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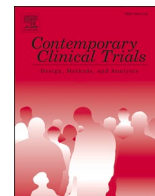
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A randomized controlled trial examining general parenting training and family-based behavioral treatment for childhood obesity: The ReFRESH study design

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ABSTRACT

Family-based behavioral treatment (FBT) is one of the most effective treatments for childhood obesity. These programs include behavior change strategies and basic parenting training to help parents make healthy diet and physical activity changes for their children. While effective, not all families respond to this program. Additional training on how to effectively deliver these behavior change strategies may improve outcomes. The authoritative parenting style is associated with many positive academic and socio-emotional outcomes in children, and is characterized by displays of warmth and support while also being consistent with setting limits and boundaries. This parenting style has also been associated with normal weight status. Furthermore, parenting training programs that promote this parenting style for children with behavioral issues have shown unintended effects on decreasing child weight status. Therefore, our goal was to examine the effect of adding more intensive parenting training to FBT on child weight status. We randomized 140 children and their parent to either FBT or FBT + Parenting Training (FBT + PT). Assessments were conducted at baseline, mid-treatment (month 3), post-treatment (month 6), 6-month follow-up (month 12), and 12-month follow-up (month 18). Primary outcome was change in child weight status. Secondary outcomes were rates of drop-out, treatment adherence, and acceptability. If effective, this program may provide another alternative for families to help improve outcomes in childhood obesity management.

1. Introduction

Family-based behavioral treatment (FBT) is one of the most effective intensive health behavior and lifestyle treatment (IHBLT) programs for childhood obesity. [1] These programs teach parents behavioral strategies that can be used to change dietary and physical activity behaviors for themselves and their children. However, some studies suggest that only 30–40% of children decrease in weight status during these programs, with a similar proportion maintaining their weight. [2–4] Early response to treatment may predict longer-term outcomes, [2,4,5] but it

is unclear what predicts early response. One study showed that greater parental monitoring and alterations to the home food environment (i.e., stimulus control) influenced how a child responds to treatment. [6] However, it has also been suggested that *how* one delivers and implements these behavioral strategies may be important as well.

Parenting styles are thought to provide the context in which specific behavioral strategies are delivered and interpreted by the child. [7] Thus, parenting styles may be able to modify the impact of specific behavioral strategies that are taught in FBT. [8–11] One study demonstrated that limiting the consumption of sugar-sweetened beverages

Abbreviations: FBT, Family-based Behavioral Treatment; FBT + PT, Family-based Behavioral Treatment + Parenting Training; IHBLT, Intensive Health Behavior and Lifestyle Treatment; BMI, Body Mass Index; BMIZ, Body Mass Index z-score; OW/OB, Overweight or Obesity; %BMIp95, percent from the 95th BMI percentile; ΔBMIp95, difference from the 95th BMI percentile; CDC, Centers for Disease Control and Prevention.

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among teens was most effective at decreasing consumption if parents displayed a more authoritative parenting style (i.e., high levels of involvement and moderate levels of strictness or demandingness). [12] Furthermore, restrictive feeding behaviors in the context of authoritative parenting was associated with lower caloric intake while restrictive feeding in the context of authoritarian parenting (i.e., high expectations and demands for behavioral control, but low warmth) was associated with greater caloric intake. [13] Finally, authoritative parenting styles that display warmth and involvement have been associated with greater fruit and vegetable intake. [14–16] The effect of general parenting styles on weight management outcomes has not been well studied.

Of the general parenting styles (i.e., authoritative, indulgent/ permissive, authoritarian, and neglectful), the authoritative parenting style has been most consistently associated with lower BMI and normal weight status. [17–19] However, few studies have evaluated the impact of authoritative parenting on weight loss efforts. In one study where parents of children with behavioral issues were taught to use an authoritative parenting style, there was an unintended outcome of decreased child BMI z-score immediately post-treatment and 3–5 years later compared to children in the control group. [20] Furthermore, in a single-arm pilot trial, Rhee et al. (2016) found that warm authoritative parenting behaviors at baseline may be associated with decreased child weight status during a 16-week behavioral weight loss program. [21]

Given these results, one group in Australia added a lifestyle training component to a generalized parenting program to facilitate weight loss, and compared it to either a waitlist control group [22] or the parenting program alone. [23] These studies found that the parenting training (PT) + lifestyle intervention led to a decrease in BMI z-scores (mean 0.20 BMIz units) immediately and up to 1 year post-treatment. [22,23] These changes were obtained with a 12-week program that involved nine 90-min group sessions and three 20-min phone sessions. While these programs obtained comparable changes in BMI z-score as traditional FBT, they did not offer instruction on diet or physical activity related behavior change skills. In addition, they did not compare the effect of these programs to FBT alone.

1.1. Study objectives

The goal of this study, the Reinforced, Enhanced, Families, Responsibility, Education, Support and Health (ReFRESH) study, was to adapt the current FBT program to include a greater focus on general parenting training, and compare the efficacy of this new program (FBT + PT) to standard treatment (FBT). The randomized control trial (NCT02976636, R01DK106157) aimed to recruit 160 children aged 7–12 years old with overweight or obesity (OW/OB) and a caregiver who was responsible for feeding the child. Both interventions were group-based interventions that included 20 sessions over a six-month period and follow-up assessments at 6- and 12-months post-treatment. We hypothesized that FBT + PT would show greater decreases in child body weight (BMI z-score) compared to FBT at post-treatment and 6- and 12-months post-treatment. Due to the potential greater intensity of treatment in the FBT + PT program, our secondary aims were to examine rates of drop-out, treatment adherence, and acceptability of FBT + PT compared to FBT. Given the novelty of including more intensive parenting training in FBT for childhood obesity, our exploratory aims were to examine mediators and moderators of weight loss. We hypothesized that weight loss would be mediated by changes in parenting skills and behavioral lifestyle skills, as well as self-efficacy to engage in behavior change. We also hypothesized that baseline parenting style and child characteristics (e.g., executive function, impulsivity, and responsiveness to food cues) would moderate treatment effects.

1.2. Study design

1.2.1. Trial design

ReFRESH was a two-arm randomized controlled trial comparing FBT to FBT + PT among children between the ages of 7–12 years old with OW/OB. A small pilot study was conducted to determine initial acceptability and feasibility of this program and inform content of the intervention (data unpublished, included in Supplement 1). Assessments were conducted at baseline, mid-treatment (month 3), post-treatment (month 6), 6-month follow-up (month 12), and 12-month follow-up (month 18). The primary outcome was change in child weight status measured as BMI z-score. We also included change in %BMIp95 (percent from the 95th BMI percentile) and Δ BMIp95 (difference from the 95th BMI percentile) based on recommendations to use these measures in longitudinal weight management trials and for children with very high BMI (>97th percentile). [24,25] Families were randomized using a block design ('blockrand' software [26]) based on child sex and parent weight status (healthy weight vs. OW/OB). Randomization was conducted by the study statistician who was blinded and did not interact with study participants.

1.3. Participants

The goal was to recruit 160 children between the ages of 7–12 years old with a BMI \geq 85th and < 99.9th percentile and a parent. However, due to the difficulties with recruitment during the COVID-19 pandemic, the sample was reduced to 140 children and a parent or caregiver (herein referred to as "parent") who was responsible for feeding the child.

1.4. Inclusion and Exclusion criteria

Inclusion criteria for the study were: 1) Children between the ages of 7 and 12 years old; 2) BMI \geq 85th and < 99.9th percentile, to limit children who had severe obesity and were in need of more intense medical treatment; 3) Children with a parent who was willing to attend 20 weekly group sessions and be randomized to either treatment arm; 4) At least one parent who had OW/OB (BMI \geq 25); and 5) a parent who spoke English at a 5th grade level or higher.

Exclusion criteria included: 1) Children taking medication that affected their appetite or weight (e.g., high-dose steroids, SSRIs); 3) Children with severe developmental delay or disability that would affect participation (e.g., cerebral palsy); 4) Children or parent with psychiatric illness that would limit treatment participation (e.g., eating disorder, conduct disorder, psychosis, suicidality); 5) Families who would be moving out of the area within the time frame of the study.

1.5. Recruitment

Recruitment efforts were primarily conducted through pediatric primary care networks in San Diego County. Families with children in the above-mentioned age range and weight criteria were also identified in the electronic health record, and traditional letters or electronic messages were sent to inform them of this study opportunity. Online advertisements, school flyers, and advertisements at community events were also used. Parents interested in the study were directed to complete an online screening tool to determine initial eligibility. Parents who met initial criteria then completed a phone screen and were invited to attend an orientation meeting to learn more about the study. If both parent and child were still interested in participating, they completed the consent process and baseline BMI was checked for eligibility. Recruitment activities occurred between April 2017 to April 2021.

1.6. Assessment timeline and outcome measures

Parent-child dyads completed assessments at baseline (month 0),

mid-treatment (month 3), post-treatment (month 6), 6-month follow-up (month 12), and 12-month follow-up (month 18) (Table 1). Primary outcome measures included anthropometry (height and weight metrics) for both parent and child. Additional measures included self-report questionnaires (e.g., parenting behaviors, feeding behaviors), videotaped family meals, neurocognitive tasks, attendance, adherence measures, and satisfaction surveys. Assessments were conducted by research assistants who were blind to study group assignments.

1.7. Measures

1.7.1. Demographics and anthropometry

Parents self-reported parent and child age, sex, race/ethnicity, and parent income and educational background. Parents also reported on their and their child’s weight history, dieting behaviors, medical history, and medication use.

Child and parent height were obtained using a Seca 222 mechanical telescopic measuring rod. Height was recorded twice to the nearest 0.1 cm, and the average value used for analysis. Body weight in kilograms was measured on a Tanita Digital Scale (model WB-110 A), recorded twice to the nearest 0.1 kg, and the average value used for analysis. Standard procedures were used with participants wearing light clothing and no shoes. [27] Body mass index was calculated using the formula (BMI = [kg/m²]). BMI z-scores and percentiles were derived based on age and gender specific norms from the National Center for Health Statistics growth curves. [28] During the COVID-19 pandemic, Bluetooth scales (Withings) were provided so families could continue to track weight changes during the intervention. Height was measured at home using provided tape measures.

1.7.2. Parenting

Self-report and objective measures of parenting were obtained in this study.

The **General Parenting Observational Scale (GPOS)** [29] is a standardized protocol that assesses emotional (e.g., warmth and affection, negative affect) and behavioral (e.g., firm discipline and structure) dimensions of parenting, and has demonstrated good interrater reliability (weighted kappa coefficients ranging from 0.85 to 0.98).

1.7.3. Child’s Report of Parental Behavior Inventory (CRPBI)

[30] The 30-item version [31] [32] was completed by the child and used to assess three dimensions of parenting: acceptance vs. rejection, psychological control vs. autonomy, and firm vs. lax control. Since parents have been reported to rate themselves higher on acceptance and being firm than a child’s report, [33] we only obtained child report of their parent’s parenting style. If there were two parents involved in caretaking, children completed this measure for both parents.

1.7.4. Comprehensive General Parenting Questionnaire (CGPQ)

[34] This is an 85-item parent self-report questionnaire that measures five constructs of parenting: Nurturance, Behavioral Control, Structure, Overprotection, and Coercive Control.

1.7.5. The Parenting Scale

[35] This scale measures parent discipline strategies, including permissive or inconsistent discipline, coercive discipline, and emotional discipline and irritability. This scale is sensitive to the effects of parenting training and has been used in previous parenting training interventions (e.g., the Incredible Years Program).

1.7.6. Parent feeding and lifestyle behaviors

The Comprehensive Feeding Practices Questionnaire (CFPQ) [36] is a 49-item measure that assesses parental feeding practices and contains 12 subscales: Child Control, Emotion Regulation, Encourage Balance and Variety, Environment, Food as Reward, Involvement, Modeling, Monitoring, Pressure, Restriction for Health, Restriction for Weight Control, and Teaching about Nutrition.

1.7.7. The Lifestyle Behavior Checklist (LBC) [37]

This scale measures child weight-related problem behaviors and lifestyle specific parenting self-efficacy and yields scores for 2 dimensions – the Problem scale and the Confidence scale. The Problem scale assesses the extent to which children experience certain behaviors (e.g., eating too quickly, playing too many computer games, and teasing because of their weight) and is a parent report measure. The Confidence scale assesses parent confidence to manage these behaviors.

1.7.8. Eating behavior and Dietary intake

The eating behavior and dietary intake assessment was designed by

Table 1
Child and Parent Assessments.

Measures	Instrument	Child or parent	Base-line	Mid-tx (3 mos)	Post-tx (6 mos)	6-mos Follow-up	12-mos Follow-up
Anthropometry	Height and weight	C, P	X	X	X	X	X
Demographics	Age, sex, race, ethnicity, education, income, medical history, weight history, medications	P, Pc	X				
Parenting	General Parenting Observational Scale	C, P	X		X	(X)	(X)
	Child Report of Parent Behavior Inventory	C	X		X	X	X
	Comprehensive General Parenting Questionnaire	P	X		X	X	X
	The Parenting Scale	P	X		X	X	X
Diet and Physical Activity	Eating Behavior questions	P	X	X	X	X	X
	Accelerometer	C, P	X		X	X	X
Feeding and lifestyle behaviors	Comprehensive Feeding Practices Questionnaire	P	X	X	X	X	X
	Lifestyle Behavior Checklist	P	X		X	X	X
	Eating Disorder Evaluation	P	X		X	X	X
Executive Functioning	BRIEF-2	P	X				
	NIH Toolbox	P, C	X				
	Stop-Signal Task-Food	P, C	X				
Treatment Attendance, Adherence, Acceptability	Attendance	C, P		X			
	Habit books (self-monitoring)	C, P		X			
	Satisfaction survey	C, P		X	X		

C = Child assessment.
P = Parent assessment.
Pc = Parent assessment of child.

the study team to measure whether participants were following the suggested behavioral targets outlined in the program. Parents reported on such behaviors as consumption of sugar-sweetened beverages, fruits and vegetables, fast food, and breakfast.

1.7.9. Physical activity

Objective physical activity and sedentary behavior data was collected using the GT3X+ ActiGraph accelerometer (ActiGraph, LLC; Pensacola, FL). The ActiGraph device has been validated and calibrated for use with children and adults in controlled and field conditions. [38] All parents and children were asked to wear the ActiGraph for 7 days. Participants were asked to re-wear the device if it was not worn for at least 5 days and > 10 h each per day. Outcome variables included mean minutes per day of sedentary activity (adjusted for monitor wear time), and light, moderate, and vigorous intensity PA.

1.7.10. Executive functioning

Executive functioning was assessed using tasks and self-report measures. The **NIH Toolbox Cognitive Battery (NIHTB-CB)** [39] [40–42] was used to measure attentional control, cognitive flexibility, and general cognitive abilities. Specifically, the Flanker Inhibitory Control and Attention Test, Dimensional Change Card Sort Test, Picture Sequence Memory Test, Picture Vocabulary Test, and Oral Reading Recognition Test were administered. To measure domain specific executive functioning around food, the **Stop Signal Task-Food Version (SST-Food)** [43,44] was administered using pictures of calorically dense food or neutral objects (e.g., chair). The two primary outcomes, stop signal reaction time for food pictures (SSRT-Food) and neutral pictures (SSRT-Neutral) were compared to assess food-specific impulsivity versus general impulsivity.

The **Behavior Rating Inventory of Executive Function–2 (BRIEF-2)** [45] was completed by parents to measure overall child executive functioning. This 63-item measure includes ten clinical scales which form three sub-scales: Behavioral Regulation, Metacognition, and Global Executive Composite score which represents the child's overall executive function.

1.7.11. Treatment attendance, adherence, and acceptability

Attendance at weekly treatment sessions were tracked by group leaders. Drop-out rates were monitored throughout the study. Adherence to recommendations in both treatment arms and self-monitoring records were collected weekly. Parents and children were asked to complete a satisfaction survey at the end of the study to determine overall liking of the study and usefulness of the different strategies that were taught.

2. Intervention

Both intervention arms included traditional FBT content focusing on nutrition, physical activity, behavior change skills, and basic parenting skills. [46] FBT + PT included additional parenting training materials and utilized more interactive training components such as role plays. Families were randomized to attend 60-min parent and child group sessions in one of two office locations (La Jolla, CA or San Marcos, CA). After the start of the COVID-19 pandemic (March 2020), all group meetings were transitioned to virtual format using the HIPAA-compliant, password-protected Zoom platform.

2.1. Treatment format

Families in both treatment arms (FBT and FBT + PT) received 20 sessions over six months. The 60-min group sessions were held weekly for 16 weeks followed by every other week for 8 weeks. Parent and child groups occurred simultaneously but in different rooms. Different group leaders delivered FBT or FBT + PT. Core concepts provided in both arms included information on nutrition, increasing physical activity,

decreasing sedentary activity, effective behavioral strategies for weight-loss, and basic parenting strategies. The content for child groups were modified to be age appropriate and no parenting concepts were discussed. Families received handouts each week that supported the topic for that session. See **Table 2** for session topics.

In addition to attending group sessions, parent-child dyads received 20-min behavior coaching sessions every other week for a total of nine sessions. Each dyad was assigned to meet with their behavior coach before or after the group meeting. During coaching, the behavioral coach reviewed eating habits, physical activity behaviors, and the child's motivation system. They also engaged in problem-solving with the family and helped set goals for the following week. The overall goal of the intervention was to help children decrease their age-adjusted BMI percentile by losing ½ to 1 lb. per week or maintain their current weight. [47] If interested, parental weight loss was encouraged as research outcomes have demonstrated a correlation between parent and child weight loss. [48] However, not all parents had OW/OB and parent weight loss was not required.

2.2. Usual care control group: Family-based behavioral treatment (FBT)

Dietary recommendations were based on the USDA MyPlate guidelines. [49] Parents were encouraged to decrease portion sizes, increase variety and healthy food options, particularly fruits and vegetables, and decrease foods that were high in fat or added sugars. For children, the initial goal was to consume 1000 to 1200 kcal/day. Calorie ranges were adjusted if children were more active, older, or were losing >1–2 lbs./week. If parents were interested in weight loss, they were given a calorie goal that was 500–1000 kcals lower than what they needed to maintain their current weight (current weight in lbs. x 12 = kcals needed to maintain current weight). Calorie goals were adjusted if parents lost >1–2 lbs./week. Minimum calorie recommendations were never below 1000 kcals/day for children or 1200 kcals/day for adults.

Physical activity recommendations focused on increasing lifestyle and physical activity and decreasing sedentary activities. Children were encouraged to engage in at least 90 min of physical activity 5 out of 7 days each week. Parents were encouraged to engage in at least 60 min of physical activity 5 out of 7 days each week.

Behavioral change recommendations included a variety of skills to help establish and maintain behaviors that would support healthy lifestyles. Parents and children were asked to self-monitor their dietary and physical activity behaviors and record this in a "habit" book (using myfitnesspal.com or on paper). [50,51] Parent-child dyads were taught to reflect on these entries and engage in self-regulatory behaviors to adjust food intake and activity levels.

In addition to self-monitoring, parents and children were taught about stimulus control, goal setting, behavior chains (i.e., understanding how behaviors, emotions, and thoughts are linked and lead to subsequent behaviors), problem-solving, planning for high-risk situations, cognitive restructuring (i.e., identifying negative or self-defeating beliefs and modifying or replacing them with more encouraging and adaptive thoughts), and relapse prevention. Stimulus control helped families improve the home environment by increasing fruits and vegetables and removing high-calorie foods.

Basic parent management skills were taught to help parents engage children in establishing new habits and motivating them to sustain these new habits. These skills include positive reinforcement, modeling, and reward systems. [52] The reward system was designed so children could earn points for engaging in healthy behaviors that were taught in ReFRESH. As the children earned points, they were able to trade those points for rewards that were previously determined by the parent-child dyad.

Behavior coaches helped families make behavior changes. They discussed how to implement program skills, problem-solve barriers, and set small change goals each week with the parent and child.

Table 2
Order and Content of Treatment Sessions.

Session #	FBT	FBT + PT	Parenting training elements added to FBT + PT
1	Introduction: Energy balance, self-monitoring, family meetings	Introduction: Energy balance, self-monitoring, family meetings	Emphasize importance of parent attention and special time
2	Healthy Eating	Healthy Eating	Emphasize persistence coaching when eating healthy
3	Stimulus Control/ Home Environment	Positive Parenting	Positive reinforcement, reward chart, modeling healthy behavior, effective use of praise and encouragement
4	Physical Activity	Stimulus Control/ Home Environment	Avoid pairing praise and criticism, look for the positive, avoid sarcasm
5	Motivation Systems/ Positive Parenting	Physical Activity	Teach through encouragement - promote pro-social behaviors with contingent positive reinforcement
6	Behavior Chains	Behavior Chains	Teach through encouragement - turn complaints into positive recommendations, make positive requests
7	Problem Solving	Setting Limits	Encouraging cooperation - provide children with clear, firm and respectful directions to increase compliance
8	Lifestyle/ Sedentary Behaviors	Problem Solving	Problem-solving with active skills learning, promoting process not solution
9	Problem Solving: High Risk Situations	Lifestyle/ Sedentary Behaviors	Setting clear limits, using non-coercive discipline strategies, following through with limits
10	Motivation	Problem Solving: High Risk Situations	Ignoring misbehavior, natural consequences, time out consequences
11	Responsibility	Motivation	Staying motivated: pros and cons to making healthy choices, setting up routines and clear expectations
12	Review: Open forum to address challenges	Responsibility	Monitoring children's activities when they are away from home
13	Behavior Chains: High Risk Situation Activities	Tricky Hunger/ Emotional Eating	Observing and managing your emotions
14	Tricky Hunger/ Emotional Eating	Body Image/ Teasing	How to give and get support from family members, positive self-talk
15	Shopping on a Budget	Social Support/ Sabotage	Managing conflicts with other family members
16	Meal Planning	Shopping on a Budget	Review of setting limits
17	Body Image/ Teasing	Meal Planning	Review of positive parenting styles: Importance of parent attention and special time
18	Social Support/ Sabotage	Review: Open forum to address challenges	Persistence coaching
19	Relapse Prevention	Relapse prevention	Dealing with child discouragement, build on their strengths, motivate with praise

Table 2 (continued)

Session #	FBT	FBT + PT	Parenting training elements added to FBT + PT
20	Graduation: Review	Graduation: Review	Review curriculum: emphasize parent autonomy to implement behavioral changes & positive parenting techniques

FBT = Family-based Behavioral Treatment.

FBT + PT = Family-based Behavioral Treatment + Parenting Training.

2.3. Intervention group: Family-based behavioral treatment plus parenting training (FBT + PT)

All elements of FBT were included in FBT + PT. In addition, parents received more in-depth parenting education based on positive parenting fundamentals [53,54] and active skills training to reinforce these parenting behaviors. The parenting training components were adapted from the Incredible Years Program (IYP) [55] and Parent-Child Interaction Therapy (PCIT). [56] Previous pilot testing informed which components from these programs were particularly valued by parents and should be included (Supplement 1). In addition to learning how to use positive reinforcement strategies and reward systems (as in FBT), parents were taught to use more effective discipline strategies (e.g., setting rules and routines, limit setting), improved communication techniques, and how to regulate their own emotions. Parents in FBT + PT were also exposed to active skills training (i.e., video modeling, role playing and behavioral practice in class, group discussions and problem-solving, and emotion regulation training) to increase skills adoption. [57,58] With video modeling, parents were able to observe others interacting with children in ways that promoted positive behaviors. [59] Parents were also given a weekly vignette during group treatment to role-play with another participating parent. This vignette would allow them to practice how they would address the situation with their child using the skills taught in treatment. Following role-play, the group would discuss successes and challenges of the exercise and receive immediate feedback. These methods have been shown to be effective at producing behavioral changes, [60,61] and is not currently used in traditional FBT.

The importance and effectiveness of using positive reinforcement, labeled praises, and rewards was taught in order to shape positive health behaviors. [62–64] Parents were encouraged to validate their child's emotions related to health activities while also helping their child persist with healthy choices. Positive phrasing was taught to help children make healthy choices by letting them know what they *can* do versus what they *cannot* (e.g., “You can choose a fruit for snack” instead of, “Don't grab the chips.”). Additionally, parents were encouraged to engage in 10 min of one-on-one time daily with their child to facilitate a more positive parent-child relationship. [65] Parent self-care was encouraged throughout treatment to prevent burnout.

Limit setting education was provided to further shape child behaviors: active ignoring, direct commands, forced choices, and setting structure and consequences. Direct commands and forced choices were encouraged to help guide children to make healthy choices (e.g., “We can either go on a walk or you can ride your bike. Which do you choose?”). Techniques of how to set structure in the home were emphasized to help make meal planning and healthy activities more predictable, consistent, and easier to achieve. These limit setting techniques have been shown to assist children in developing self-control and delayed gratification. [66]

2.4. Treatment Fidelity

Group leaders and behavior coaches had a range of backgrounds

including clinical psychology, pediatrics, post-doctoral fellows, students of marriage and family therapy, or bachelor's level research coordinators with training in psychology or public health. Different group leaders and behavioral coaches were assigned to each intervention arm and provided treatment to the same arm throughout the study. All group leaders and behavior coaches attended a two-day training conducted by experts in the field of pediatric weight loss (KNB, KER) and parenting training (SP). Those assigned to FBT did not attend the training that pertained to delivering PT. Prior to the start of the intervention, behavior coaches listened to the recorded coaching sessions of a skilled behavior coach. All interventionists attended a 90-min weekly supervision meeting to review content and problem-solve any issues that arose. During the intervention, behavior coaches and group leaders had access to the study coordinator and investigators to assist with any emergent situations. All group sessions and coaching sessions were audiotaped and 10% of audio recordings were reviewed. A random sampling of recordings from each behavioral coach and group leader were reviewed. Research assistants who were blind to treatment arm were trained to conduct fidelity checks.

3. Statistical analysis

3.1. Sample size and Power calculations

Empirical power and sample size calculations were conducted to support the primary aim (Aim 1). We expect changes in BMIz of 0.11, 0.15, 0.07, and 0.03 in FBT [67] and at least changes of 0.11, 0.30, 0.25, and 0.20 in FPT-PT [22] across the mid-point, post-treatment, 6-month and 12-month follow-up assessments respectively. We generated 10,000 multivariate normal random samples of correlated outcomes using covariance estimates from previous trial data (range 0.35–0.55) and analyzed the datasets using linear mixed effects models (LME) for repeated assessments of BMIz. The percentage of datasets with significant effects for the hypothesis of greater reductions in BMIz (i.e., >80% of treatment by time effects with p 's < 0.05) provided a simulation-based estimate of power. We found that assuming a combined sample size of 160 and setting alpha at 0.05, we would have power > 81% to detect treatment by time effects (median effect of 0.08, SD 0.02), when testing our primary hypothesis, allowing for up to 20% attrition. The recruitment of a sample of 140 and new empirical estimates suggested power was reduced but remained in an acceptable range of >79% for primary hypothesis given same expected effects. To evaluate the Exploratory Aim, both mediation paths from FBT-PT to mediators (path 'a') and mediators to engagement outcomes (path 'b') are expected to be medium to large effects [68,69] and simulation of mediational effects [60] suggest adequate power (>0.80) with this sample.

3.2. Data analyses

Analyses will be based on linear mixed models [70–72] implemented in R statistical software [58] and Mplus 8.1. [33] Primary outcomes evaluation first will follow an Intention to Treat principle with all allocated participants included in analyses. Planned covariates for primary outcome, change in BMI z-score, will include gender, ethnicity, and parent weight status. For models evaluating the Primary Aim, fixed effects will include coefficients for time, treatment, and time by treatment interactions. Significance tests will focus on the treatment by time interactions. We will use these same primary outcome models when we examine changes in alternative anthropometric values (i.e., %BMIp95 and Δ BMIp95).

Analyses of our Secondary Aims will examine rates of drop-out, treatment adherence, and acceptability of FBT + PT compared to FBT. Survival analysis will assess the effect of FBT + PT relative to FBT in decreasing risk for treatment drop-out (defined as subject refusal to continue treatment or failing to return to treatment without notification). Regression models for counts of sessions attended will quantify

any differences in the probability of completing between FBT + PT and FBT. Patient and therapist ratings of treatment acceptability and whether participants believe that the FBT + PT or FBT components address issues that are particularly relevant to them will be used to compare differences in acceptability. Planned covariates in all models of secondary aims outcomes will mirror primary analyses. Exploratory analyses comparing FBT + PT and FBT on repeated assessments of parenting style (2–4 measures); diet and physical activity; feeding/lifestyle behaviors, parent confidence (5 measures); and executive function measures (3 measures) will include use of generalized linear mixed effects models with p -values adjustment for false discovery rates. [73]

3.3. Missing data

The default handling of missing data in mixed models is to make use of all available information from each individual (i.e., no data or cases are deleted) in estimating model parameters. [70] This approach is both efficient and unbiased, provided that the missing data mechanism is ignorable, the model is correctly specified, and estimated using full likelihood procedures. [70] If the missing data mechanism is not ignorable then the model will result in biased estimates. One non-ignorable approach to handling missing data in a longitudinal context is pattern mixture modeling. [74,75] This approach stratifies participants based on their missing data pattern. A separate model is fit for each pattern and then estimates and standard errors are typically combined across the different patterns to obtain an average for the sample. Both the model-default likelihood approach and pattern mixture model are advocated as optimal approaches to handling missing data. [76] Results from both models will be compared using a likelihood ratio test and results from the better fitting model will be reported.

4. Discussion

FBT is one of the CDC approved and most consistently effective IHBLT programs for childhood obesity. [77] However, there is still room for improvement. Parenting training alone has been shown to have an impact on weight, even when it is not combined with lifestyle interventions. [20] Since parenting training has been shown to decrease negative parenting techniques like threats and criticisms, [68,69] it may be able to moderate how specific behavioral strategies are delivered and provide additional support for the adoption of healthy lifestyle behaviors. [8,9] As such, targeting parenting style in the context of IHBLT may have positive impacts on treatment outcomes as well as implications for future child academic, emotional, and behavioral health. [78–80] To date, very few studies have evaluated the impact of parenting training on weight loss in school-age children or adapted these programs to include behavioral lifestyle treatment. This is one of the first studies to evaluate the additive effect of FBT + PT on child weight status compared to traditional FBT.

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CRediT authorship contribution statement

Kyung E. Rhee: Writing – original draft, Validation, Supervision, Resources, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Conceptualization. **Takisha Corbett:** Writing – review & editing, Supervision, Project administration, Data curation, Conceptualization. **Shamin Patel:** Writing – review & editing,

Supervision, Project administration, Conceptualization. **Dawn M. Eichen:** Writing – review & editing, Supervision, Project administration, Investigation, Formal analysis, Data curation. **David R. Strong:** Writing – review & editing, Methodology, Investigation, Formal analysis, Conceptualization. **Cheryl Anderson:** Writing – review & editing, Supervision, Methodology, Investigation, Conceptualization. **Bess Marcus:** Writing – review & editing, Supervision, Methodology, Investigation, Conceptualization. **Kerri N. Boutelle:** Writing – review & editing, Supervision, Project administration, Methodology, Investigation, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

No data was used for the research described in the article.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.cct.2024.107562>.

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