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Design of the FRESH Study: A Randomized Controlled Trial of a Parent-Only and Parent-Child Family-Based Treatment for Childhood Obesity

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Abstract

Approximately 1 out of 3 children in the United States is overweight or obese. Family-based weight loss treatment (FBT) is considered the gold-standard treatment for childhood obesity, but FBT is both staff and cost intensive. Therefore, we developed the FRESH (Family, Responsibility, Education, Support, & Health) study to evaluate the effectiveness of intervening with parents, without child involvement, to facilitate and improve the child's weight status. Targeting parents directly in the treatment of childhood obesity could be a promising approach that is developmentally appropriate for grade-school age children, highly scalable, and may be more cost effective to administer. The current paper describes the FRESH study which was designed to compare the effectiveness of parent-based therapy for pediatric obesity (PBT) to a parent and child (FBT) program for childhood obesity. We assessed weight, diet, physical activity, and parenting, as well as cost-effectiveness, at baseline, post-treatment, and at 6- and 18-month follow-ups. Currently, all participants have been recruited and completed assessment visits, and the initial stages of data analysis are underway. Ultimately, by evaluating a PBT model, we hope to optimize available child obesity treatments and improve their translation into clinical settings.

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Keywords

obesity; family-based treatment; child; randomized controlled trial

1. Introduction

Currently one in three children in the United States is overweight or obese (Ogden, Carroll, Kit, & Flegal, 2014). Childhood obesity tracks into adulthood and relates to increased health problems, medical care, and parent burden (Daniels, 2006; Dietz, 1998; Dixon, 2010; Gunnell, Frankel, Nanchahal, Peters, & Davey Smith, 1998; Key et al., 2004; Reilly & Kelly, 2011; Sorof & Daniels, 2002). Childhood obesity is also related to significant psychosocial difficulties over a lifetime (Gibson et al., 2008; Hayden-Wade et al., 2005; Luppino, de Wit, Bouvy, & et al., 2010; Puhl & Latner, 2007). Considering the health and psychosocial consequences, it is important to develop and disseminate improved childhood obesity treatments.

The current gold standard treatment program for childhood obesity, family-based treatment (FBT), is delivered concurrently or simultaneously to both parents and children, and includes diet and physical activity education and behavior therapy techniques. FBT for childhood obesity is considered effective in the short-term and long-term (Epstein, Paluch, Roemmich, & Beecher, 2007; Sung-Chan, Sung, Zhao, & Brownson, 2013). Research shows maintenance of weight loss 10 years after follow-up, and approximately 1/3 of children who participated in FBT were no longer overweight, which is more successful than the rates of weight loss and maintenance in adults (Epstein et al., 1994; Epstein et al., 1995; Epstein et al., 2007). However, FBT is both time and personnel intensive, and is may be less convenient for busy families as it requires attendance by both parent and child.

Because parents play a major role in the overweight or obese child's life, it is logical that parents should be considered the agent of change for the treatment of childhood obesity. Behavioral treatment programs that target both parent and child but only treat the parent (PBT) are potentially promising for a number of reasons, including decreased treatment costs, developmental appropriateness for the child, favorable preliminary data and the possibility of improved scalability. The initial studies using a PBT model showed that children lost significantly more weight in a PBT program compared to a control program (child-focused) (Golan et al., 1998) and these differences were maintained 7 years later (Golan & Crow 2004). In our pilot trial, we found that weight losses for children and overweight parents in PBT were non-inferior to FBT post-treatment and 6-months post-treatment (Boutelle et al, 2011). In another trial, delivered in Cooperative Extension Offices in rural communities, children lost significantly more weight in a PBT and FBT program compared to a control group at post-treatment and 6-months follow-up. This study did not find any significant differences in weight losses between PBT and FBT at any of the timepoints (Janicke et al, 2008). However, PBT was more cost-effective than FBT (Janicke et al, 2009). A recent study showed that a PBT program for African American families showed significant improvements in child BMI compared to a control group post-treatment (Mazzeo et al., 2014).

These data taken together suggest that a PBT model may produce outcomes in child weight loss similar to FBT, and could be more cost-effective than FBT. To date, no study has evaluated an appropriately powered, tightly controlled trial examining PBT for childhood obesity that includes long-term follow-up and compares the cost of providing these treatments. Due to the rising rates of obesity in children and adults, PBT could prove extremely useful to clinicians, researchers and public health personnel as they intervene in the childhood obesity epidemic.

2. Study Objectives

In the FRESH (Families, Responsibility, Education, Support and Health) is a randomized clinical trial, 150 overweight 8–12 year old children and at least one of their parents were randomly assigned to one of two group-based conditions; a parent-only intervention (PBT) or a parent + child intervention (FBT). The intervention and data collection occurred between July of 2011 and July of 2015. Both treatment arms provided a behavioral treatment program for childhood obesity for 6 months, and participants were followed and assessed at the 6- and 18-month follow-up visits. The overall intent of this study was to compare PBT to FBT on variables of interest in children and parents, including change in weight status, dietary intake, physical activity, parenting and cost-effectiveness. The primary hypothesis was that PBT would be more cost effective than FBT, but would not produce inferior weight loss. We also predicted that participants in PBT would demonstrate changes that were not inferior to FBT in diet, physical activity, parent weight change, and parenting.

3. Study Design

3.1 Trial design

FRESH was a two-arm, parallel group, randomized controlled trial comparing PBT to FBT for childhood obesity. The major difference between PBT and FBT was the attendance of the child. Assessments were conducted at baseline, post-treatment, and at the 6- and 18-month follow-up visits. The primary outcome measures were change in child weight status (body mass index (BMI kg/m²), BMI-Z (standardized BMI), and age and gender adjusted BMI-percentile) and cost effectiveness over the 24-month duration of the study. Secondary outcomes include dietary intake, physical activity, parent weight, and parenting skills.

3.2 Participants

Participants in the study were 150 parent-child dyads. All children were 8–12 years old and overweight or obese; at least one parent was also overweight or obese. One hundred and fifty children (mean BMI = 26.36; mean BMI-Z = 2.02; mean age = 10.41; % female = 66.4) and their parent (mean BMI = 31.9; mean age = 43.01; % female = 87.1; race/ethnicity = 52.3% Hispanic, 27.1% Non-Hispanic White, 20.1% Other) were randomly assigned to either FBT or PBT. In a minority of families (n=8, 5.33%), the biological overweight or obese parent could not participate in the intervention. In these cases, children attended treatment with the parent who was responsible for the majority of food purchasing and preparation.

3.3 Inclusion/Exclusion Criteria

Inclusion criteria for the FRESH study included: 1) response to an advertisement for the study, 2) child between the ages of 8 and 12 years old, 3) child BMI between the 85th and 99.9th percentile for age and gender, 4) one biologic parent in the household with a BMI 25 kg/m² (i.e., overweight) 5) a parent who was willing to participate who could read English at a minimum of a 5th grade level, 6) family willingness to commit to 6 months of treatment and 18 months of follow-up, and 7) ability to attend groups on designated evenings. Exclusion criteria for the study included: 1) child psychiatric disorder diagnosis (based on a clinical interview) that would interfere with treatment participation (e.g., autism, severe depression), 2) child diagnosis of a serious current physical disease (such as diabetes) for which physician supervision of diet and exercise was needed, 3) family with food restrictions, such as food allergies, or religious or ethnic practices that limit the foods available in the home, 4) child with physical difficulties that limit the ability to exercise, 5) child with an active eating disorder (based on a clinical interview), 6) parent psychiatric disorder (self-report) that would interfere with treatment participation (e.g., substance abuse/dependence), 7) concurrent enrollment in a weight management program.

3.4 Recruitment and retention

Families with an overweight or obese child were recruited from the San Diego, California metropolitan area. Families were recruited through primary care physicians, listserves, local advertisements, online advertisements, and school mailings. All families who called to express interest in the study were screened over the telephone by the study recruitment coordinator. If participants met initial criteria, they were invited to attend a study orientation to learn more about the purpose of the study. Families who were still interested after the orientation were asked to sign consent and assent forms and to schedule a baseline assessment.

Several strategies were used to maximize participant retention. During treatment, study interventionists offered make-up sessions when families were unable to attend, either over the telephone or in clinic. If a family missed a session without prior notification, the study interventionist called the parent to schedule a make-up session. Each week, treatment materials were mailed to families who were not present for sessions. Birthday cards and seasonal newsletters were also mailed to families to encourage engagement in the program and to maintain updated addresses that permitted future contacts. All mailings requested that participants contact the FRESH study coordinator with any changes to their contact information. We also requested contact information for two close friends or relatives to further enhance our ability to locate participants.

3.5 Assessment and outcome measures

All measurements along with corresponding time points are listed in Table 1. Children and their parents completed four assessments: baseline, post-treatment, 6-month follow-up and 18-month follow-up. Assessments included anthropometry, self-report questionnaires, and structured clinical interviews. Data collection was conducted by trained staff and supervised by psychologists.

3.6 Measures

3.61. Anthropometry (Child and Parent)—Height and weight were measured in duplicate by trained staff at each assessment time point and treatment visit. Results were translated to adult BMI for parents ($BMI=[kg/m^2]$), and age-adjusted BMI, BMI-Z, and BMI percentile using CDC growth charts for children (Kuczmarski et al., 2000). The average of the two values will be used for analysis.

3.62. Medical History and Current Medication Use (Parent)—When families were initially screened for participation, a research staff member inquired about current medication use and the presence of medical conditions that could interfere with treatment. Additionally, at baseline and the 18-month follow-up visit, a medical history questionnaire was administered to the parent that assessed personal weight history in addition to past or current presence of medical and psychiatric diagnoses in the parent or child.

3.63. Mini International Neuropsychiatric Interview for Children and Adolescents version 6.0 (MINI, Child)—The MINI (Sheehan et al., 2010) is a structured clinical interview designed to assess psychiatric diagnoses in children. The MINI is based on diagnostic categories as classified in the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV-TR). Trained interviewers administered the MINI to children at baseline to determine the presence of a psychiatric disorder warranting study exclusion. The MINI has demonstrated adequate reliability and validity (Sheehan et al., 1998).

3.64. The Eating Disorder Examination version 12.OD/C.2182 (ChEDE; Child)—The ChEDE (Fairburn & Cooper, 1993) is a structured clinical interview that assesses disordered attitudes and behaviors related to eating, body-shape and weight, and eating disorder symptoms defined in the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV-TR). Trained interviewers administered a subset of questions from the ChEDE interview including the Eating Concern Subscale, the Bulimic Episodes and Other Episodes of Overeating Diagnostic Items, and the Self-Induced Vomiting Diagnostic Item. The ChEDE was administered at baseline, post-treatment, and at the 18-month follow-up visit, and it was used to exclude those children meeting criteria for bulimia nervosa, and to determine the presence and number of episodes of binge eating across the study time period. The ChEDE has been shown to be reliable and valid in a pediatric population (Bryant-Waugh, Cooper, Taylor, & Lask, 1996; Watkins, Frampton, Lask, & Bryant-Waugh, 2005).

3.65. Dietary Recalls (Child and Parent)—Dietary intake was assessed with three 24-hour multiple-pass dietary recalls on three non-consecutive days, via telephone interview (Karvetti & Knuts, 1985). All interviews used the Nutrition Data Systems for Research (NDS-R) nutrient calculation software. Because dietary practices have been found to vary by time of week (Beaton, Milner, Corey, & al., 1979), interviews were scheduled to capture both weekend and weekdays dietary intake. This procedure is well established, and our techniques have been previously described (Pierce et al., 2007). Dietary recalls were obtained at baseline, post-treatment, and at the 18-month follow-up visit. Although self-report dietary intake data are known to have limited accuracy, this strategy may capture qualitative data and may reflect change over time in a given individual.

3.66. Accelerometers (Child and Parent)—Physical activity was assessed with the Actigraph accelerometer (model GT1M, www.theactigraph.com) which is a small, lightweight, uni-axial accelerometer worn on a belt around the waist for 7 consecutive days. Participants recorded the times that they did not wear the Actigraph (e.g. while sleeping, swimming), as well as time spent engaging in physical activity and sedentary activity. Physical activity of the child and parent were assessed at baseline, post-treatment, and at the 18-month follow-up visit. The Actigraph accelerometer has been shown to be a reliable and valid measure of physical activity in children (O’Neil, Fragala-Pinkham, Forman, & Trost, 2014).

3.67. Child Report of Parent Behavior Inventory (CRBPI; Child and Parent)—Parenting style was assessed with the 56-item CRBPI (Schludermann & Schludermann, 1970). In the CRBPI, children answer a set of questions that assess maternal and paternal parenting behaviors, separately. In the parent report version, parents answered the same set of questions about their own parenting style. The 56-item CRPBI yields 4 parenting-style scales: authoritative, authoritarian, permissive, and neglectful (Margolies & Weintraub, 1977). The 56-item CRPBI has been shown to be reliable and valid in a study of 4th to 6th grade children (Margolies & Weintraub, 1977).

3.68. McMaster Family Assessment Device (FAD; Parent)—Family functioning was assessed with the FAD (Epstein, Baldwin, & Bishop, 1983), a self-report measure of family functioning that was completed by the parent. The FAD yields a total score as well as six scales of family functioning: problem solving, behavior control, communication, affective responsiveness, affective involvement, and roles. The FAD has been shown to have good internal reliability and validity (Miller, Epstein, Bishop, & Keitner, 1985).

3.69. Treatment Experience Diary (TED; Parent)—The TED was used to collect travel information and medical utilization for each parent-child dyad to calculate cost-effectiveness. Travel information was documented at each weekly session during the intervention, and included the time spent traveling to the session, mileage used, and childcare costs incurred. Medical utilization was assessed at baseline, weekly during the intervention, and at the 6-month follow-up timepoint. Parents were asked to describe healthcare utilization for themselves and their children during the previous six months. Specifically, parents were asked to report the cost of prescription medications, healthcare visits, emergency room hospitalizations, and individual and group counseling sessions.

3.70 Treatment acceptability questionnaire—At the post-treatment and 18-month follow-up assessments, parents and children completed a self-report questionnaire designed by the study staff to measure acceptability of treatment. The questionnaire assessed overall liking of the FRESH program, barriers that interfered with treatment participation, and perceptions associated with group assignment (e.g., “How convenient was the group you were assigned?”).

3.71. Additional measures of treatment adherence—In addition to pre and posttreatment assessments, adherence and attendance data were obtained weekly during the

treatment program. Adherence was measured by collecting weekly food diaries and goal setting assignments from parents and children.

3.72 Assessment procedures—Results of the baseline assessments were discussed in a weekly supervision meeting led by clinical psychologists to determine whether or not families had met inclusion criteria. Assessors described findings from the clinical interview that may have warranted study exclusion (e.g., child depressive symptoms). When children reported symptoms that could likely interfere with study participation and engagement, families were excluded from the study. Examples of this included severe depression, suicidal ideation, depression related to family functioning/conflict. During the supervision meeting, assessors also described any concerning eating disordered behaviors that were revealed during interviews and decisions were made about how to intervene, if necessary. Throughout the course of the study, one child exhibited a marked increase in eating disorder symptoms (e.g., preoccupation with weight/shape, guilt after eating) that were directly addressed by the child's behavioral coach and a supervising clinical psychologist. Study staff members expressed concern to the child, completed additional assessment, and shared their observations with the child's parent, with her permission. A referral was also made for eating disorder treatment

4. Intervention

Parent-child dyads were randomly assigned to PBT or FBT stratified by gender of the child. All participants attended group-based treatment that included 20 visits over 6 months. Treatment visits were a total of 90 minutes in length (i.e., 60 minutes of group treatment and 30 minutes of behavioral coaching). Over the course of the trial, two different locations were used to administer the intervention, a university-based clinic and a community clinic. This protocol was informed by previous randomized controlled trials of FBT (Boutelle et al., 2011; Epstein, Valoski, R. R. Wing, & J. McCurley, 1990; Wilfley et al., 2007). Parents in PBT and FBT attended a parent group, in which the components of treatment were delivered to parents in a mix of didactic teaching, discussion, and activities. Children in the FBT arm also attended a child group, which attempted to target child behaviors by providing nutrition, physical activity and behavioral skills information in an age-appropriate fashion. Children in the PBT group did not attend any treatment meetings. However, children in the PBT group learned program material from their parents, outside of treatment sessions. Similar to parents in the FBT group, parents in the PBT group were instructed to share program materials with their child and review program materials daily. Families were not reimbursed for childcare and childcare was not provided to families assigned to the PBT group. Parents in both groups attended a half an hour meeting with a behavioral coach on the same night, either before or after group, to assist families in overcoming individual barriers and to stay focused on treatment goals.

4.1 Group Topics

The overall goal of treatment was to reduce the child's BMI percentile by creating a negative energy balance designed to result in ½ pound to 1 pound of weight loss per week for children (Barlow & Dietz, 2007). The intervention also aims to decrease parent weight

(i.e., for overweight parents only), since parent weight loss is an important predictor of child weight loss (Boutelle, Cafri, & Crow, 2012; Wrotniak, Epstein, Paluch, & Roemmich, 2004). Key group topics fell into one of three main categories: diet, physical activity, and behavioral/parenting strategies. Group topics are listed in Table 2. Children in FBT child group learned about the same topics as their parents (except for parenting strategies), but their materials were adapted to be developmentally appropriate.

Group sessions included information about dietary recommendations based on the Traffic Light Diet. The Traffic Light Diet categorizes foods into red, yellow and green foods based on their nutritional value, fat content, and sugar content (Epstein, Wing, Koeske, & Valoski, 1984). The Traffic Light Diet was designed to be simple enough for parents and eight-year old children to understand. Parents were prescribed the same eating plan as the children to facilitate child adherence. The dietary goals for the child included a kilocalorie range goal of 1000–1200 kcal/day for five out of seven days, eating at least five fruits and vegetables five out of seven days, and eating fifteen servings or less of red foods per week. Parent dietary goals were similar, but with an increased kilocalorie range (1200–1400 kcal/day for five out of seven days). Based on weight loss, energy values can be adjusted, but never below 1000 kcal/day for children and 1200 kcal/day for adults.

Group sessions included information regarding physical activity and sedentary activity. Parents and children learned about physical activity and sedentary activity and their impact on weight and health. Simultaneously, treatment encouraged families to increase their lifestyle activity (i.e., activity that takes place during everyday life, such as taking the stairs instead of the elevator and housecleaning). Parents and children learned to shape their physical activity and sedentary activity behaviors to attain the following goals: 14 hours or less of sedentary activity a week (outside of school and homework), at least 90 minutes/day of physical activity for children five out of seven days per week, and at least 60 minutes/day of physical activity for adults five out of seven days per week.

Group sessions also focused on behavioral skills. Group topics included teaching parents how to implement stimulus control strategies to change their home food and physical activity environment. Didactic information was provided to educate parents about the importance of eating together as a family, increasing accessibility to healthy foods (e.g., having freshly cut fruit in the refrigerator), and disconnecting eating from other activities (e.g., not eating in front of the television). Parents also learned problem-solving skills to manage barriers that interfere with program adherence. Additionally, group topics focused on the importance of planning in advance for high risk food situations (e.g., holidays and birthdays). Self-monitoring was emphasized as an important predictor of weight loss (Kirschenbaum, Germann, & Rich, 2005). Parents and children recorded food intake, physical activity, and completion of family meetings in “Habit Books” each week that they were enrolled in treatment. With close assistance from their behavioral coach, children and parents learned effective strategies for accurately recording kilocalorie intake such as measuring out portions, reading food labels, and consistently recording their dietary intake several times throughout the day,. Additionally, parents and children monitored and recorded their weight twice weekly, at home, in between treatment sessions.

Finally, a critical component of group sessions was a focus on teaching positive parenting skills. Parents were educated about basic behavioral principles, and they were encouraged to use verbal praise and alternative reinforcement strategies throughout the intervention. Modeling was discussed as an integral strategy of facilitating behavioral changes in children. Parents were encouraged to work with their child as a “team” and to join them in making healthy behavior changes. Daily meetings between parents and children were recommended as a method of improving communication about eating/exercise and to implement skills learned in treatment (e.g., recording in the habit book). One way that parents could build new behaviors and maintain behaviors that have been acquired was by following a behavioral reinforcement system. For example, in both PBT and FBT, children and parents were both awarded points for meeting program goals (e.g., eating within the prescribed kilocalorie range, achieving physical activity goals, consuming at least 5 fruits and vegetable servings per day). Behavioral coaches, parents, and children collaboratively decided whether points had been earned, and in ambiguous situations (e.g., if it was unclear whether the fruit and vegetable goal had been met due to a partially completed habit book), the behavioral coach would defer to the parent to make the final decision about whether the points were earned by the child. Points were then traded in for small, medium and large prizes that were agreed upon by parents and children at the beginning of treatment.

4.2 Behavioral coaching

Behavioral coaching sessions were conducted by trained clinical psychology graduate students and post-doctoral fellows with either parent-child dyads in FBT or parents alone in PBT. The purpose of the coaching sessions was to provide individualized feedback and support toward meeting program goals. The half-hour sessions were highly structured and intended to emphasize and reinforce self-monitoring, treatment and homework compliance, and behavioral goal-setting. Standardized protocols were used to guide the sessions, and identical protocols were used for FBT and PBT. Each session included a review of child and parent progress with weight loss and self-monitoring, and shaping of behavioral goals associated with weight loss. Behavioral goals included daily kilocalorie limits, minimum daily physical activity requirements, maximum weekly sedentary activity requirements, daily limitations on high-fat, high-sugar foods, daily requirements for fruit and vegetable intake, self-monitoring, and completion of daily meetings. Specific feedback on BMI change was not provided unless it was requested by parents or children.

4.3 Treatment Fidelity

Group interventionists for the FRESH program were Ph.D. level post-doctoral fellows and licensed clinical psychologists and behavioral coaches were graduate level doctoral students. All interventionists completed a day-long training course conducted by a leading expert in behavioral weight loss (DW). The training included presentation and teaching on fundamental components of behavioral weight loss strategies, observation of taped sessions, and review of the treatment protocols. All group sessions and behavioral coaching sessions were audio-recorded and reviewed by supervisors on a weekly basis. All interventionists during the study attended a 1.5 hour weekly supervision meeting, which included case review, listening to audiotapes and reviewing the upcoming treatment protocol. Formal fidelity monitoring was also completed. A graduate student with training in family-based

childhood obesity treatment listened to and rated 86 behavioral coaching sessions to ensure that major program components were addressed and that FBT and PBT were identical in content.

5. Data Analysis

5.1 Statistical Analyses – Non-inferiority

The planned analyses for the study aims will be based on mixed-effects repeated measures analysis of variance models. An unstructured covariance matrix and a random-effect error term will be included to account for the possible additional variation resulting from individuals in a group treatment. Non-inferiority (Piaggio, Elbourne, Altman, Pocock, & Evans, 2006; Pocock, 2003) will be used to determine whether the PBT (parent only) intervention produces changes in weight, diet, physical activity, parent weight change, and parenting that are not inferior to the parent-child intervention (FBT). Hypotheses will be tested using contrasts of the intervention conditions at post-treatment and follow-up time points (6 and 18 months) while controlling for variables at baseline. Non-inferiority hypotheses are supported if the upper bound of the 90% confidence interval of the least squares mean difference (i.e., PBT-FBT) is less than the pre-specified non-inferiority bound. The approach leads to inferences at the 95% confidence level.

5.3 Statistical Analyses – Cost Effectiveness

Cost effectiveness (C-E) ratios will be calculated to show the cost per BMI-Z change for children and BMI for parents. Because most obese children have an obese parent, and because treatment of obese children can result in parental weight loss, C-E ratios will be calculated a) for child and parent weight loss, and b) for child weight loss only. Measured costs include the cost of gas used for traveling to and from treatment sessions, time spent at treatment, childcare costs incurred by families attending the program, drug costs, and health care utilization. Two types of uncertainty will need to be tested using multi-way sensitivity analyses when conducting the cost analyses. Variables included in the sensitivity analyses will include unit cost of initial evaluation, unit cost of PBT (i.e., parent-only) visits and unit cost of FBT (i.e., parent+child) visits. Second, in order to address the statistical uncertainty in directly measured variables, confidence intervals will be estimated for the cost per BMI-Z and BMI change via a non-parametric bootstrap using bias-corrected and accelerated intervals based on 10,000 resamples (Efron, 1982; Efron & Tibshirani, 1986). 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 four possible quadrants. This is of particular importance in a trial where effectiveness is anticipated to be equivalent. In this instance, the C-E ratios obtained can become mathematically unstable and the use of bootstrapping aids greatly in the interpretation of the results.

5.4 Power analysis

In order to calculate power for the FRESH study, focus was on non-inferiority tests for the primary outcome of child weight using values standardized for age and gender (Kuczmarski et al., 2000). The approach to power analyses adopted for this study treated post-intervention and follow-up data as distinct outcomes, with the intervention condition as a predictor and

baseline measurement as a covariate. All power calculations were made using SAS® Proc Power with $\alpha = .10$ (corresponding to use of the upper bound of the 90% confidence interval to test hypotheses).

For hypotheses concerning child weight loss, focus was on BMI standardized for age and gender expressed as a percentile (BMI-P). A non-inferiority bound of .02 BMI-P will be used (i.e., population values less than .02 indicate non-inferiority of PO to PC). The covariate-adjusted mean difference between the interventions in the population was posited to be 0. It should be noted that this assumes equality of subgroup covariate means (which is reasonable given random assignment) and equal subgroup weights of the regression of the dependent variable onto the covariate (an assumption of the ANCOVA model). Using the pilot data we calculated the covariate-adjusted pooled standard deviation of change in BMI-P at post-treatment and six month follow-up to be .0127 and .0378, respectively. If there is no difference in average BMI-P between children in PO and PC, with 150 families, we expect to have power >0.95 to detect whether the lower bound of a 90% confidence interval would fall above our non-inferiority margin of -0.02 given expected standard deviations in BMI-P over similar time intervals.

These power calculations can be regarded as liberal for two reasons. First, there will be some information lost due to attrition. Although we will use maximum likelihood estimation in our ITT analysis of primary outcomes, missing data may affect the precision of our models and thus power may be lowered. If we assume 10% attrition, our functional sample size would be 135 and using the same design, we estimate power would remain >0.90 . Another factor that may make our initial power calculations liberal is the assumption that observations are independent, when in fact some interdependency of weight outcomes may be introduced by having individuals treated within the same intervention groups. In the preliminary study the point estimate of the variance corresponding to people run in groups was zero for BMI-P. Nevertheless, it is reasonable to consider the effect on power of assuming a non-zero variance. Specifically, we expect the variance will be increased by a factor of $1+(m-1)*ICC$, also known as the design effect, where m is the average number of people in a group and ICC is the intraclass correlation coefficient reflecting the interdependence of outcomes from individuals within the same group. Using an ICC of .03 and an average group size of 13, the variance is estimated to be increased by a factor of 1.36. Given the functional sample size of 135 proposed based on missing data, a revised functional sample size based on the design effect can be calculated to be 99 (i.e., total sample size/design effect = $135/1.36$). Recalculating power based on a value of 99 leads to power estimates of $>.99$ and .82 for post-treatment and six month follow-up, respectively.

5.5 Missing Data

Missing data will be handled by fitting two statistical models under the assumption that the missing data mechanism is ignorable. The first is a mixed-effects regression model that makes use of all observed values, which has been referred to as mixed-effects regression substitution model (Siddique & Belin, 2008). The same models will be fit to data that have been imputed using multiple imputation (Rubin, 1987).

6. Discussion

The FRESH study is the first randomized controlled trial comparing PBT and FBT with 18 months of follow-up. The FRESH study will provide integral knowledge of whether PBT can produce similar outcomes as FBT for the child and parent, and whether the cost-effectiveness is similar or favored toward one of the arms. The FRESH study will compare PBT and FBT outcomes regarding child and parent weight status, as well as parent and child dietary intake, parent and child physical activity, and parenting skills. Importantly, we will evaluate the cost-effectiveness of the two arms, which could be important to third party payers. Further analysis of FRESH data will allow us to evaluate attrition, adherence and attendance patterns throughout treatment.

The FRESH study was designed to evaluate PBT, a modified treatment modality that could reduce financial and logistical burden on families and healthcare organizations, while maintaining the gold standard of rate of treatment success that has been previously documented in FBT. A PBT program could enhance the dissemination of this model to community clinics, workplaces and medical clinics. Since PBT requires significantly less staff (one or two group leaders compared to two to four group leaders) and less space, it may be easier to disseminate to sites where there is less staff available. PBT groups offer flexibility in scheduling, since groups can be offered during the day or in the evenings when children may not be available or busy. Anecdotally, we have found that rooms for two groups (i.e., parent and child groups) compared to one group is challenging in medical and community clinics that are often limited on space. Coordinating group attendance with children can also be challenging, especially for working parents, who need to leave their workplace, pick up a child, and get to the group site. Finally, if PBT outcomes are similar/non-inferior to FBT, it is possible that PBT could be implemented in clinics using a guided self-help model (Boutelle, Norman, Rock, Rhee, & Crow, 2013) and offer even more flexibility in scheduling and increased accessibility to effective treatment. However, this model remains to be tested in more rigorous randomized controlled trials.

FRESH is unique, in that it is a tightly controlled trial (conducted primarily in a University clinic) and it will provide long-term follow-up (18 months). These factors will allow us to directly compare these two models with less variability in sample characteristics. Since FRESH was conducted in San Diego, it will also offer the opportunity to evaluate these models in Hispanic families, which to date has not been tested. Furthermore, the FRESH study will offer unique data for secondary data analyses on whether parenting skills and style change similarly in both PBT and FBT.

As in all studies, the FRESH study has limitations. First and foremost, it was conducted in a University clinic with well-trained staff, and the treatments may not translate as well to the community. However, we are hopeful that a PBT program could translate to the primary care clinics since a modified FBT program delivered in primary care resulted in significantly greater child weight losses compared to usual care (Quattrin, Roemmich, Paluch, Epstein, & Ecker, 2012; Quattrin, Roemmich, Paluch, Epstein, & Ecker, 2014). Additionally, the demographics of the FRESH study were unique (50% Hispanic), and may not translate to other ethnic groups (e.g., African Americans and Asians). Furthermore, Tanner staging was

not conducted to account for pubertal changes in children that could have partially explained weight trajectories throughout the study period. It is important that future childhood obesity studies account for puberty growth spurts in their analyses. However, despite these limitations, the FRESH study will be the first to compare PBT and FBT with an 18-month follow-up, and provide data on child and parent weight change and cost-effectiveness.

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Table 1**Schedule of Assessments and Measures**

Measure	Timepoint				
	Screening	Baseline	Post-treatment	6-month follow-up	18-month follow-up
Parent consent/child assent	x				
Demographic information	x				
Child Measures					
Anthropometry	x	x	x	x	x
Clinical Interviews (EDE, MINI)		x			
Medical history questionnaire	x	x			x
Child health behaviors (dietary recalls, accelerometry)		x	x		x
Parenting/family functioning		x	x	x	x
Treatment acceptability questionnaire			x		x
Parent Measures					
Anthropometry	x	x	x	x	x
Medical history questionnaire	x	x			x
Parent health behaviors (dietary recalls, accelerometry)		x		x	x
Measures to assess parenting/family functioning		x	x	x	x
Cost-effectiveness (travel information, medical utilization)		x	x	x	
Treatment acceptability questionnaire			x		x

Table 2**FRESH Group Psychoeducational Topics**

Session #	Topic
1	Introduction
2	Healthy eating
3	Motivation system and parenting skills
4	Make your home environment healthy
5	Red and green physical activity
6	Behavior chains
7	Healthy shopping on a budget
8	Emotion, stress, and eating
9	Lifestyle activity
10	High-risk situations part 1
11	High-risk situations part 2
12	Problem solving
13	Responsibility
14	Staying motivated with more physical activity
15	Review and planning healthy habits
16	Open discussion
17	Ordering right in the real world
18	Teasing and body image
19	Relapse prevention
20	Graduation