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Publication Date

2023

DOI

10.1016/j.cct.2022.106996

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Author manuscript

Contemp Clin Trials. Author manuscript; available in PMC 2023 February 26.

Published in final edited form as:

Contemp Clin Trials. 2023 January ; 124: 106996. doi:10.1016/j.cct.2022.106996.

Design of the FRESH-DOSE study: A randomized controlled noninferiority trial evaluating a guided self-help family-based treatment program for children with overweight or obesity

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Abstract

Overweight and obesity affect 45% of children and increases the risk for several negative health sequelae. Family-Based Behavioral Treatment (FBT) is the most efficacious treatment for child weight management and consists of nutrition and physical activity education, behavior change skills and parenting skills training. FBT is time and staff intensive and can include 20, 60-min separate groups for parents and children, as well as 20-min behavior coaching sessions to help problem solve barriers to implementing the skills learned and individualize the program. Guided self-help (GSH) therapies involve providing families a manual to review independently and brief coaching sessions by an interventionist to facilitate adherence. We developed a GSH version of FBT (gshFBT) which provides a manual to both parents and children and includes 14, 20-min coaching sessions over 6-months. The current study randomized 150 children (mean age = 10.1 years (SD = 1.38); mean BMI% = 97.3% (SD = 2.84); mean BMIz = 2.09 (SD = 0.40); 49% female; 43% Hispanic) and one of their parents (mean age = 41.8 years (SD = 6.52); mean BMI = 32.0 (SD = 7.24); 87.3% female; 43% Hispanic) to either a group-based FBT program or a

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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.

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gshFBT program. Assessments are conducted at baseline, post-treatment (6 months), 6-month follow-up (12 months) and 12-month follow-up (18 months). Primary outcomes are child weight change (BMIz) and cost effectiveness. Recruitment occurred between May 2017 and October 2021 and follow-up assessments are underway. Given the public health concern for children with obesity and the low level of access to FBT, gshFBT could prove extremely useful to provide intervention to a greater proportion of the population.

Keywords

Weight management; Weight loss; Child; Family-based treatment; Guided self-help; Lifestyle intervention

1. Introduction

Approximately 45% of youth have overweight or obesity (OW/OB) [1], which is associated with a myriad of negative physical and psychosocial health consequences [2–8]. Family-based behavioral treatment (FBT) is the most efficacious treatment for children with OW/OB [9]. FBT programs include nutrition and physical activity education, behavior change skills, and parenting skills training [10,11]. FBT often includes separate parent and child group sessions and individualized family behavior coaching sessions. Despite the efficacy of FBT, these programs are costly [12]. The group nature of these interventions requires a large amount of space and staff and requires attending at a predetermined time (e.g., groups are offered only one night a week), making these interventions challenging for providers to offer and patients to access. Furthermore, the treatment is burdensome as the treatment includes at least 23 direct contact hours over six months. Studies show that only 18% of families who are offered FBT enroll [13]. Thus, more feasible and cost-effective interventions are needed.

Guided self-help (GSH) is a less intensive treatment modality that delivers programs containing the same information in a more distilled form. GSH interventions provide educational materials to read at home coupled with short visits with an interventionist to promote adherence. GSH sessions for weight management include reviewing weight changes and self-monitoring of food intake and physical activity, in addition to problem solving barriers to implementation of recommendations. GSH therapies are feasible and efficacious for the treatment of eating disorders [14,15], depression and anxiety [16], and weight loss [17]. We developed a GSH version of FBT for families (gshFBT) and demonstrated that it was feasible, acceptable, and showed significant decreases in child standardized BMI scores (BMIz) compared to a waitlist control at post-treatment and 6 month follow-up [18]. Furthermore, we demonstrated in a nonrandomized pilot study that gshFBT is noninferior to FBT on changes in child BMIz [19]. A recent primary care study found that families attended twice as many gshFBT sessions compared to FBT [20]. Thus, we believe that gshFBT could be a viable alternative to the more intensive FBT and will be both easier to disseminate and more cost effective.

Both FBT and gshFBT require organization, completion of self-monitoring, resisting temptation, goal setting, planning, and problem solving. Since children have not completed

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frontal lobe maturation (important in many of these skills) [21], parents are essential to include. Children have little control over the home food environment and meals, what physical activities the child engages in, and in structure to decrease sedentary behaviors. Thus, parenting and the ability to cognitively implement the program (using executive functioning skills) can influence how successful children are in gshFBT or FBT.

2. Study objectives

In the Families, Responsibility, Education, Support and Health-Dual Options for Sustained Effectiveness (FRESH-DOSE) randomized clinical trial (NCT03096132), 150 children ages 7–12 and their parent a) are randomized to one of two programs: FBT or gshFBT delivered to the parent-child dyad. Both treatments last six months and planned outcome assessments at 12- months after treatment are currently underway. The primary aims of the study are to evaluate whether gshFBT is noninferior to FBT.

a) The term “parent” will be used throughout, however, any care-giver living in the home who is responsible for the child’s dietary intake may participate.

on child weight loss (BMIz) and whether gshFBT is more cost-effective. Secondary aims include evaluating the effects of both arms on parent and child eating behaviors, parent and child physical activity, parent BMI and parenting skills. Exploratory aims include evaluating moderators and mediators of the treatments on child weight status over time.

3. Study design

3.1. Trial design

FRESH-DOSE is a two-arm, randomized controlled trial comparing FBT to gshFBT among children with OW/OB and their parent. Assessments are conducted at baseline, post-treatment, and 6- and 12-month follow-up timepoints. The primary outcomes are change in child standardized BMI (BMIz) and cost effectiveness over the 18-month duration of the study. Families are randomized in a block design (blockrand) [22] to FBT or gshFBT by gender of the child and weight status of the parent (OW/OB or healthy weight).

3.2. Participants

Participants in the study are 150 children (mean age = 10.1 years (SD = 1.38); mean BMI% = 97.3%(SD = 2.84); mean BMIz = 2.09 (SD = 0.40); 49% female; 43% Hispanic) and one of their parents (mean age = 41.8 years (SD = 6.52); mean BMI = 32.0 kg/m^2 (SD = 7.24); 87.3% female; 43% Hispanic).

3.3. Inclusion/exclusion criteria

Inclusion criteria for parent-child dyads are: a) 7–12 year old child whose BMI is ≥85th and < 99.9th percentile [23], b) parent who can read English at a minimum of a 5th grade level, c) parent and child willing to attend all treatment and assessment sessions and be randomized to either treatment arm; d) child and parent are free from psychiatric illness that may affect participation (e.g., active suicidality, active eating disorder); e) child is free from any medical conditions that impact weight or may affect participation in physical activity or

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treatment (e.g., cerebral palsy or psychiatric disorders that make group participation difficult (e.g., conduct disorder or uncontrolled ADHD)); f) child is not taking medications that may impact their weight (e.g., high dose steroids, ADHD medications) unless medication dosage is stable and not prescribed for weight or appetite.

3.4. Recruitment

Parents of a child with OW/OB are recruited from San Diego metropolitan area. Parent-child dyads are recruited through primary care physician offices, listservs, ResearchMatch, letters mailed to families identified as potentially eligible through electronic medical records, local and online advertisements, and school flyers. Parents who respond to recruitment efforts complete an online screen to determine initial eligibility. Then parents complete a phone screen and attend an orientation to learn more about the study. If they remain eligible and interested in participating after the orientation, parents provide informed consent, children provide assent, anthropometric measures are completed, and they complete baseline assessments. Recruitment occurred between April 2017 and May 2021.

3.5. Assessment and outcome measures

Parent-child dyads complete assessments at the following time-points: baseline (month 0), during treatment, post-treatment (month 6), 6-month follow-up (month 12), and 12-month follow-up (month 18). Assessments include anthropometry, self-report questionnaires, tasks, and structured clinical interviews. Baseline assessments began in May 2017 and the final 12-month follow-up data collection should be completed in January 2023.

3.6. Measures

Measures and timepoints are listed in Table 1.

3.6.1. Demographics and screening—Demographics (Parent only). Parent and child age, gender, race-ethnicity, and parent socio-economic status are reported.

Medical history and current medication use (Parent only). During screening, parents are queried about current medications and the presence of medical conditions that could interfere with treatment for either the parent or the child. Parents report any changes in medical status and medications throughout treatment and at follow-up.

Mini International Neuropsychiatric Interview for children and adolescents version 6.0 (MINI-KID, Child only) [24]. The MINI-KID is a structured, diagnostic interview used to assess DSM-5 and ICD-10 disorders in children aged 6–17 years. Trained interviewers administer the MINI-KID to children at baseline to determine the presence of a psychiatric disorder warranting study exclusion. Interview assessments are discussed in a weekly supervision meeting led by a licensed clinical psychologist to determine whether families meet inclusion criteria.

3.6.2. Anthropometry (parent and child)—Height is measured using a Seca 222 mechanical telescopic measuring rod in triplicate and recorded to the nearest 0.1 cm. Body weight in kilograms is measured on a calibrated Tanita Digital Scale (model WB-110A)

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and recorded to the nearest 0.1 kg. Height and weight are converted to body mass index (BMI = [kg/m^2]) for parents, and BMIz for children [23]. When in-person anthropometric assessments could not occur due to the Covid-19 pandemic, Bluetooth scales (Withings) were provided, and height was estimated at home using provided tape measures.

3.6.3. Cost effectiveness (parent only)—We will use micro-costing methods [25], including cost-capture of staffing time and overhead, and monthly surveys from families for the actual costs of attending treatment, including mileage, lost wages and child care cost. Parents also report healthcare utilization, prescriptions and any medical or psychological intervention needed for themselves and their child monthly during treatment.

3.6.4. Physical activity (parent and child)—*Actigraph accelerometers*. Physical activity is assessed with an Actigraph accelerometer (model GT3X+, http://www.theactigraph.com) which is a small, lightweight, uni-axial accelerometer worn on a belt around the waist for 7 consecutive days [26,27]. Participants record the times that they do not wear the Actigraph (e.g., while sleeping, swimming), as well as time spent engaging in physical activity and sedentary activity.

3.6.5. Eating behavior and dietary intake (parent and child)—*Eating behavior and dietary intake practices*. Parents and children respond to specific dietary intake and eating behavior questions adapted from Project EAT [28–31] that are related to program goals (e.g., sugar-sweetened beverages, fruit and vegetable consumption, fast food consumption, breakfast consumption).

3.6.6. Parenting (parent and child)—The Children's Report of Parent Behavior Inventory (CRPBI; Child only) [32]. The CRPBI is a 30-item child report questionnaire that measures maternal and paternal parenting behaviors. The CRPBI results in three parenting style scales for each parent; psychological control versus psychological autonomy, parental acceptance versus rejection, and firm versus lax control.

The Comprehensive Feeding Practices Questionnaire (CFPQ; Parent only) [33]. The CFPQ 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.

3.6.7. Executive functioning (parent and child)—NIH Toolbox Cognitive Battery (NIHTB-CB) [34–42]. The NIHTB-CB is used to measure attentional control, cognitive flexibility, and general cognitive abilities using the Flanker Inhibitory Control and Attention Test, Dimensional Change Card Sort Test, Picture Sequence Memory Test, Picture Vocabulary Test, and Oral Reading Recognition Test.

Stop Signal Task-Food Version (SST-Food) [41,42]. The SST-Food is used to measure motor inhibition to food and non-food cues. Participants respond as fast as possible to a stimulus unless a stop signal is presented after a variable delay. On each trial, participants are asked to discriminate between a picture of calorically dense food or neutral object (e.g., chair).

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The two primary outcomes, stop signal reaction time for food pictures (SSRT-Food) and neutral pictures (SSRT-Neutral) will be compared to assess for food-specific impulsivity versus general impulsivity. Higher SSRTs indicate decreased inhibitory control.

Behavior Rating Inventory of Executive Function–2 (BRIEF-A and BRIEF-2).[53,54] The BRIEF-A is a 75 item measure of an adult's executive functions in his or her everyday environment. The BRIEF-2 is a 63 item parent report measure of the child's executive functions. Both questionnaires include nine clinical scales as well as a global executive composite score.

3.6.8. Acceptability and adherence (parent and child)—Treatment acceptability questionnaire. Parents and children complete a self-report questionnaire designed by the study staff to measure acceptability of treatment. The questionnaire assesses overall liking and helpfulness of the FRESH-DOSE program and perceptions associated with group assignment.

Treatment adherence. Adherence and attendance data are obtained weekly during the treatment program. Attendance is recorded by group leaders and adherence to self-monitoring is measured by collecting weekly self-monitoring from participants in both programs.

4. Intervention

Over the course of the trial, the intervention was delivered at one of two university-based research spaces (La Jolla, CA and San Marcos, CA) or virtually via HIPAA-compliant, password-protected Zoom links following the start of the COVID-19 pandemic (March 2020). Of note, three cohorts were treated in person and two cohorts were treated remotely.

4.1. Intervention content

The content is similar in both the FBT and the gshFBT arms (see Table 2). Content focuses on nutrition and physical activity education, behavior change skills, and parenting skills. Dietary recommendations are based on the USDA's MyPlate framework [44], which focuses on portions, variety, and moderation with respect to food choices. Parents are prescribed the same eating recommendations as the children to facilitate child adherence. The dietary goals for the child include an energy intake goal of 1000–1200 kcal/day with at least five fruits and vegetables five out of seven days. Caloric ranges are adjusted for active or older children based on weight loss, but recommendations were never made below 1000 kcal/day for children. All parents are provided a calculated number of calories needed to maintain current weight by multiplying the participant's weight in pounds by 12. For parents with OW/OB, to promote weight loss, a caloric range is provided by subtracting 500 and 1000 cal from the calories needed for weight maintenance. Anticipated weight loss using this method was 1–2 lbs./week. Recommendations were never made below 1200 kcal/day for parents.

Physical activity education includes information about physical, lifestyle, and sedentary activity, as well as physical activity for overall health and weight loss maintenance. Increased planned physical activity, increased lifestyle activity, and decreased sedentary

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activity are shaped with the following goals: 90 min/day of physical activity for children and 60 min/day of physical activity for adults five out of seven days per week, plus two hours or less of sedentary activity per day (outside of school, homework, or work).

Behavior change skills include stimulus control, parenting skills, behavior chains, managing high-risk situations, problem solving, social support, cognitive restructuring, and relapse prevention skills. Parents and children record food and energy intake, physical activity, and completion of family meetings in a "Habit Book" or an app (http://myfitnesspal.com) each week. Parents and children also track their weights at least once per week (on treatment nights) and up to one other time during the week.

Parenting skills include basic behavioral principles, positive parenting, modeling, daily meetings, and a "motivation"/behavioral reinforcement system. Children earn points for meeting program goals (e.g., tracking food intake, engaging in physical activity). Points are awarded by coaches during the first two behavioral coaching sessions. Then parents are asked to continue to tally points weekly and provide appropriate rewards as earned. Points can be traded in for small, medium, and large prizes that are agreed upon by parents and children at the beginning of treatment and modified if needed during treatment.

4.2. FBT

Parent-child dyads in the FBT arm attend group-based treatment that includes 20 group visits (16 weekly visits and four biweekly visits; 60 min each) and nine behavioral coaching sessions (every other session between sessions 2–19; 20 min each) over six months (total = 23 h). Parents and children attend parallel separate groups at a specified time of night on one weekday per week. Parent group includes a mix of didactic teaching, group discussion, and activities. Children attend a parallel group at the same time, which aims to engage children by providing information regarding nutrition, physical activity and behavioral skills in an age-appropriate group discussion which includes games related to session topics. Behavior coaching in the FBT arm focuses on adherence to program components, reviewing weight changes and self-monitoring, problem-solving challenges that arise, and behavioral goal setting.

4.3. gshFBT

The intervention in the gshFBT arm includes the same content as FBT, however, parent-child dyads meet individually with the interventionist for one 1-h visit and 13, 20-min visits over the course of six months (total = 5.3 h). Parent-child dyads are given a chapter to review prior to coaching sessions with an FBT topic for the meeting. gshFBT behavioral coaching sessions are similar to those provided in FBT; however, they also include monitoring of whether parent and child reviewed the written materials. Behavioral coaching sessions occur at a standing day and time of the families' choosing but are rescheduled when necessary.

4.4. Treatment fidelity

Group interventionists and behavioral coaches include licensed clinical psychologists, postdoctoral fellows, advanced clinical psychology and marriage and family therapy

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students, and bachelor-level research coordinators, all of whom were supervised by a licensed clinical psychologist. Prior to working on the study, all interventionists complete a two-day training with the PI, who is a licensed clinical psychologist. All group sessions and behavioral coaching sessions are audio-recorded and reviewed by supervisors as needed and interventionists attend a weekly 2-h supervision meeting.

5. Statistical analyses

5.1. Sample size and power calculation

Empirical power analyses were conducted to support sample size selection for the evaluation of primary aims. Power estimates were assessed by generating 1000 multivariate random samples that were matched to the expected response patterns for each condition using the same correlation structure of assessments over time as observed in our previous studies evaluating changes in BMIz in our lab. We expected that both gshFBT and FBT will result in a significant change in weight equivalent to a medium effect (Cohen's d = 0.50) or a change in BMIz ≥0.15 and that the magnitude of this change will not be larger than our specified inferiority margin. We computed the upper bound of the 90% confidence interval for between treatment effects on BMIz and counted the number of times a value fell outside the margin of inferiority. With allowance for 20% missing data, our originally proposed sample of 160 produced upper bound values ≤0.02 in >96% of 1000 samples. With the onset of COVID, we re-assessed power given a slightly reduced sample of 150. Results suggested we would maintain adequate power as simulations produced upper bound values ≤0.02 in >86% of 1000 samples.

5.2. Data analyses

5.2.1. Primary aim 1:Non-inferiority of child weight loss—We will use linear mixed effects models (LME) to examine repeated measurements of BMIz assessed at post-treatment and at 6- and 12-month follow-up assessments. Planned covariates include age, gender, weight status of the parent, corresponding baseline values of BMIz, cohort and effect of time. The main effect of treatment group will provide an estimate and standard error of differences in the magnitude of change in child weight. Non-inferiority hypothesis will be supported if the upper bound of the 90% CI for the main effect of treatment (gshFBT vs FBT) is above our pre-specified non-inferiority margin. This non-inferiority margin reflects the range of expected changes in BMIz that would be expected if the treatment effects of gshFBT on weight were not substantially less than expected in FBT. We set the upper bound of 0.02 BMIz units using the covariate adjusted pooled standard deviation of changes in BMIz at post-treatment and 18-month follow-up observed in our previous study [45]. This is equivalent to each treatment resulting in a margin of change in BMIz ranging from −0.13 to −0.17. All analyses will be conducted using an Intention To Treat (ITT) and Per Protocol (PP) samples to ensure similar findings [46,47].

5.2.2. Primary aim 2: Cost effectiveness—Cost-effectiveness ratios will be calculated wherein the effectiveness measure will be weight loss and the cost-effectiveness ratio will reflect the cost per pound weight loss for the child and the parent. Costs will be generated from the following sources: 1) The Center for Medicare Services (CMS)

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website for episodes of clinical care (initial clinical evaluations, psychotherapy, emergency room, outpatient medical visits, hospitalization), 2) Drug costs will be obtained from the most current version of the Red Book (http://truvenhealth.com; *RED BOOK Online®*), 3) Costs for time spent traveling to and from treatment and time spent at treatment will be calculated for each parent participating based on population average wage rates, 4) IRS mileage deduction rates will be used to calculate costs of travel to and from treatment visits, 5) Parents utilizing childcare during study visits will be asked the amount they pay for child care and 6) Staffing and space costs will be calculated using average wage rates and current space costs.

Two types of uncertainty will be addressed in the cost-effectiveness analyses. First, data-based cost minimization or cost-effectiveness analyses such as those proposed involve some assumptions; uncertainties in those assumptions will need to be tested using multi-way sensitivity analyses. Variables in the sensitivity analyses will include unit cost of initial evaluation, unit cost of gshFBT visits and unit cost of FBT visits. Second, in order to address the statistical uncertainty in directly measured variables, confidence intervals will be estimated for the cost per pound of weight loss via a non-parametric bootstrap using bias-corrected and accelerated intervals based on 10,000 resamples [48]. We propose bootstrap estimates because primary data will be available and we do not anticipate the data for either costs or effectiveness will be normally distributed. Results for cost and effectiveness will be plotted for the 10,000 interventions, allowing for examination of the frequency with which the results fall into each of the four possible quadrants.

5.2.3. Secondary aims: Parent and child eating behaviors, physical activity, parent BMI, and parenting skills—We will use LME models of baseline, post-treatment, and 6- and 12-month follow-up assessments for eating behaviors, physical activity, parent BMI and parenting. We will use graphical approaches and unconditional models to assess fit of linear and non-linear effects of time, including planned covariates of age, cohort, gender, and baseline BMIz/BMI to mirror primary outcome models. The effect of time will quantify impact of treatments on each outcome. A treatment by time interaction will assess whether changes differed across treatments.

5.2.4. Exploratory aims—Exploratory aims include evaluating demographic (e.g., gender, age, educational level), weight (e.g., parent baseline BMI, child baseline BMIz), executive functioning and parenting style as potential moderators of treatment efficacy. We will use primary outcome models to evaluate each proposed moderator of differences in treatment effectiveness. We will conduct a series of analyses for demographic, weight, and executive functioning and parenting style variables. For each set, we will add individual terms along with an interaction between examined moderator(s) and the main effect of treatment group assignment.

To assess mediators (e.g., parenting skills) of the gshFBT and the FBT treatment on child body size over time (BMIz) we will use parallel process growth models [49] to evaluate the association between changes (e.g. slopes) in parent skills and changes (e.g., slopes) in weight outcomes (BMIz) at post-treatment, 6- and 12-month follow-up assessments. We expect both gshFBT and the FBT to have positive effects on parenting skills and increased

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parenting skills to be associated with greater weight loss. Significant associations between slopes will provide support for improved parenting skills as a hypothesized mechanism of these treatments' efficacy. Since this trial was conducted during the COVID-19 pandemic lockdown, we will also evaluate the effect of modality on outcomes.

5.3. Missing data

The maximum-likelihood (ML) based analysis using the observed data from all cases assumes missing data is missing at random (MAR) and the missing data is a function of the observed outcomes and covariates. The MAR mechanism is considered ignorable missingness and this assumption has been shown to perform well in the analysis of weight loss RCTs. The plausibility of the MAR assumption with ML can be improved by using an inclusive analysis strategy that incorporates auxiliary variables [50,51] as correlates of missingness. The distinction between ignorable (MAR) and non-ignorable missingness (MNAR) is generally not empirically testable and we acknowledge the possibility that data may be missing not at random (MNAR). Therefore, we propose to perform MNAR sensitivity analyses using pattern mixture models. For infrequently observed patterns we will apply the Hedeker and Gibbons [52] approach that uses a binary variable in the model to denote missing data at one or more time points.

6. Discussion

FBT is the recommended approach for children with OW/OB. However, the program is time, staff, and space intensive. Our group has developed a GSH version of FBT that is delivered to the parent and child. The FRESH-DOSE study is an ongoing randomized controlled non-inferiority trial comparing the more intensive group-based FBT program with a GSH program delivering the same content to the parent-child dyad, but in a less intensive manner. The FRESH-DOSE study will provide important information about whether the gshFBT program is noninferior to and more cost effective than the FBT program. Additionally, this trial will also determine the effect of both treatments on parent and child eating behaviors, parent and child physical activity, parent BMI and parenting. Furthermore, to learn more about both treatments, we will evaluate important moderators and mediators of gshFBT and FBT treatment on child body size over time. Additionally, due to the COVID-19 lockdowns, we will be able to evaluate the effect of treatment modality on outcomes, including BMIz and attendance. The FRESH-DOSE study could provide important evidence regarding the gshFBT program and could change the way weight management programs are provided to parents and school-aged children.

Acknowledgements

This work was supported by the National Institutes of Health [R01DK108686, UL1TR001442]. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

Data availability

The authors do not have permission to share data.

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Table 1

Parent and child measures.

	Instrument	Parent or child	Timepoint				
			Baseline	During trt	Post trt	6-mon f-up	12-mon f-up
Demographics and screening	Medical history questions	P	X				
	Age, gender, race/ethnicity, grade in school, SES	P, C, Pc	X				
	MINI-Kid	C	X				
Anthropometry	Height and Weight	P, C	X	X	X	X	X
Cost-effectiveness	Health care utilization	P	X	X	X	X	X
Energy Balance	Eating behavior questions	P, C	X	X	X	X	X
	Accelerometer	P, C	X		X	X	X
	EDE, chEDE	P, C	X		X	X	X
Parenting	CRBPI	C	X	X	X	X	X
	CFPQ	P	X	X	X	X	X
Executive Functioning	Flanker	P, C	X				
	DCCS	P, C	X				
	Stop task-Food	P, C	X				
	BRIEF	P, C	X				
	Picture Vocabulary	P, C	X				
	Oral Reading Recognition	P, C	X				
Treatment acceptability	Acceptability	P, C			X		
Treatment adherence	Attendance	P, C		X			
	Self-monitoring in habit books	P, C		X			

P=Parent, C=Child, Pc = Parent report of child.

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Table 2

FBT and gshFBT time and topics during 6-month intervention period.

	Group FBT	**gshFBT**
Time	1 h parent/child separate group and 20 min behavioral coaching	20 min behavioral coaching except Week 2
Week 1	Introduction	Introduction
Week 2	Healthy Eating	Healthy Eating (1 h)
Week 3	Stimulus Control/Home Environment	Stimulus Control/Home Environment
Week 4	Physical Activity	Physical Activity
Week 5	Motivation Systems/Positive Parenting	*No Session*
Week 6	Behavior Chains	Motivation System/ Parenting Skills
Week 7	Problem Solving	*No Session*
Week 8	Lifestyle/Sedentary Behavior	Behavior Chains: High Risk Situations
Week 9	Problem Solving: High Risk Situations	*No Session*
Week10	Motivation	Problem Solving: High Risk Situations
Week11	Responsibility	*No Session*
Week12	Review	Lifestyle & Sedentary Behaviors
Week13	Behavior Chains: High Risk Situations	*No Session*
Week14	Emotional Eating	Responsibility
Week15	Body Image/Teasing	*No Session*
Week16	Meal Planning	Emotional Eating
Week17	*No Session*	*No Session*
Week18	Social Support/Sabotage	Body Image & Teasing
Week19	*No Session*	*No Session*
Week20	Shopping on a Budget	Shopping on a Budget & Meal Planning
Week21	*No Session*	*No Session*
Week22	Relapse Prevention	Social Support
Week23	*No Session*	*No Session*
Week24	Graduation	Relapse Prevention