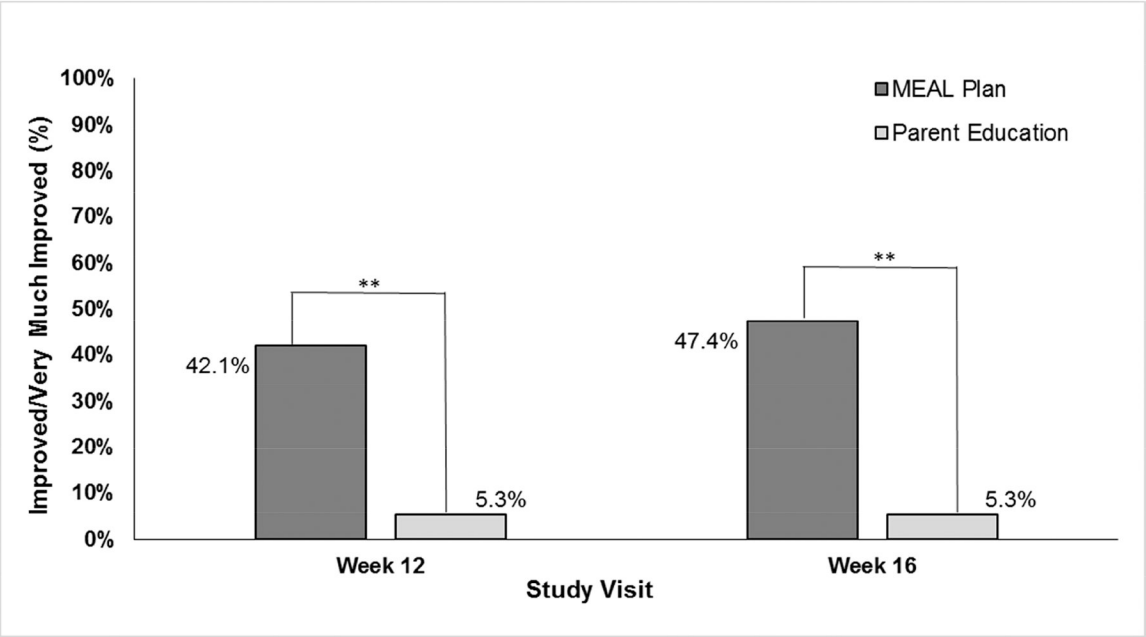

FIGURE 2.

Bar graph representing the percentage of participants that were rated as improved or much improved at weeks 12 and 16 based on CGI-I scores. The dark shaded bars represent the MEAL Plan participants and the light shaded bars represent the Parent Education participants. The ** indicates a significant difference in response rate at the 0.05 level. Subjects that dropped out or did not complete the assessment visit were classified as no improvement.

TABLE 1.

Sample Baseline Characteristics by Treatment Group

	Total Sample (n = 38)	MEAL Plan (n = 19)	Parent Education (n = 19)
Age (months); mean (SD)	58.7 (13.8)	58.3 (14.6)	59.1 (13.4)
Gender, *N*(%)			
Female	6 (15.8%)	3 (15.8%)	3 (15.8%)
Male	32 (84.2%)	16 (84.2%)	16 (84.2%)
Race/ethnicity, *N*(%)			
White	21 (55.3%)	12 (63.2%)	9 (47.4%)
Black	11 (29.9%)	4 (21.0%)	7 (36.8%)
Other	6 (15.8%)	3 (15.8%)	3 (15.8%)
Ethnicity			
Hispanic	1 (2.6%)	0 (0%)	1 (5.3%)
Non-Hispanic	37 (97.4%)	19 (100%)	18 (94.7%)
Intelligence Quotient (IQ)[a], N (%)			
<70	18 (51.4%)	10 (55.6%)	8 (47.1%)
≥70	17 (48.6%)	8 (44.4%)	9 (52.9%)
Educational Placement, N (%)			
Regular classroom	7 (18.4%)	3 (15.8%)	4 (21.1%)
Special education classroom	17 (44.7%)	10 (52.6%)	7 (36.8%)
Preschool	9 (23.7%)	3 (15.8%)	6 (31.6%)
None	5 (13.2%)	3 (15.8%)	2 (10.5%)
Number of adults in the home, *N*(%)			
1	2 (5.3%)	2 (10.5%)	0 (0%)
2	31 (81.6%)	15 (79.0%)	16 (84.2%)
3 or more	5 (13.1%)	2 (10.5%)	3 (15.8%)
Maternal education, N (%)			
Advanced degree	11 (29.0%)	6 (31.6%)	5 (26.3%)
College degree	11 (29.0%)	6 (31.6%)	5 (26.3%)
Some college	12 (31.6%)	5 (26.3%)	7 (36.8%)
High school graduate	3 (7.9%)	1 (5.3%)	2 (10.5%)
Not in Household	1 (2.6%)	1 (5.3%)	0 (0%)
Height (cm); mean (SD)	110.9 (9.0)	110.3 (9.7)	111.4 (8.5)
Weight (kg); mean (SD)	20.2 (3.9)	19.7 (4.1)	20.6 (3.8)
Weight (kg) Median (25^{th} - 75^{th})	20.0 (16.9 – 22.0)	18.3 (16.6 – 21.6)	20.8 (19.0 – 22.4)
BMI (kg/m^2) Median (25^{th} - 75^{th})	16.0 (15.2 – 16.9)	15.9 (15.5 – 16.6)	16.1 (15.0 – 18.5)
BMI Percentile Median (25^{th} - 75^{th})	64 (41 – 85)	63 (46 – 79)	69 (35 – 96)
Weight Category Status[b]			
Underweight (<5^{th} percentile)	1 (2.6%)	0 (0%)	1 (5.3%)

	Total Sample (n = 38)	MEAL Plan (n = 19)	Parent Education (n = 19)
Normal (5th-<85th percentile)	27 (71.1%)	17 (89.5%)	10 (52.6%)
Overweight (85th - <95th percentile)	3 (7.9%)	1 (5.3%)	2 (10.5%)
Obese (≥ 95th percentile)	7 (18.4%)	1 (5.3%)	6 (31.6%)
Baseline Clinical Scores			
SCQ[c] Mean (SD)	18.6 (5.0)	18.1 (5.6)	19.1 (4.4)
Vineland[d] Mean (SD)			
Daily Living	70.7 (14.0)	71.3 (15.2)	70.0 (13.1)
Socialization	68.4 (12.5)	70.3 (15.8)	66.3 (7.9)
Communication	72.9 (16.2)	74.1 (17.6)	71.6 (15.1)
Aberrant Behavior Checklist Mean (SD)			
Irritability	13.5 (9.0)	12.2 (8.1)	14.8 (10.0)
Social Withdrawal	10.1 (6.3)	8.6 (5.3)	11.6 (7.1)
Stereotypic Behavior	5.2 (4.3)	4.2 (3.5)	6.2 (4.8)
Hyperactivity	19.5 (9.6)	19.4 (8.6)	19.5 (10.8)
Inappropriate Speech	3.6 (2.9)	3.4 (3.0)	3.8 (2.8)
CGI Severity			
Moderately Ill	18 (47.4%)	7 (36.8%)	11 (57.9%)
Markedly Ill	20 (52.6%)	12 (63.2%)	8 (42.1%)

[a] N = 35, (18 treatment, 17 control);

[b] BMI referenced against sex- and age-specific normative ranges;

[c] N = 37, (19 treatment, 18 control);

[d] N = 31, (15 treatment, 16 control)

TABLE 2.

Baseline, 12 Week, and 16 Week Score on Key Outcome Measures

	MEAL Plan[a] (n=19)	Parent Education (n=19)	Adjusted Mean Difference (95% CI)[b]	P-value[c] (Effect Size)[d]
BAMBI				
Total Score				
Baseline	42.11 (11.74)	44.00 (8.90)	--	
Week 12	37.16 (5.75)	43.76 (7.67)	−6.15 (−10.74, −1.56)	0.010 (0.60)
Week 16	37.84 (7.57)	45.34 (7.83)	−7.04 (−12.57,−1.51)	0.014 (0.68)
Food Selectivity				
Baseline	14.53 (3.70)	15.22 (1.85)	--	--
Week 12	14.21 (1.48)	14.38 (1.98)	−0.28 (−1.48,0.92)	0.636 (0.10)
Week 16	13.51 (2.11)	15.05 (1.18)	−1.50 (−2.76, −0.25)	0.020 (0.51)
Disruptive Mealtime Behaviors				
Baseline	10.95 (4.64)	11.63 (5.02)	--	--
Week 12	8.05 (2.04)	11.72 (3.97)	−3.43 (−5.38,−1.47)	<0.001 (0.72)
Week 16	8.87 (3.89)	12.57 (4.24)	−3.42 (−6.16,−0.69)	0.016 (0.72)
Food Refusal				
Baseline	8.42 (3.11)	9.78 (2.75)	--	--
Week 12	7.11 (2.26)	9.01 (2.53)	−1.51 (−3.03, 0.01)	0.051 (0.51)
Week 16	7.40 (2.36)	9.67 (2.52)	−1.88 (−3.62, −0.14)	0.036 (0.63)
Mealtime Rigidity				
Baseline	8.21 (3.61)	7.23 (3.22)	--	--
Week 12	8.58 (2.61)	8.48 (3.56)	−0.25 (−2.17, 1.68)	0.794 (0.07)
Week 16	8.15 (2.31)	8.11 (3.75)	−0.46 (−2.29, 1.38)	0.615 (0.13)
Grams Consumed				
Baseline	4.63 (6.66)	11.42 (18.90)	--	
Week 12	21.96 (30.04)	9.30 (35.36)	12.66 (−4.40, 29.71)	0.141 (0.87)
Week 16	35.01 (33.18)	4.25 (31.80)	30.76 (13.40, 48.12)	0.001 (2.13)

SE= standard error;

[a] Data are presented as least square means (SD) from the mixed models;

[b] Adjusted mean difference= differences of least-squares means from mixed model conditioned on baseline score;

[c] P-value from mixed model conditioned on baseline score - value of $p < 0.05$ are statistical significant;

[d] Effect size calculated from the absolute value of the adjusted means differences divided by the pooled standard deviation at baseline.

TABLE 3.

Parent satisfaction rating of the Autism MEAL plan post intervention (N = 16)

Item	Average Rating (SD)	N (%) Rated 5/6
1. I am satisfied with the Parent Group.	5.63 (0.5)	16 (100%)
2. The behavioral recommendations were effective in improving my child's mealtime behaviors.	5.56 (0.63)	15 (93.8%)
3. There are benefits to receiving behavioral recommendations in a group format.	5.69 (0.6)	15 (93.8%)
4. My family will continue to use the behavioral recommendations from this program.	5.94 (0.25)	16 (100%)
5. My child's feeding/behavior is better than before starting the Parent Group.	5.69 (0.6)	15 (93.8%)
6. The Parent Group content and materials were appropriate and useful.	5.75 (0.45)	16 (100%)
7. I would recommend this Parent Group to a friend if he/she needed similar help.	5.94 (0.25)	16 (100%)
8. I plan to use the behavioral recommendations while outside of my home.	5.63 (0.62)	15 (93.8%)
9. The behavioral recommendations were effective in improving my child's behavior outside of meals.	5.5 (0.73)	14 (87.5%)
10. The length of the parent group was appropriate to meet my/my child's needs.	5.25 (1.24)	13 (81.3%)

Scale: 1 = Strongly Disagree; 6 = Strongly Agree, with higher scores reflecting greater levels of satisfaction. Average of overall satisfaction = 5.66 ± 0.65