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Adapting Family-Based Treatment for Pediatric Obesity: A Randomized Controlled Pilot Trial

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Abstract

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Objective: This pilot study aimed to refine and test an adaption of family-based treatment (FBT) for eating disorders that addressed the distinct clinical needs of adolescents with overweight or obesity in the absence of eating disorder pathology. Our hypothesis was that FBT for pediatric obesity (FBT-PO) would be feasible to implement and superior to a nutrition education counseling (NEC) condition delivered to both parents and patients, thereby controlling for key information dissemination across groups while manipulating active therapeutic content and strategy.

Method: Seventy-seven adolescents were randomized to FBT-PO or NEC across two sites.

Results: Results supported our core prediction, in that weight status among adolescent study participants receiving FBT-PO remained stable while increasing among participants randomized to NEC. Attrition was high in both conditions.

Conclusions: FBT-PO, while not seeming to yield a marked decrease in BMI *z*-score, may arrest an otherwise-occurring weight-gain trajectory for these adolescents. This efficacy finding is consistent with the overall PO literature supporting parental involvement in the treatment of PO. Future research efforts should address retention in FBT-PO.

Keywords

pediatric obesity; family-based treatment; overweight; adolescence

Pediatric obesity (PO) is a significant public health concern given the long-term consequences of increased morbidity and mortality, and the persistence of obesity into adulthood (Simmonds, Llewellyn, Owen, & Woolacott, 2016; Twig et al., 2016). Recent (2011–2014) statistics reveal that 17% of children and adolescents in the United States are categorized as obese, with this rate varying as a function of age, ethnicity, and head of household education level (Ogden, Carroll, Fryar, & Flegal, 2015; Ogden et al., 2016). While prevalence trends of PO in the US have fluctuated to some extent over the past several decades, the rate specifically among adolescents has risen at a level suggesting that genetic factors are not exclusively implicated in PO and that environmental contributors and epigenetic processes must be identified and modified (Ogden et al., 2015; Ogden, Carroll, Kit, & Flegal, 2014; Ogden et al., 2016; Yanovski, 2015).

Among the potential “obesogenic” environmental risk factors, maintaining factors, and correlates of PO that have been studied (e.g., related to the built environment and physical activity, and to out-of-home food sources and energy intake; Townshend & Lake, 2017) are parent-related variables, which collectively inform the importance of family-based interventions. Children and adolescents’ eating habits are heavily influenced by features of their physical and social context, parts of which are shaped by parents (Tzou & Chu, 2012). For example, youth are more likely to eat foods that are both accessible and frequently available in their households (Couch, Glanz, Zhou, Sallis, & Saelens, 2014; Ong, Ullah, Magarey, Miller, & Leslie, 2017). Parental modeling is also strongly related to their children’s eating habits, such that fruit and vegetable intake have been found to be highly correlated among parents and their children (Draxten, Fulkerson, Friend, Flattum, & Schow, 2014; Ong et al., 2017). Regular family meals, which provide opportunities for parent-child interaction, predict healthier eating habits (e.g., higher consumption of fruits, vegetables, and calcium-rich foods, and lower consumption of foods and beverages with poor nutrient

density) and weight status in children and adolescents (Hammons & Fiese, 2011; Neumark-Sztainer, Larson, Fulkerson, Eisenberg, & Story, 2010).

Parenting style, in general and relation to feeding practices has also been studied in PO. Findings support the theory that authoritative parenting practices, in which parents prioritize what they believe is in their child's best interest while also accommodating some degree of child preferences, are optimal relative to authoritarian or permissive parenting styles, and are associated with lower child body mass index (BMI) and increased consumption of healthier foods (Kakinami, Barnett, Seguin, & Paradis, 2015; Kiefner-Burmeister, Hoffmann, Zbur, & Musher-Eizenman, 2016; Langer, Seburg, JaKa, & Sherwood, 2017; Shloim, Edelson, Martin, & Hetherington, 2015; Sokol, Qin, & Poti, 2017). In fact, parental monitoring may have a curvilinear relationship with children's dietary behaviors whereby it is increasingly health-promoting only up to a certain level, beyond which it becomes counterproductive (Vaughn et al., 2016). Risk for maladaptive eating attitudes and behaviors associated with PO is attenuated by a higher-quality parent-child relationship (Blewitt, Bergmeier, Macdonald, Olsson, & Skouteris, 2016). Moreover, overweight children and adolescents who perceive their family as more cohesive and supportive, and report more shared family meals, engage in more physical activities, eat more nutritious diets, and report better psychological functioning (Boutelle, Fulkerson, Neumark-Sztainer, Story, & French, 2007).

Not surprisingly, data from the PO treatment literature highlight that the most efficacious interventions include some degree of parental involvement (Janicke et al., 2014; Niemeier, Hektner, & Enger, 2012; Sung-Chan, Sung, Zhao, & Brownson, 2013), with structure ranging from parents being the exclusive targets of treatment (e.g., Boutelle, Cafri, & Crow, 2011), being seen separately from their children (e.g., Kalarchian et al., 2009), or being seen conjointly (e.g., Anderson, Newby, Kehm, Barland, & Hearst, 2015). Family-based treatment is a crucial element in addressing PO because parents can control and modify the home environment to promote healthier choices and behaviors. However, a greater degree of parent involvement may not consistently yield better outcomes (Kitzmann & Beech, 2006). It is possible that the relationship between family involvement and successful weight loss does not follow a "one size fits all" model. Rather, the optimal level of parental involvement may be a function of the child's age and psychosocial development (Vaughn et al., 2016). In particular, the literature has not adequately addressed the unique needs of adolescents and the optimal quality and quantity of parental involvement at this stage of development, and few adolescent trials have systematically evaluated the inclusion of family members (Altman & Wilfley, 2015; Hingle, O'Connor, Dave, & Baranowski, 2010; Nowicka & Flodmark, 2008; Niemeier et al., 2012).

Family-based treatment (FBT) for eating disorders is a three-phased outpatient intervention for adolescents with anorexia nervosa, bulimia nervosa, and related transdiagnostic presentations that is characterized by a systematic approach of enlisting parents as the primary agents of symptom management during the acute stages of illness, and titrating down their involvement as the pathology recedes (Couturier, Kimber, & Szatmari, 2013; Le Grange & Lock, 2007; Lock & Le Grange, 2013; Stiles-Shields, Hoste, Doyle, & Le Grange, 2012). FBT provides a strong foundation for application to the significant problem of PO because of its attention to parental engagement strategies, its demonstrated efficacy in

correcting maladaptive eating and related behaviors, its explicit agenda of blame reduction, its disease-based model, and its emphasis on promoting normal physical and psychosocial development for the child or adolescent. FBT enhances parenting capacities by fostering an authoritative parenting style, increasing competence and self-efficacy in facilitating healthier behaviors and outcomes for children. FBT also assists adolescents in ultimately achieving developmentally targeted levels of independence.

FBT was adapted and manualized for PO (FBT-PO) in an earlier, unpublished pilot case series. As part of the current study, this pilot manual was refined and expanded using an iterative treatment development process (see Method/Study Design and Treatment Development). FBT-PO (Loeb et al., 2015; Stiles-Shields, Celio Doyle, Le Grange, & Loeb, 2018) maintains the underlying tenets of the original FBT protocols for children and adolescents with eating disorders, and also modifies the model for a non-psychiatric weight disorder. This adaptation recognizes that PO is not a form of psychopathology and that individuals with PO do not exhibit the developmental regression seen in severe eating disorders. Thus, FBT-PO modulates the quality and intensity of parental involvement as a function of chronological developmental stage, not severity of condition. FBT-PO has trans-developmental applicability with corresponding elements for children, pre-adolescents, and adolescents. For example, the adolescent module incorporates the idea that this stage of development requires sensitivity to both adolescents' increasing need for independence and continued reliance on parents for resources and structure in the home. The primary goals of FBT-PO are to (a) empower parents to implement systems-level changes in the home that are health-promoting and appropriate for application to all family members (e.g., are not excessively rigid or restrictive), and (b) to ultimately transition the identified patient to a developmentally appropriate level of autonomy around optimal self-care, in relation to energy intake and expenditure. FBT-PO positively shapes parent-related variables that are associated with child eating and weight, as reviewed above, such as modeling health-oriented choices and behaviors, increasing availability and accessibility of healthier foods, reducing criticism and blame, and implementing regular family meals. It also allows for changeable dietary recommendations, guided by an individualized family-level needs assessment, as well as by best practices and evolving findings from nutrition science. Finally, FBT-PO aims to increase parents' capacity to combat components of the "toxic" environment (e.g., easy access to inexpensive, fast, palatable processed foods; barriers to physical activity) that contribute to PO (Schwartz & Brownell, 2007).

Beyond the treatment development component, the current study aimed to test the feasibility and efficacy of the adolescent module of FBT-PO in a two-site, pilot randomized controlled trial (RCT) comparing it to a nutritional education control (NEC) condition. Our primary outcome measure was change in BMI *z*-score, and our hypothesis was that FBT-PO would be superior to NEC in modifying adolescents' weight toward a healthier level.

Method

Study Design and Treatment Development

This two-site pilot study randomized 77 adolescent participants and their parent(s) or guardians(s) to FBT-PO or NEC. The study was reviewed and approved by the Institutional

Review Boards at each site. The research was conducted from September 2008 to June 2013. Initial telephone screening to preliminarily review eligibility was conducted with 215 callers, a subset of whom later presented for a more elaborate study assessment (see Figure 1). The study used a computer-generated random allocation sequence with equivalent probability of randomizing to each of the two interventions; assignments were stored in envelopes sequentially numbered, filled and sealed by a research assistant external to the study team. Randomization was done by site, following in-person consent, assent, determination of eligibility in an assessment, and confirmation of interest in participating; participants were considered entered upon randomization. Study research assistants enrolled participants.

The treatment settings were two specialist eating disorders programs within academic medical centers. The study intervention was also offered for delivery directly in the collaborating department of pediatrics at each site, but all participants referred from those sources chose to receive care within the psychiatry-based eating disorders program settings. Additional primary referral sources included schools and hospital-affiliated or other local pediatric and adolescent medicine practices, made aware of the study through recruitment materials. Study therapists were clinical psychologists, clinical social workers, and advanced doctoral students in clinical psychology, and these therapists administered both interventions. Therapists were all trained in FBT by the principal investigators and primary authors, and underwent additional trainings on the PO adaptation and on NEC, followed by weekly supervision (in person at each site plus in a combined two-site supervision teleconference). Supervision used video recordings of study sessions as well as case presentations and discussion to foster fidelity and adherence to the manuals.

Therapist experiences as reviewed in supervision, along with reports of feedback from key stakeholders (parent participants, plus pediatrician referrers and co-authors), informed a planned series of FBT-PO manual revisions to: (a) elaborate specific treatment techniques as derived from core treatment principles, (b) facilitate patient engagement and retention, (c) provide troubleshooting strategies for newly identified challenges and obstacles in intervention implementation, and (d) include de-identified and amalgamated case examples for illustrative purposes. This iterative, feedback-based treatment refinement process (Hoagwood, Burns, Kiser, Ringeisen, & Schoenwald, 2001; Rounsaville, Carroll, & Onken, 2001; Weisz & Weersing, 1999) yielded three revisions to the original manual over the course of the study. Throughout the RCT, each new version was disseminated, along with additional training, to study therapists; they immediately adopted the updated version for delivery to ongoing and new study cases, as the changes amplified the details of the original version, rather than deviating from the foundation approach.

Participants

Adolescents with at least one parent or guardian willing to participate in treatment were eligible if they were ages 13–17 and met criteria for PO or overweight. PO is defined as having a body mass index (BMI) at or above the 95th percentile for age and sex; the 85th to 95th percentile range represents an overweight status and a key target for prevention and intervention (Barlow & Expert, 2007). Medical clearance for participation, from a physician

(typically pediatrician or adolescent medicine specialist), was required to be submitted prior to the initiation of the study intervention. Exclusionary criteria were: psychosis; current alcohol/drug dependence; current active suicidality; current pregnancy; current medication associated with significant weight changes (e.g., antipsychotic medication); history of bariatric surgery; history of sexual or physical abuse perpetrated by the parent who would be participating in treatment; serious medical conditions resulting in significant weight changes (e.g., endocrinologic diseases, genetic syndromes); complications of obesity that contraindicate moderate physical activity (e.g., orthopedic disorders); and eating disorders (e.g., binge eating disorder). Inclusionary and exclusionary criteria were assessed with a clinical interview plus the Eating Disorder Examination-Questionnaire (Fairburn & Beglin, 1994) as an additional screening for eating disorders, and the Child Depression Inventory (Kovacs, 1992) as an additional screening for suicidality. In families with more than one potential child participant, only one sibling from each family unit (as selected by the family) participated in the screening process. If the family was randomized to FBT-PO, siblings were encouraged to participate, per FBT protocol, as they would be anyway, but only the primary adolescent participant was assessed throughout the study for contribution to baseline and outcome data. Baseline demographic and clinical sample characteristics can be found in Table 1.

Study Interventions and Procedures

FBT-PO (Adolescent Module).—FBT-PO (Loeb et al., 2015; Stiles-Shields et al., 2018) involves 16 hour-long family sessions, divided into three phases over 24 weeks. In Phase I (Sessions 1–8), sessions are weekly; in Phase II (Sessions 9–13) and Phase III (Sessions 14–16), sessions are biweekly. At the start of each session, the therapist obtains the adolescent's height and weight, and briefly meets with the adolescent individually to identify any concerns. A family meeting that includes siblings follows. In this trial, only the adolescent module was tested.

In Phase I, parents are actively involved in making changes in their child's eating and exercise habits. Families are oriented to the need for mobilization, and the efforts required to yield the maximum effect. Early-phase strategies include: fostering parental unity (in two-parent/caregiver households); externalizing the adolescent's weight status as separate from personal identity; reducing blame toward the overweight adolescent while explaining potential contributory factors of PO; and conducting an in vivo family meal session in which the parents bring and eat food representative of the changes they are starting to make. Both suboptimal food choices or excessive quantities and overly restrictive feeding or eating practices are actively corrected. The remainder of Phase I focuses on nutrition and physical activity (applicable to general health and therefore all family members, not just the identified patient); the importance of creating and maintaining a positive, non-critical environment; the importance of parental support and monitoring; and barriers to behavior change pertinent to urban and socioeconomically disadvantaged environments.

The locus of agency for change shifts from a parent-emphasis to more of a youth-emphasis between Phases I and II of treatment, but the precise nature of parental involvement, and the degree to which responsibility is ultimately shifted toward the child, varies considerably by

developmental stage. The frequency, structure, and content emphasis of sessions also shifts to reflect these changes. Specifically, parents reduce their contact with the therapist in a parallel process, more individual time is available at the start of sessions, and family session time centers around fostering more independence in the patient around energy intake and expenditure. Education on nutrition and physical activity continues throughout Phase II. Phase III addresses broader issues of child and adolescent development and prepares the family for termination.

NEC.—Families assigned to NEC received a basic nutrition and physical activity education curriculum, delivered didactically within the same session frequency and time frame as FBT-PO. In the first half of each NEC session, the therapist distributed curriculum materials to the patient alone (after obtaining height and weight), teaching adolescents how to apply the information to their own food and exercise choices. In the second half-hour, the clinician met with the parents alone, distributing the same materials from the curriculum provided to the adolescent and teaching them how this information can influence their child's as well as their own food and exercise choices. In this sense, NEC controlled for family-level exposure to health-based information, similar to what was delivered in the nutrition and physical activity components of FBT-PO, without including the psychotherapeutic format or techniques from FBT-PO. NEC curriculum topics included the importance of regular, structured eating with an emphasis on home-based family meals; stimulus control; hunger and fullness; dietary guidelines; beverages; and reducing sedentary behaviors in favor of physical activities. NEC was adapted from a research-based PO program in the Department of Pediatrics at one of the study sites; this program was developed from evidence-based weight management curricula from the Planet Health (Gortmaker et al., 1999) and Child and Adolescent Trial for Cardiovascular Health studies (Luepker et al., 1996).

Outcome Assessment

Height and weight - obtained at evaluation, at every study intervention session attended, and at 6- and 12-month follow-up - informed BMI *z*-score, the primary outcome measure for the study. These measurements were made on a physician's scale and stadiometer with the adolescent wearing single-layer street clothes and no shoes. Attrition rates (see Figure 1) precluded the investigation of secondary outcomes or follow-up data points in this pilot study.

Statistical Analyses

Statistical Power.—Power analysis was based upon a 2-group comparison using mixed-effects models for longitudinal data (Hedeker, Gibbons, & Waternaux, 1999) with continuous outcome. Calculations assumed nonstationary AR1 error structure in that it is expected that weights (to inform BMI/BMI *z*-score) closer together in time will have a higher correlation than weights farther apart in time. Calculations also assumed 17 timepoints with 1.5% attrition in between timepoints and an intraclass correlation of 0.3. Under these assumptions, n=40 subjects per group would provide at least 80% power to detect a slightly larger than moderate effect of 0.52 for a linear trend over time.

Statistical Model.—The trajectory of zBMI was compared between treatment groups using a mixed-effect general linear model with a first-order autoregressive covariance structure. The model included a random intercept and fixed effects for treatment group, linear, quadratic and cubic effects for time (to allow for nonlinear change), as well as interactions between treatment group and each of the time effects. Analyses were based up all available data and missing data were not imputed.

Results

Retention

Figure 1 displays the flow of participation from evaluation through follow-up. Overall, 79% of participants (61/77) commenced the assigned study intervention following evaluation and randomization, 39% (30/77) completed more than half of the intervention phase of the study, 25% (19/77) completed all study sessions, 12% (9/77) participated in 6-month follow-up, and 5% (4/77) in 12-month follow-up. The pattern of retention was similar for the FBT-PO and NEC conditions. Among FBT-PO participants, 84% (32/38) returned for session one, 39% (15/38) attended more than half of prescribed sessions, 24% (9/38) completed all sessions, 11% (4/38) agreed to be assessed at 6-month follow-up and 5% (2/38) at 12-month follow-up. Among NEC participants, these percentages were 74% (29/39), 38% (15/39), 26% (10/39), 13% (5/39) and 5% (2/39), respectively.

BMI z-Score

There was a significant quadratic effect for the treatment x time interaction ($p = .035$; see Table 2), such that BMI *z*-score accelerated at a greater rate over time in the NEC group. As depicted in Figure 2, mean BMI *z*-score increased at a greater rate in the NEC condition relative to FBT-PO beginning at approximately Day 60. The pseudo R-squared effect size accounted for by treatment was .011, indicating a small effect.

Discussion

This pilot study aimed to refine and test an adaption of FBT for eating disorders that addressed the distinct clinical needs of adolescents with overweight or obesity in the absence of eating disorder pathology. In the broader PO treatment literature on family-based interventions, the adolescent stage of development has been relatively understudied. Our hypothesis was that FBT-PO would be feasible to implement and superior to a nutrition education condition delivered to both parents and patients, thereby controlling for key information dissemination across groups while manipulating active therapeutic content and strategy. Results from the study's diverse, U.S.-based sample supported our core prediction, in that it appears that weight status among study patients receiving FBT-PO remained stable while increasing among participants randomized to NEC. Thus, FBT-PO, while not seeming to yield a marked decrease in BMI *z*-score, may arrest an otherwise-occurring weight-gain trajectory for these adolescents. This efficacy finding is consistent with the overall PO literature supporting parental involvement in the treatment of PO (Janicke et al., 2014; Niemeier, Hektner, & Enger, 2012; Sung-Chan, Sung, Zhao, & Brownson, 2013).

As PO is not a psychiatric condition, we expected families to prefer receiving study interventions within the departments of pediatrics, rather than in the psychiatry-based eating disorder specialty clinics. This was not the case. The similar patterns of attrition in FBT-PO and NEC suggest that retention in FBT-PO was not differentially affected by treatment setting. They also indicate that FBT-PO was not uniquely vulnerable to treatment disengagement more generally among this population. Approximately 20% of attrition occurred before session one; at mid-intervention the rate was about 60%, and by the end of treatment 75%. Treatment dropout represents the major limitation of our study and raises questions about feasibility, regardless of intervention type. Definitions and rates of attrition vary considerably across both naturalistic and controlled studies of weight management programs for youth (Skelton & Beech, 2011), rendering comparisons complex. It is nonetheless evident that engagement and retention remain significant feasibility challenges for the delivery of FBT-PO and for the larger scope of PO interventions in the field (Hampl, Paves, Laubscher & Eneli, 2011), and are thus valuable targets of future research efforts. Models that incorporate home- or community center-based treatment delivery systems should be considered to reduce practical barriers to care access, and additional motivational techniques in the treatment protocol may improve psychological engagement. Such efforts should also continue to incorporate family-based models across the child development spectrum, including adolescence, as the current study exemplifies.

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Highlights:

- Family-based treatment (FBT) for eating disorders was adapted to address the distinct clinical needs of adolescents with overweight or obesity in the absence of eating disorder pathology.
- A randomized controlled trial comparing FBT for pediatric obesity (FBT-PO) to nutritional education counseling (NEC) found that BMI *z*-score remained stable during the observation period among adolescents in the FBT-PO condition while increasing among participants in the NEC condition. Attrition was high in both conditions.
- FBT-PO, while not appearing to produce a marked decrease in weight status, may stabilize an otherwise-occurring increase in BMI *z*-score. Future research efforts should address retention in FBT-PO.

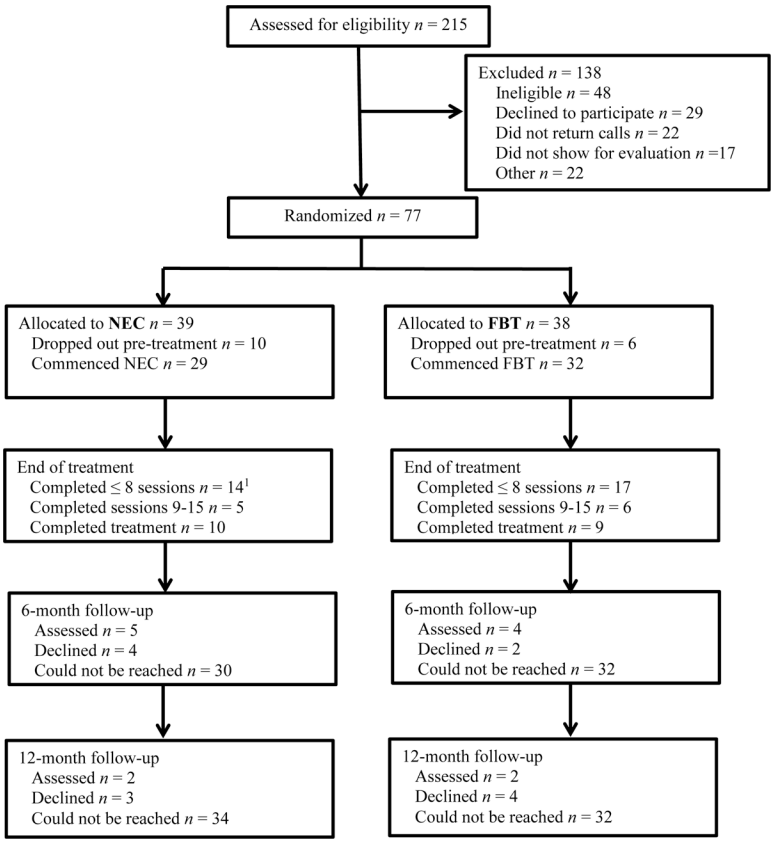

Figure 1.

Participant flow chart following Consolidated Standards of Reporting Trials guidelines for family-based treatment (FBT) and nutrition education counseling (NEC) conditions.

[1] One participant was exited from the study for suicidality and referred to a higher level of care

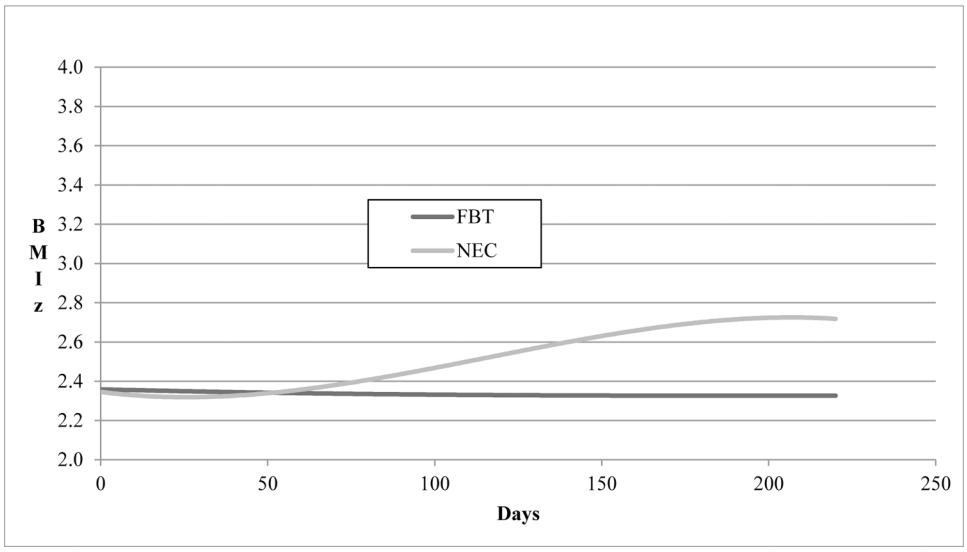

Figure 2.
BMI z-scores across time in family-based treatment (FBT) and nutrition education counseling (NEC) conditions.

Table 1

Participant Demographics and Baseline Clinical Characteristics

	NEC	FBT	Total
Age in Years, mean (SD)	15.2 (1.6)	14.9 (1.5)	15.1 (1.6)
Self-Identified Gender, no. (%)			
Male	12 (30.8)	13 (34.2)	25 (32.5)
Female	27 (69.2)	25 (65.8)	52 (67.5)
BMI Measurements, mean (SD)			
BMI	36.2 (6.8)	36 (4.1)	36.1 (5.6)
BMI for-age-percentile	98.4 (1.7)	98.8 (0.9)	98.6 (1.4)
BMI *z*-score	2.3 (0.4)	2.3 (0.2)	2.3 (0.3)
Weight Status			
Obese, no. (%)[1]	36 (92.3)	38 (100)	74 (96.1)
Overweight, no. (%)[2]	3 (7.7)	0 (0)	3 (3.9)
Self-Identified Race/Ethnicity, no. (%)			
White	5 (14.7)	7 (20.6)	12 (17.6)
Black/African American	18 (52.9)	17 (50)	35 (51.5)
Native American	0 (0)	0 (0)	0 (0)
Hispanic/Latino	8 (23.5)	9 (26.5)	17 (25)
Asian American	0 (0)	0 (0)	0 (0)
Other	2 (5.9)	0 (0)	2 (2.9)
Not Identified	1 (2.7)	1 (2.9)	2 (2.9)

Note. NEC, nutritional education counseling; FBT, family-based treatment; BMI, body mass index (calculated by weight in kilograms divided by height in meters squared)

[1] Obese BMI is at or above 95th percentile for age and sex

[2] Overweight BMI is 85th to 95th percentile for age and sex

Table 2

Estimates of Fixed Effects for BMI Z-Score

						95% Confidence Interval	
Parameter	**Estimate**	***SE***	***df***	***t***	***p***	**Lower Bound**	**Upper Bound**
Intercept	2.36	0.06	52.72	42.19	.000	2.25	2.47
Linear	0.00	0.00	152.88	−0.29	.774	0.00	0.00
Quadratic	0.00	0.00	397.65	0.12	.903	0.00	0.00
Cubic	0.00	0.00	393.90	−0.05	.964	0.00	0.00
Treatment	−0.01	0.08	53.95	−0.16	.871	−0.18	0.15
Treatment * Linear	0.00	0.00	147.01	−0.80	.427	−0.01	0.00
Treatment * Quadratic	0.00	0.00	399.86	2.11	.035	0.00	0.00
Treatment * Cubic	0.00	0.00	394.70	−1.78	.077	0.00	0.00