Title

Guided Self-Help vs Group Treatment for Children With Obesity: A Randomized Clinical Trial.

Journal

Pediatrics, 155(2)

ISSN

0031-4005

Authors

Boutelle, Kerri N

Rhee, Kyung E

Strong, David R

et al.

Publication Date

2025-02-01

DOI

10.1542/peds.2024-066561

Peer reviewed

Guided Self-Help vs. Group Treatment for Children with Obesity: A Randomized Clinical Trial

Kerri N. Boutelle, PhD[1,2,3] Kyung E. Rhee, MD, MSc, MA[1] David R. Strong, PhD,[2] Michael A. Manzano, MA,[3] Rebecca S. Bernard, PhD,[1] Dawn M. Eichen, PhD,[1] Cheryl C.A. Anderson, PhD, MPH, [2] Bess H. Marcus, PhD,[4] Natacha Akshoomoff, PhD,[1] and Scott J. Crow, MD[5]

Affiliations: [1] Department of Pediatrics, UC San Diego, La Jolla, CA, [2] Herbert Wertheim School of Public Health and Human Longevity Science UC San Diego, La Jolla, CA, [3] Department of Psychiatry, UC San Diego, La Jolla, CA, [4] Department of Behavioral and Social Sciences, Brown University School of Public Health, Providence, RI, [5] Department of Psychiatry, University of Minnesota, Minneapolis, MN

Address Correspondence to: Kerri Boutelle, Ph.D. University of California San Diego, 9500 Gilman Drive, MC 0874, La Jolla, CA 92093. kboutelle@ucsd.edu

Short Title: Guided Self-Help for Children with Obesity

Conflict of Interest Disclosures (includes financial disclosures): None

Funding/Support: The study was funded by the National Institutes of Health (NIH grants R01DK10868, UL1TR001442).

Role of the Funder/Sponsor: The NIH had no role in the design and conduct of the study.

Clinical Trial Registration: ClinicalTrials.gov Identifier: NCT03096132

Abbreviations: BMI-body mass index (kg/m2); BMIz-child standardized BMI scores; %BMIp95-percentage of the 95th BMI percentile; COVID-19-Coronavirus 2019; CI-confidence interval; EAT- Eating and Activity over Time; FBT-family-based treatment; gshFBT-guided self-help family-based treatment; FRESH-DOSE-Families, Responsibility, Education, Support and Health-Dual Options for Sustained Effectiveness; HIPAA- The Health Insurance Portability and Accountability Act; MVPA-moderate and vigorous intensity physical activity; ITT-intent-to-treat; LME-linear mixed effects; L95 = Lower bound of the 95th Credible Interval; OW/OB overweight and obesity. p = probability that 0 is under the estimated posterior distribution. U95 = Upper bound of the 95th Credible Interval, PSY=Psychologist, MFT=Marriage and Family Therapist, RA=Research Assistant, PI=Principal Investigator

Article Summary: For children with obesity, a guided self-help treatment provides similar outcomes to a more intensive group intervention, but in less time and with less cost.

What is known: Family-based Behavioral Treatment (FBT) for pediatric obesity is staff and time intensive (weekly groups and behavioral coaching). A guided self-help FBT (gshFBT) can provide the same information but in short visits every other week provided to the individual parent-child dyad.

What this study adds: gshFBT is noninferior to FBT on child weight loss but is provided in less time and with less cost. gshFBT could be used to provide weight loss programs to a greater proportion of the families in need.

Contributors Statement

Dr. Kerri Boutelle conceptualized and designed the study, developed the treatment arms, oversaw the administration of the study, participated in analysis of the data (including cost analysis), drafted the initial manuscript, and critically reviewed and revised the manuscript.
Dr. Kyung Rhee conceptualized and designed the study, supervised any medical concerns, and critically reviewed and revised the manuscript.
Dr. David Strong conceptualized and designed the study, conducted the randomization and data analyses (including the cost analysis), and critically reviewed and revised the manuscript.
Michael Manzano developed the treatment protocols, provided the treatment, and critically reviewed and revised the manuscript.
Dr. Rebecca Bernard supervised the treatment and critically reviewed and revised the manuscript.
Dr. Dawn Eichen conceptualized and designed the study, coordinated and supervised data collection, and critically reviewed and revised the manuscript.
Dr. Cheryl Anderson conceptualized and designed the study, and critically reviewed and revised the manuscript.
Dr. Bess Marcus conceptualized and designed the study, and critically reviewed and revised the manuscript.
Dr. Natacha Akshoomoff conceptualized and designed the study, and critically reviewed and revised the manuscript.
Dr. Scott Crow conceptualized and designed the study, contributed to the cost analysis, and critically reviewed and revised the manuscript.

All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

Abstract

Background and Objective. Family-based Behavioral Treatment (FBT) for children with obesity is provided in weekly parent and child groups over 6 months. A guided self-help FBT program (gshFBT) provides the same content to the dyad in short meetings. Both interventions provide the same content, however, gshFBT provides this content in less time (FBT=23 hours, gshFBT=5.3 hours). The study aimed to evaluate whether gshFBT is noninferior to FBT on child weight loss and cost-effectiveness.

Methods. 150 children between the ages of 7.0 and 12.9 years with a BMI between the 85th and 99.9th percentile and their parent were recruited and randomized to a 6-month program of gshFBT (n=75) or FBT (n=75) and were followed 12-months post-treatment**.**

Results. 150 children (mean age=10.1 yrs, 49% female, mean BMIz=2.09) and their parent (mean age=41.5 yrs, 87% female, 45% Hispanic, 37% White non-Hispanic, 9.7% Asian, 4.8% Black, 7.3% Other) were recruited from the San Diego Metropolitan area. Joint LME models showed that gshFBT was noninferior to FBTon child weight loss (ΔBMIz =-0.02 (90%CI -0.08-0.05, p=0.65); Δ BMIp95% = -1.57 (90%CI –4.46-1.31, p=0.28)) and cost less (cost/dyad gshFBT=$1,498; FBT=$2,775).

Discussion. The gshFBT program provided similar weight losses for children, with less contact hours and with lower cost than FBT. The reduced time and ease of scheduling for the family in gshFBT will allow for an increased reach of treatment to a greater proportion of the families in need.

Introduction

Approximately 45% of youth have overweight or obesity (OW/OB),[1] which is associated with negative physical and psychosocial health consequences.[2-8] Family-based behavioral treatment (FBT) is an empirically supported Intensive Health Behavior and Lifestyle Treatment for children with OW/OB supported by the American Academy of Pediatrics Clinical Practice Guidelines.[9] FBT includes nutrition and physical activity education, behavior change skills, and parenting skills.[10,11] Review papers suggest that FBT is effective in reducing adiposity, and that this effect is stronger in interventions with higher levels of contact hours.[12] Ten year FBT follow-up data shows that one third of children who participate in FBT no longer have obesity.[13 14] FBT is provided in weekly group sessions with individualized behavioral coaching sessions over 6 months. The group format creates challenges for families to attend weekly at predetermined times and requires significant staff and space, which ultimately reduces access to FBT. In fact, only 18% of families who are offered FBT actually enroll.[15]

We developed a guided self-help version of FBT (gshFBT) that provides the same core skills as FBT, but with less contact time. gshFBT is delivered to parent and child dyads in short visits (20 minutes) every other week with written psychoeducational materials provided to read between sessions. gshFBT meetings focus on reviewing weight changes and self-monitoring and problem-solving barriers to implementing program recommendations. In a pilot study, we found that gshFBT was feasible, acceptable, and decreased child standardized BMI scores (BMIz) compared to a waitlist control up to 6-months post-treatment.[16] When comparing these results to a historical cohort in a nonrandomized study, we found that gshFBT was noninferior to FBT on changes in child weight.[17]

The goal of this study was to examine the efficacy of this treatment format in a fully powered randomized controlled trial and evaluate if gshFBT is noninferior to group-based FBT on child weight outcomes at post-treatment and 6- and 12- month follow-up timepoints. We also evaluate the costs of both programs. Secondary aims include evaluating the effects of both arms on parent BMI, parent and child eating behaviors, and parent and child physical activity.

Methods

Study Design

The Families, Responsibility, Education, Support and Health-Dual Options for Sustained Effectiveness (FRESH-DOSE) was a randomized noninferiority trial (NCT03096132) conducted at the Center for Healthy Eating and Activity Research at the University of California (UC) San Diego between April 2017 and February 2023. Details of the trial design have been published [18] and the formal protocol is available in the Supplement. In this parallel design, participants were randomly assigned in an equal ratio to either gshFBT or FBT by the statistician using a block randomization procedure conducted with blockrand[19] by sex of the child and weight status of the parent (OW/OB or healthy weight). Assessments were conducted at baseline (month 0), during treatment (weight and cost), post-treatment (month 6), 6-month follow-up (month 12) and 12-month follow-up (month 18). Investigators and outcome assessors were blinded to allocations until all assessments were completed. Participants received the following incentives at assessments: baseline, $75; post-treatment, $50; 6-month follow-up, $100; 12-month follow-up, $100. The institutional review board at UC San Diego approved the study, and parents provided consent and children provided assent.

Eligibility and Recruitment

Eligibility included a child between 7.0 and 12.9 years of age with a BMI between the 85th and 99.9th percentiles, a parent who could read English at a minimum of a 5th grade level, and willingness to attend all treatment and assessments and agree to be randomized to either treatment arm. Exclusionary criteria included a major child or parent psychiatric illness that may affect participation, child medical condition that could impact weight or participation in physical activity or treatment, or child medication that may impact weight (unless the medication dosage was stable and not prescribed for weight loss). Families were recruited through pediatricians, listservs, ResearchMatch, letters mailed to families identified as potentially eligible through electronic medical records, local and online advertisements, and school flyers.

Intervention

The intervention was delivered at one of two university-based research spaces (La Jolla, CA or San Marcos, CA) or virtually via HIPAA-compliant, password-protected Zoom links following the start of the COVID-19 pandemic (March 2020). When the lockdowns occurred, group and behavior coaching sessions were

switched to telehealth. We provided both FBT groups and gshFBT meetings remotely and emailed any materials to the family. We also provided Bluetooth scales (Withings) to collect remote weight and provided tape measures to collect remote height. Of note, three cohorts were treated in person and two cohorts were treated remotely.

Both gshFBT and FBT provided the same nutrition and physical activity recommendations, parenting skills, and behavior modification strategies. gshFBT provided psychoeducation in manuals to be read at home, and brief 20-minute meetings every other week with a behavioral coach. FBT provided psychoeducation in weekly 60-minute separate and simultaneous parent and child group sessions and biweekly meetings with a behavior coach (23 direct contact hours over 6-months; 20 60-minute groups and 9 individual 20-minute biweekly behavior coaching sessions). gshFBT was provided to a single child-parent dyad and provided 5.3 direct contact hours over 6 months (13 20-minute visits and 1 60-minute visit).

Outcome Assessments

Assessments with child-parent dyads were conducted at baseline (month 0), during treatment, post-treatment (month 6), and 6- and 12-month follow-up (months 12 and 18, respectively). Data collection was conducted by trained staff who were blind to condition. The primary outcomes were child BMI-for-sex/age z score (BMIz)[20] and percentage of the 95th BMI percentile (%BMIp95)[21] and program cost.

A cost-minimization analysis (CMA) was determined to be the most appropriate form of economic evaluation since the treatments were found to be noninferior.[22] We initially planned to capture additional cost metrics (e.g., actual costs of attending treatment (mileage, lost wages, childcare costs), and health care utilization), however, once there were required lockdowns due to the COVID-19 pandemic, and the treatment was delivered remotely, these costs were no longer applicable. Thus, we only include costs of personnel, space and materials in this paper. Personnel costs accounted for a psychologist who supervised the treatment providers and served as a group leader and a coach, masters level therapists who served as a group leaders and coaches, bachelor level staff as behavioral coaches, and a bachelor level staff member to check in and weigh participants. Mean personnel salaries used average wage rates[23] and only included the number of hours spent on program delivery.

Fringe benefits were provided by the UC San Diego Research Policy Analysis and Coordination center, and used the 2023 UCPath composite benefit rates set by UC San Diego.[24] Actual rent was calculated as room/hour used for the trial. The cost index year was 2023.

Secondary outcomes included BMI of the parent BMI (kg/m^2), physical activity and eating behaviors for parent and child. Physical activity was assessed with an ActiGraph GT3X+ accelerometer (ActiGraph, LLC; Pensacola, FL) worn around the waist for 7 consecutive days.[25,26] A minimum of 5 valid days with $\geq$ 10 hours per day or >3000 minutes on $\leq$4 days out of 7 days of wear time was required to accommodate error and noncompliance. A day started at midnight and ended at 11:59 pm. Non-wear time was defined as $\geq$ 90 min of consecutive zero counts and a spike tolerance of 2 min with a 30-minute window of zero counts upstream and downstream of each observed spike.[27] All accelerometer data extraction, processing, and transformed summaries of 30-second epoch was conducted by ActiLife software, version 6.13.5 (ActiGraph Corp). Epoch-by-epoch estimates of activity categorized into intensity-weighted summaries of physical activity using calibration thresholds previously validated for adults[28] and children.[29] Outcome variables were mean minutes per day of moderate and vigorous intensity physical activity (MVPA). Specific dietary intake and eating behavior questions were adapted from Project EAT[30-33] that were related to program goals (e.g., sugar-sweetened beverages, fruit and vegetable consumption, fast food consumption, breakfast consumption). Feasibility was assessed by number of sessions attended and overall attrition. Acceptability was assessed using questions designed by the study team, such as the convenience of their assigned group and how much they liked the program. Demographics including age, gender, race, and ethnicity questions were self-reported.

Power And Sample Size Selection

Empirical power analyses were conducted to support sample size selection for the evaluation of primary aims. We expected that both gshFBT and FBT would result in a significant absolute change in weight equivalent to a medium effect (Cohen's d = 0.50) or a change in BMIz of |0.15|. The minimum absolute effect of gshFBT on BMIz was expected to be at least half as strong as the expected effect of FBT which typically generates decreases in BMIz from -0.13 to -0.17.[9] Thus, we expected gshFBT would result in BMIz changes that were not less than 0.065 (-0.13/2 = 0.065) BMIz units when compared to FBT, the lower bound of our specified

inferiority margin. Power estimates were assessed by modeling 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 computed the treatment effect of gshFBT compared to FBT 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 values greater than 0.065 in >96% of 1000 samples. With the onset of COVID-19, we re-assessed power for a slightly reduced sample of 150. Results suggested we would maintain adequate power as simulations produced values greater than 0.065 in >86% of 1000 samples.

Statistical Analysis

Primary outcome evaluations used linear mixed effects (LME) models with joint imputation of missing values with the JointAI[34] package and R software[35] using 80,000 iterations and 3 chains to support MCMC convergence as assessed with Gelman-Rubin criterion.[36] Models included planned covariates (age, sex, race/ethnicity), baseline BMIz, cohort, and treatment assignment. Model estimates are presented with 95% Credible Intervals (95%CI) and tail probability (p-values) reflecting how likely a value of 0 is under the estimated posterior distribution. LME model compared changes in BMI at posttreatment, and 6- and 12-month follow-up between gshFBT to FBT. These models also compared gshFBT to FBT on posttreatment BMI and rate of change in BMI after treatment (BMI × time).

Results

Participant Flow and Baseline Demographics

We pre-screened 1610 parent-child dyads who expressed interest and enrolled 150 parent-child dyads (**Figure 1**). We used generalized estimating equations[37] to evaluate the odds of missing data at post-treatment, 6- and 12-month follow-up assessments, which did not differ across treatments (p=0.11). Child weight was available for 81%, 77%, and 76% at post-treatment, 6- and 12-month assessments for gshFBT and 88%, 77%, and 73% at post-treatment, 6- and 12-month assessments for FBT. Child and parent surveys were available for 80% and 56% at 6- and 12-month assessments. We observed significant increases in the probability

of missed surveys over time (p=0.04) related to the provision of assessments online once the pandemic started. Accelerometer readings were available for 63%, 54%, and 48% at post-treatment, 6- and 12-month assessments and 81% provided 4 or more days of assessment. Patterns of missing surveys or accelerometer assessments did not differ by treatment assignment or demographic characteristics (p's >0.10). **Table 1** lists demographic and initial BMI status for each treatment group.

Primary outcomes: Child weight loss and cost effectiveness

Child weight loss. We used LME models with joint estimation of missing data (joint LME) to examine repeated measurements of BMIz or %BMIp95 assessed at post- treatment and at 6- and 12-month follow-up. Significant decreases in BMIz and %BMIp95 from session 1 to the end of treatment (see **Figure 2**) were observed for both gshFBT and FBT (BMIz: b=-0.09, 95%CI = -0.12 to -0.06, p<0.001; percent 95th: b=-3.01, 95%CI = -4.21 to -1.82, p<0.001). The adjusted main effect of treatment group across post-allocation assessments provided an estimate and standard error of differences in the magnitude of change in child BMIz. **Figure 2** displays child mean BMIz and %BMIp95 for groups. In joint LME models, BMIz in gshFBT was -0.02 (90%CI -0.08 - 0.05, p=0.65) lower than in FBT. In joint LME models, %BMIp95 in gshFBT was -1.57 (90%CI –4.46 - 1.31, p=0.28) lower than in FBT. On average, children in gshFBT and FBT reduced their BMIz by -0.11 (sd=0.19) and -0.06 (sd=0.17) at post-treatment, -0.12 (sd=0.18) and -0.09 (sd=0.25) at 6-month and -0.07 (sd=0.25) and -0.12 (sd=0.37) at 12-month follow-up, respectively. On average, children in gshFBT and FBT reduced their %BMIp95 by -2.01 (sd=6.23) and -1.98 (sd= 8.38) at post-treatment, -3.81 (sd= 8.78) and -2.67 (sd= 10.01) at 6-month and -0.04 (sd= 9.60) and -1.08 (sd= 13.76) at 12-month follow-up, respectively.

*Cost Minimization Analysis***.** Since the efficacy of the treatments was noninferior, we focused on the comparative costs of each treatment. The average costs for the treatment of one parent-child dyad in person in gshFBT was $1,498 and for FBT was $2,775 (see **eTables 1-3**).

Secondary Outcomes: Parent Weight Loss, Child and Parent Energy Intake, Child and Parent Physical Activity

Parent Weight Loss: Significant decreases in BMI from session 1 to the end of treatment were observed for both gshFBT and FBT (BMI: b=-0.42, 95%CI = -0.64 to 0.19, p<0.01). Joint LME models of parent BMI at post-treatment and at 6- and 12-month follow-up were conducted in the intent-to-treat (ITT) sample and planned

covariates. The parents BMI in gshFBT were -0.16 (90%CI –0.70 - 0.39, p = 0.57) lower than in FBT (See **eTable 4** for mean (sd) across the timepoints) which was not statistically significant.

Child Physical Activity. Adjusted difference in MVPA was not significantly different for gshFBT and FBT across post-treatment, 6- and 12-month follow-ups (MVPA b = 31.79, 95%CI = -21.11 – 84.78, p=0.23). Sedentary time was higher for gshFBT than FBT across the post-treatment, 6-and 12-month follow-ups (Sedentary b = 195.91, 95%CI = 0.83 – 390.63, p=0.049; See **eTable 4** for mean (sd) across the timepoints).

Parent Physical Activity. For parents, levels of MVPA were not significantly different for gshFBT and FBT across post-treatment, 6- and 12-month follow-ups (MVPA b = -17.93, 95%CI = -57.17 – 21.75, p=0.37). Sedentary time was not significantly different for parents in gshFBT than FBT across the 6 and 12-month follow-ups (b = 159.19, 95%CI = -36.8 – 354.9, p=0.11). See **eTables 4- 5** for mean (sd) across the timepoints and models.

Child and Parent Eating Behaviors

In an ITT evaluation of treatment effect of eating behavior (see **eTables 6-7**), adjusted ordered logistic models of frequency of sugar-sweetened beverages, fruit, and vegetable servings with joint imputation of missing values did not support a significant difference between gshFBT and FBT over 6- and 12-month assessments for either children or parents (p's range = 0.31 – 0.75; see **eTables 6-7**).

Feasibility and Acceptability

We had high rates of attendance in both treatments with a median of 93% (25^{th} – 75^{th} = 46% – 100%) in gshFBT and 80% (25^{th} – 75^{th} = 62% – 90%) sessions attended in FBT. Negative binomial regression did not support a difference in the percentage of session attended for gshFBT or FBT (IRR=0.93, 95%CI=0.79-1.09, p=0.36). Rates of attendance were significantly lower for families with household income <$50K relative to those with income of $100k or more (IRR = 0.69, 95%CI=0.55-0.88, p <0.003). Rates of attendance were not related to child age, sex, race-ethnicity, pre-treatment child BMIz, pre-treatment parental BMI or parental marital status (p's >0.10).

Parents on average rated 'Agree' (median = 4, IQR = 3.67–4.58) on a series of five-point Likert agreement ratings of six acceptability and satisfaction post-treatment questions (coefficient Alpha = 0.87). There were no differences in average ratings between gshFBT and FBT (b=-0.34, se = 0.14, p=0.79).

Discussion

This study demonstrated that a guided self-help version of FBT is noninferior to a group based 6-month FBT program for weight loss among children with OW/OB with 12 months of follow-up. Consistent with our pilot data,[17] the gshFBT program was noninferior to FBT on child weight outcomes at post-treatment and at the 6- and 12-month follow-ups. Our data also showed that gshFBT costs less due to reduced face-to-face time, staff, and overhead. The gshFBT format also allows for greater flexibility in scheduling and does not require as much office space or staff to provide. Overall, results suggest that gshFBT is a viable alternative model of providing FBT to families with a child with OW/OB in much less time with similar outcomes. gshFBT can increase access to treatment by allowing greater flexibility in scheduling and not requiring as much office space or staff to provide.

There were no significant differences in gshFBT and FBT on parent weight change, parent and child physical activity and parent and child eating behavior, although the weight changes were less than we had expected. The pandemic significantly affected eating and physical activity,[38] and research shows that FBT programs had attenuated efficacy.[39] The attenuated efficacy could be due to reduced food options, increased availability of food in the home, lack of physical activity, remote education and increased screen time, screen fatigue by the time that the programs were delivered in the evening, increased stress, isolation, changes in mental health, increased distraction when attending groups remotely, lack of personal contact and connection. Additionally, height in the remote waves was measured using a tape measure, which affected the accuracy of BMIz/%BMIp95 during that time, but this was distributed across both groups and shouldn't affect the group comparison. Children in this study were also heavier at baseline than children in our previous study,[40] which has been shown to affect weight loss in youth.[41] These factors individually and in concert could affect outcomes in the current trial.

There are many benefits to both group and individual treatment for child weight loss. Group treatment provides social support, normalization of challenges, and interpersonal learning. However, groups are time intensive and are typically offered at specific times of the day which can make it challenging to attend for busy families. Treatment with the individual parent-child dyad, on the other hand, provides individualized attention, and flexibility in appointments, but does not include social support or learning from other families. Although there are strengths and weaknesses to both, our data show that there were similar outcomes when the program was applied in a group or to an individual dyad, which is consistent with other childhood disorders.[42,43] Our data also suggest that gshFBT is similarly acceptable and had similar retention rates compared to FBT. This is important as only 18% of families who are offered group FBT actually enroll.[15] In a pragmatic effectiveness study conducted in primary care offices, data showed that families attended twice as many gshFBT sessions (52.9% of sessions) compared to FBT (22.5% of sessions.[44] Given that gshFBT has similar outcomes on child weight status, and reduced cost, it is a more cost-effective method of providing weight management for children with OW/OB. Furthermore, given the flexibility of scheduling it can potentially increase the reach of this type of treatment for families who need it.

Strengths and Limitations

This study has several strengths and weaknesses that should be considered. Strengths of the study include the randomized design, the use of noninferiority testing, the racial/ethnic diversity of the families, the use of a validated treatment protocol, and the 18-month observation period. However, study participants were treatment-seeking families with 7- to 12-year-old children whose BMI percentile was less than 99.9%, limiting the generalizability to families with children of other ages and higher weight. Additionally, as mentioned previously, this study was partially conducted during the pandemic, which could have influenced outcomes.

In considering clinical applications, gshFBT was developed to be implemented in a community medical or clinical setting in 20-minute visits. This project also demonstrated the feasibility of providing gshFBT remotely. Since most of the learning is achieved by the family reading manuals in between appointments, gshFBT can be implemented by paraprofessionals, which should make it easier to staff. On the other hand, considering the stigma and social isolation experienced by many

children with obesity, it is possible that a group setting would be more beneficial for some children. Future research should explore parent and child preference of modality.

Conclusions

Moving forward, gshFBT could be a viable modality for families with a child with OW/OB that provides similar outcomes to the group-based FBT program, costs less and can be provided by paraprofessionals, to ultimately improve the reach of this treatment to a greater proportion of the families in need.

Acknowledgements and Data Sharing

Additional Contributions: We thank the children and parents for participating in the study. We recognize the contribution of all children and parents who participated in the study and the staff and students at the Center for Healthy Eating and Activity Research at University of California San Diego.

Data Sharing: Deidentified individual participant data will be made available, in addition to study protocols, the statistical analysis plan, and the informed consent form. The data will be made available upon publication to researchers who provide a methodologically sound proposal for use in achieving the goals of the approved proposal. Proposals should be submitted to Dr. Kerri Boutelle at kboutelle@health.ucsd.edu. Data use agreements will be required.

References

1. Woolford S, Sidell M, Li X, et al. Changes in body mass index among children and adolescents during the COVID-19 pandemic. *JAMA*. 2021;326(14):1434-1436. doi:10.1001/jama.2021.15036
2. Sahoo K, Sahoo B, Kumar Choudhury A, Yasin Sofi N, Kumar R, Singh Bhadoriao A. Childhood obesity: causes and consequences. *J Fam Med Primary Care*. 2015;4(2):187-192. doi:10.4103/2249-4863.154628
3. McCrindle B. Cardiovascular consequences of childhood obesity. *Can J Cardiol*. 2015;31(2):124-130. doi:10.1016/j.cjca.2014.08.017
4. Rankin J, Matthews L, Cobley S, et al. Psychological consequences of childhood obesity: psychiatric comorbidity and prevention. *Adolesc Health Med Ther*. 2016;7:125-146. doi:10.2147/AHMT.S101631
5. Faienza M, Wang D, Fruhbeck G, Garruti G, Portinacasa P. The dangerous link between childhood and adulthood predictors of obesity and metabolic syndrome. *Intern Emerg Med*. 2016;11(2):175-182. doi:10.1007/s11739-015-1382-6
6. Park M, Falconer C, Viner R, Kinra S. The impact of childhood obesity on morbidity and mortality in adulthood: a systematic review. *Obes Rev*. 2012;13(11):985-1000. doi:10.1111/j.1467-789X.2012.01015.x
7. Lloyd L, Langley-Eans S, McMullen S. Childhood obesity and risk of the adult metabolic syndrome: a systematic review. *Int J Obes (Lond)*. 2012;36(1):1-11. doi:10.1038/ijo.2011.186
8. Janicke D, Harman J, Jamoom E, Simon S, Zhang J, Dumont-Driscoll M. The relationship among child weight status, psychosocial functioning, and pediatric health care expenditures in a medicaid population. *J Pediatr Psychol*. 2010;35(8):883-891. doi:10.1093/jpepsy/jsp122
9. Wilfley D, Tibbs T, Van Buren D, Reach K, Walker M, Epstein L. Lifestyle interventions in the treatment of childhood overweight: a meta-analytic review of randomized controlled trials. *Health Psychology*. 2007;26(5):521-532. doi:10.1037/0278-6133.26.5.521
10. Epstein L. Family-based behavioural intervention for obese children. *Int J Obes Relat Metab Disord*. 1996;20 Suppl 1:S14-21.
11. Epstein L, Myers M, Raynor H, Saelens B. Treatment of pediatric obesity. *Pediatrics*. 1998;101 (3 Pt 2):554-570.
12. Skinner AC, Staiano AE, Armstrong SC, et al. Appraisal of Clinical Care Practices for Child Obesity Treatment. Part I: Interventions. *Pediatrics*. Feb 1 2023;151(2)doi:10.1542/peds.2022-060642
13. Epstein L, Valoski A, Wing R, McCurley J. Ten-year outcomes of behavioral family-based treatment for childhood obesity. *Health Psychol*. 1994;13(5):373-383.
14. Epstein L, Paluch R, Roemmich J, Beecher M. Family-based obesity treatment, then and now: twenty-five years of pediatric obesity treatment. *Health Psychol*. 2007;26(4):381-391. doi:doi: 10.1037/0278-6133.26.4.381
15. Riggs K, Lozano P, Mohelnitzky A, Rudnick S, Richards J. An adaptation of family-based behavioral pediatric obesity treatment for a primary care setting: group health family wellness program pilot. *The Permanente Journal*. 2014;18(3):4-10. doi:10.7812/TPP/13-144
16. Boutelle K, Norman G, Rock C, Rhee K, Crow S. Guided self-help for the treatment of pediatric obesity. *Pediatrics*. 2013;131(5):e1435-e1442. doi:10.1542/peds.2012-2204
17. Bergmann K, Mestre Z, Strong D, et al. Comparison of two models of family-based treatment for childhood obesity: A pilot study. *Child Obes*. 2019;15(2):116-122. doi:10.1089/chi.2018.0250
18. Boutelle KN, Rhee KE, Manzano MA, et al. 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. *Contemp Clin Trials*. Jan 2023;124:106996. doi:10.1016/j.cct.2022.106996

19. Snow G. blockrand: Randomization for Block Random Clinical Trials. R package version 1.5. https://CRAN.R-project.org/package=blockrand. 2020;
20. Kuczmarski R, Ogden C, Grummer-Strawn L, et al. CDC growth charts: United States. *Adv Data*. 2000;314:1-27.
21. Freedman D, Woo J, Ogden C, Xu J, Cole T. Distance and percentage distance from median BMI as alternatives to BMI z score. *Br J Nutr*. 2020;124(5):493-500. doi:doi: 10.1017/S0007114519002046
22. Drummond MS, MJ; Claxton, K; Stoddart, GL; Torrance, GW. *Methods for the Economic Evaluation of Health Care Programmes*. Oxford University Press; 2015.
23. Statistics BoL. Occupational Outlook Handbook Accessed September 1, 2023. https://www.bls.gov/ooh/life-physical-and-social-science
24. Coordination URPAa. Accessed December 7, 2023. https://blink.ucsd.edu/research/sra/preparing-proposals/budgets/indirect.html#UC-San-Diego-IDC-Rates
25. Nichols J, Morgan C, Chabot L, Sallis J, Calfas K. Assessment of physical activity with the Computer Science and Applications, Inc., accelerometer: laboratory versus field validation. *Res Q Exerc Sport*. 2000;71(1):36-43. doi:10.1080/02701367.2000.10608878
26. Coleman K, Saelens B, Wiedrich-Smith M, Finn J, Epstein L. Relationships between TriTrac-R3D vectors, heart rate, and self-report in obese children. *Med Sci Sports Exerc*. 1997;29(11):1535-1542. doi:10.1097/00005768-199711000-00022
27. Choi L, Liu Z, Matthews CE, Buchowski MS. Validation of accelerometer wear and nonwear time classification algorithm. *Med Sci Sports Exerc*. Feb 2011;43(2):357-64. doi:10.1249/MSS.0b013e3181ed61a3
28. Freedson PS, Melanson E, Sirard J. Calibration of the Computer Science and Applications, Inc. accelerometer. *Med Sci Sports Exerc*. May 1998;30(5):777-81. doi:10.1097/00005768-199805000-00021
29. Evenson KR, Catellier DJ, Gill K, Ondrak KS, McMurray RG. Calibration of two objective measures of physical activity for children. *J Sports Sci*. Dec 2008;26(14):1557-65. doi:10.1080/02640410802334196
30. Neumark-Sztainer D, Story M, Hannan P, Croll J. Overweight status and eating patterns among adolescents: where do youths stand in comparison with the healthy people 2010 objectives? *AM J Pub Health*. 2002;92(5):844-851. doi:10.2105/ajph.92.5.844
31. Neumark-Sztainer D, Story M, Hannan P, Perry C, Irving L. Weight-related concerns and behaviors among overweight and nonoverweight adolescents: implications for preventing weight-related disorders. *Arch Pediatr Adolesc Med*. 2002;156(2):171-178. doi:10.1001/archpedi.156.2.171
32. Neumark-Sztainer D, Wall M, Story M, Perry C. Correlates of unhealthy weight-control behaviors among adolescents: implications for prevention programs. *Health Psychol*. 2003;22(1):88-98. doi:10.1037//0278-6133.22.1.88
33. Berge J, MacLehose R, Loth K, Eisenberg M, Fulkerson J, Neumark-Sztainer D. Family meals. Associations with weight and eating behaviors among mothers and fathers. *Appetite*. 2012;58(3):1128-1135. doi:10.1016/j.appet.2012.03.008
34. Erler NS, Rizopoulos D, Lesaffre EMEH. JointAI: Joint Analysis and Imputation of Incomplete Data in R. *Journal of Statistical Software*. 2021;100(20):1-56. doi:doi:10.18637/jss.v100.i20
35. R Core Team. _R: A Language and Environment for Statistical Computing_. R Foundation for Statistical Computing, Vienna, Austria. <https://www.R-project.org/>. 2023;
36. Rubin D. Multiple imputation for nonresponse in surveys. Wiley, New York 1987. XXIX+258. 1987;
37. Højsgaard S, Halekoh U, Yan J. The R package geepack for generalized estimating equations. *J Stat Software*. 2006;15(2):1-11.
38. Trivedi M, Frisard C, Crawford S, Bram J, Geller AC, Pbert L. Impact of COVID-19 on childhood obesity: Data from a paediatric weight management trial. *Pediatr Obes*. Dec 2022;17(12):e12959. doi:10.1111/ijpo.12959

39. Appelhans BM, French SA, Martin MA, Lui K, Janssen I. Attenuated efficacy of pediatric obesity treatment during the COVID-19 pandemic. *Obesity*. Jan 2022;30(1):45-49. doi:10.1002/oby.23313
40. Boutelle K, Rhee K, Liang J, et al. Effect of attendance of the child on body weight, energy intake, and physical activity in childhood obesity treatment: A randomized clinical trial. *JAMA Pediatr*. 2017;171(7):622-628. doi:10.1001/jamapediatrics.2017.0651
41. Goldschmidt A, Best J, Stein R, Saelens B, Epstein L, Wifley D. Predictors of child weight loss and maintenance among family-based treatment completers. *J Consult & Clin Psychology*. 2014;82(6):1140-1150. doi:doi: 10.1037/a0037169
42. Guo T, Su J, Hu J, et al. Individual vs. Group Cognitive Behavior Therapy for Anxiety Disorder in Children and Adolescents: A Meta-Analysis of Randomized Controlled Trials. *Front Psychiatry*. 2021;12:674267. doi:10.3389/fpsyt.2021.674267
43. Wergeland GJ, Fjermestad KW, Marin CE, et al. An effectiveness study of individual vs. group cognitive behavioral therapy for anxiety disorders in youth. *Behav Res Ther*. Jun 2014;57:1-12. doi:10.1016/j.brat.2014.03.007
44. Rhee K, Herreras L, Strong D, Kang-Sim E, Shi Y, Boutelle K. Guided self-help for pediatric obesity in primary care: A randomized clinical trial. *Pediatrics*. 2022;150(1):e2021055366. doi:10.1542/peds.2021-055366

Figure 1. Diagram of parent-child dyad flow through the trial

Figure 2. Mean levels of observed BMIz and %BMIp95 at baseline, post-treatment, 6- and 12-month assessments.

Table 1. Demographics and Baseline Characteristics of the Intention-to-Treat Sample

	Child		Parent	
	gshFBT	**FBT**	**gshFBT**	**FBT**
N	75	75	75	75
Age (mean, SD)	10.01 (1.21)	10.16 (1.53)	40.36 (7.76)	42.71 (6.09)
% Female	48%	49%	84%	91%
Race/ethnicity				
% White	37%	30%	37%	36%
Hispanic	45%	45%	45%	44%
Asian	8%	10%	8%	11%
African American	4%	8%	5%	4%
Other Race-Ethnicity	6%	7%	4%	4%
Income (mean, SD)				
<$50,000			20 (27%)	16 (22%)
$51,000-99,000			20 (27%)	19 (26%)
>$100,000			30 (41%)	34 (47%)
Declined to report			3 (4.1%)	3 (4.2%)
Missing			2 (2.7%)	3 (4.0%)
BMI (mean, SD)	28.02 (5.03)	28.04 (5.34)	32.39 (7.31)	31.73 (7.68)
BMIz (mean, SD)	2.10 (0.37)	2.08 (0.42)		
Percent of the 95th percentile	120.41 (20.57)	119.49 (19.84)		

27

Figure 1. Diagram of parent-child dyad flow through the trial

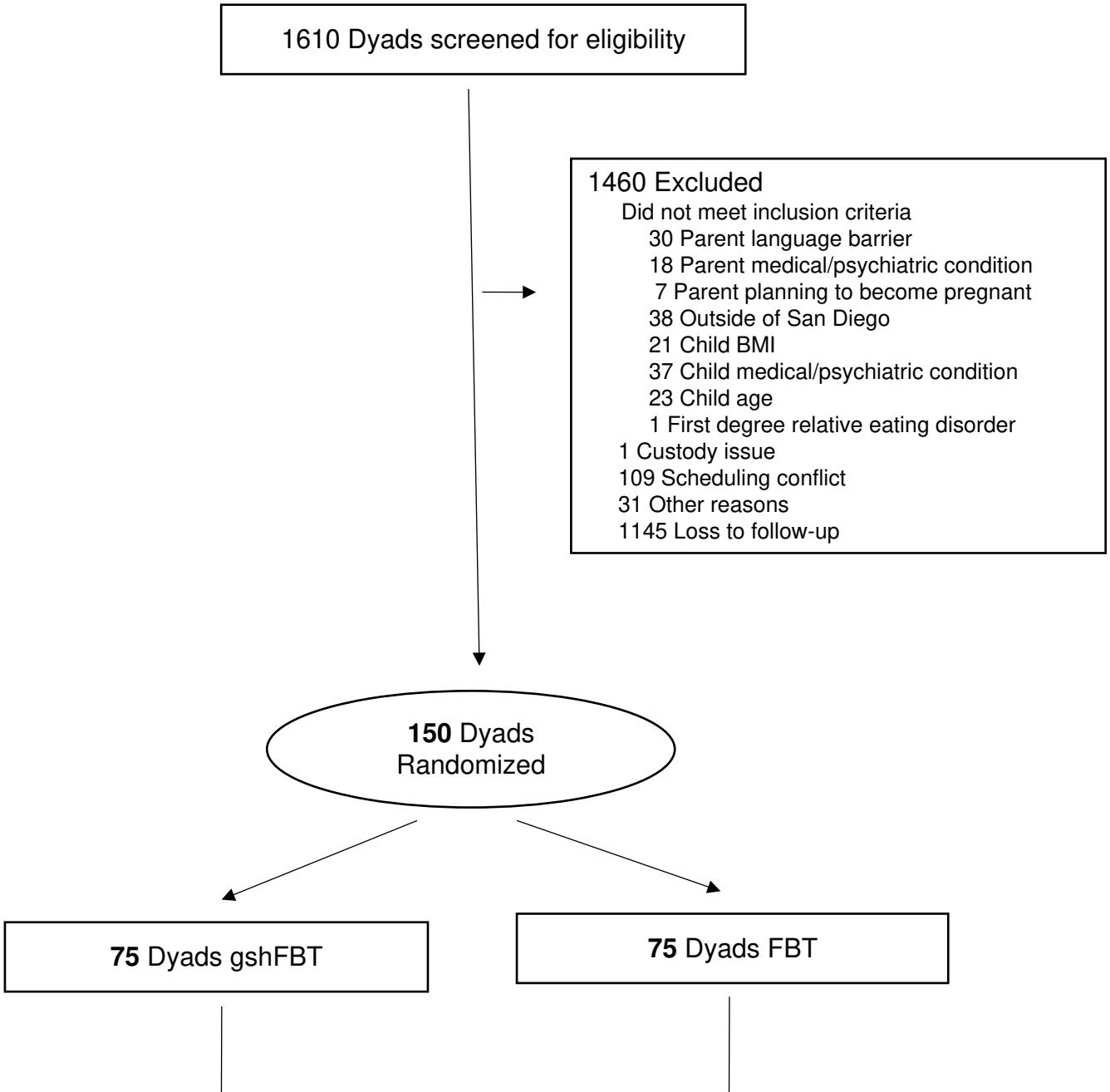
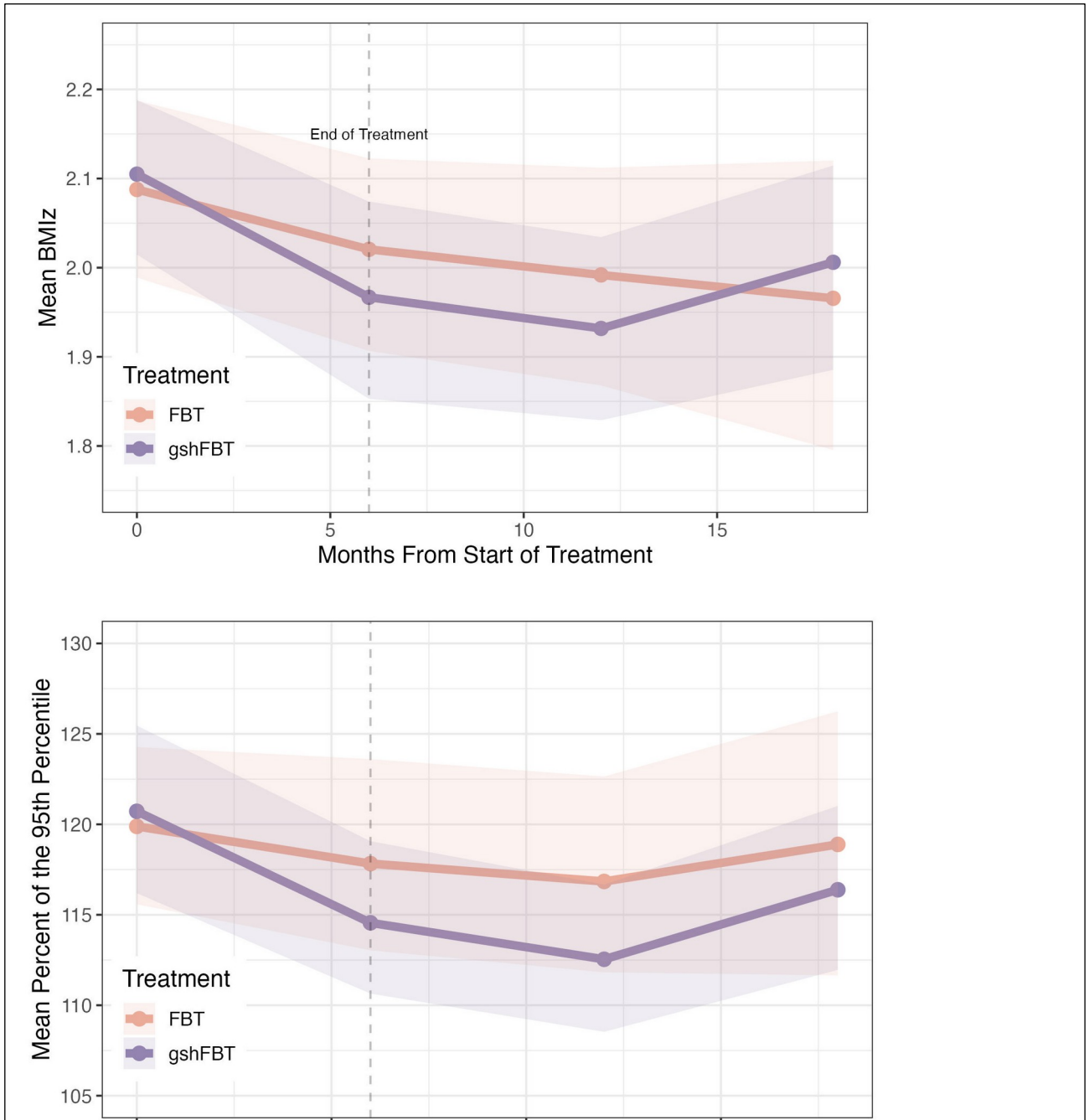


Figure 2. Mean levels of observed BMIz and %BMIp95 with standard errors at baseline, post-treatment, 6- and 12-month assessments.



eTable 1. Costs incurred during treatment per child-parent dyad in FBT and GSH

	FBT		GSH	
	Costs/15 Dyads	**Cost/1 Dyad**	**Costs/15 Dyads**	**Cost/1 Dyad**
Overhead & Material Costs	$16,628	$1,109	$8,121	$541
Staffing Costs	$24,994	$1,666	$14,342	$956
Total cost	**$41,623**	**$2,775**	**$22,464**	**$1,498**

eTable 2. Overhead Costs for FBT and GSH

	Conference room	8 offices	8 offices	Weighing room	2 Screens	2 Projectors	2 Laptops	Stadiometer	Scale	Self-monitoring booklets	Manuals	Total cost for 15 Dyads	Total cost for 1 Dyad
FBT													
	$1,002	$210	$210	$79	$2,260	$2,600	$2,396	$1,284	$2,840	$420	$3,329	**$16,628**	**$1,109**
GSH													
	$0	$105	$105	$39				$1,284	$2,840	$420	$3,329	**$8,121**	**$541**

eTable 3. Staffing Costs FBT and GSH

	FBT					GSH				
	PSY	MFT	RA	PI	Cost	PSY	MFT	RA	PI	Cost
Parent group leader	20				$988					
Parent group leader		20			$609					
Preparation for parent group	10	10			$798					
Child group leader		20			$609					
Child group leader		20			$609					
Preparation for child group		20			$609					
Behavioral coaching, 2 families per staff	20	60	80		$5,036			105		$2,916
Behavioral coaching feedback to participants	20	60	80		$5,036			105		$2,916
Supervision	30	90	120		$7,554	21		168		$5,703
Organization, copying materials, weighing participants			20		$555			20		$555
Training	8	24	32	8	$2,591	8		64	8	$2,253
Total costs for 15 families					$24,994					$14,342
Cost per parent/child dyad					$1,666					$956

eTable 4. Body weight, physical activity, and sedentary activity for parent-child dyads across the study points (estimate mean (sd))

	Baseline	Post-Treatment	6-mo follow-up	12-mo follow-up
Child BMIz				
gshFBT	2.10 (0.38)	1.97 (0.39)	1.93 (0.43)	2.01 (0.49)
FBT	2.09 (0.44)	2.02 (0.44)	1.99 (0.46)	1.97 (0.61)
Child Percent of 95th				
gshFBT	120.72 (20.94)	114.56 (17.13)	112.54 (16.16)	116.38 (-17.75)
FBT	119.89 (19.84)	117.83 (22.11)	116.84 (20.91)	118.89 (27.22)
Parent BMI				
gshFBT	32.48 (7.45)	31.30 (7.00)	31.93 (7.34)	32.10 (6.59)
FBT	31.73 (7.68)	31.4 (7.76)	31.17 (7.31)	31.78 (7.50)
Child MVPA (min/wk)				
gshFBT	183.46 (115.77)	222.50 (136.79)	237.82 (167.61)	250.69 (213.04)
FBT	166.66 (102.44)	235.87 (131.03)	180.62 (116.05)	159.46 (122.10)
Child Sedentary (min/wk)				
gshFBT	2483.06 (737.98)	2348.25 (727.45)	2948.76 (886.49)	2824.03 (837.59)
FBT	2652.51 (921.95)	2522.42 (920.15)	2517.14 (753.57)	2924.73 (1,187.33)
Parent MVPA (min/wk)				
gshFBT	180.77(122.51)	170.97 (116.60)	171.94 (83.81)	169.62 (114.55)
FBT	162.62 (134.21)	156.59 (149.03)	201.15 (124.37)	179.19 (146.43)
Parent Sedentary (min/wk)				
gshFBT	3377.40 (839.47)	3544.24 (1,099.68)	3194.56(1,168.85)	3177.13 (1,161.22)
FBT	3538.69 (829.90)	3677.12 (832.55)	3153.58 (928.26)	3464.16 (1,200.34)

eTable 5. Evaluation of treatment related differences in physical activity and sedentary behavior over post-treatment, 6- and 12-month assessments.

		Effect of gshFBT vs FBT	L95	U95	p
Children					
	MVPA (min/wk)	31.79	-21.11	84.78	0.24
	Sedentary Time (min/wk)	195.91	0.83	390.63	0.05
Parents					
	MVPA (min/wk)	-17.93	-57.17	21.75	0.37
	Sedentary Time (min/wk)	159.19	-36.80	354.90	0.11

Note: All mixed-effects regression models used a joint imputation with adjustment for planned covariates and corresponding baseline values. MVPA = Moderate to Vigorous Physical Activity. L95 = Lower bound of the 95th Credible Interval. U95 = Upper bound of the 95th Credible Interval. p = probability that 0 is under the estimated posterior distribution.

eTable 6. Parent report of child and parent eating behaviors by group over time

		gshFBT			FBT		
		Baseline	6-month follow-up	12-month follow-up	Baseline	6-month follow-up	12-month follow-up
Child							
Average servings of sugar sweetened beverages/day	0	32 (45%)	27 (63%)	21 (50%)	36 (49%)	24 (52%)	26 (63%)
	1	20 (28%)	9 (21%)	11 (26%)	28 (38%)	15 (33%)	11 (27%)
	2	12 (17%)	6 (14%)	6 (14%)	7 (9.6%)	7 (15%)	2 (4.9%)
	3	5 (7.0%)	1 (2.3%)	2 (4.8%)	0 (0%)	0 (0%)	0 (0%)
	4	2 (2.8%)	0 (0%)	2 (4.8%)	2 (2.7%)	0 (0%)	2 (4.9%)
	Unknown	4	32	33	2	29	34
Average servings of fruit/day	0	4 (5.6%)	2 (4.8%)	1 (2.4%)	5 (6.8%)	5 (11%)	3 (7.3%)
	1	24 (34%)	11 (26%)	13 (31%)	24 (33%)	11 (24%)	16 (39%)
	2	21 (30%)	12 (29%)	14 (33%)	20 (27%)	17 (37%)	9 (22%)
	3	9 (13%)	7 (17%)	7 (17%)	19 (26%)	6 (13%)	8 (20%)
	4	9 (13%)	5 (12%)	5 (12%)	3 (4.1%)	5 (11%)	2 (4.9%)
	5	2 (2.8%)	3 (7.1%)	0 (0%)	1 (1.4%)	2 (4.3%)	1 (2.4%)
	6	2 (2.8%)	2 (4.8%)	2 (4.8%)	1 (1.4%)	0 (0%)	2 (4.9%)
	Unknown	4	33	33	2	29	34
Average servings of vegetables/day	0	11 (15%)	5 (12%)	4 (9.5%)	15 (21%)	6 (13%)	7 (17%)
	1	27 (38%)	14 (33%)	13 (31%)	26 (36%)	16 (35%)	15 (37%)
	2	20 (28%)	13 (31%)	15 (36%)	17 (23%)	15 (33%)	8 (20%)
	3	9 (13%)	6 (14%)	6 (14%)	9 (12%)	3 (6.5%)	6 (15%)
	4	0 (0%)	2 (4.8%)	4 (9.5%)	2 (2.7%)	5 (11%)	2 (4.9%)
	5	4 (5.6%)	2 (4.8%)	0 (0%)	4 (5.5%)	1 (2.2%)	2 (4.9%)
	6	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (2.4%)
	Unknown	4	33	33	2	29	34
Parent							
Average servings of sugar sweetened beverages/day	0	40 (56%)	30 (70%)	23 (58%)	47 (64%)	27 (59%)	29 (73%)
	1	13 (18%)	7 (16%)	8 (20%)	17 (23%)	15 (33%)	5 (13%)
	2	12 (17%)	5 (12%)	4 (10%)	5 (6.8%)	3 (6.5%)	6 (15%)
	3	3 (4.2%)	0 (0%)	4 (10%)	3 (4.1%)	1 (2.2%)	0 (0%)
	4	3 (4.2%)	1 (2.3%)	1 (2.5%)	1 (1.4%)	0 (0%)	0 (0%)
	Unknown	4	32	35	2	29	35
Average servings of fruit/day	0	8 (11%)	1 (2.3%)	0 (0%)	14 (19%)	2 (4.4%)	2 (5.0%)
	1	26 (37%)	13 (30%)	15 (37%)	22 (30%)	13 (29%)	11 (28%)
	2	18 (26%)	10 (23%)	13 (32%)	20 (27%)	21 (47%)	17 (43%)
	3	10 (14%)	11 (26%)	10 (24%)	11 (15%)	4 (8.9%)	4 (10%)
	4	2 (2.9%)	4 (9.3%)	2 (4.9%)	1 (1.4%)	3 (6.7%)	2 (5.0%)
	5	3 (4.3%)	3 (7.0%)	0 (0%)	2 (2.7%)	2 (4.4%)	3 (7.5%)
	6	3 (4.3%)	1 (2.3%)	1 (2.4%)	3 (4.1%)	0 (0%)	1 (2.5%)
	Unknown	5	32	34	2	30	35
Average servings of vegetables/day	0	5 (7.0%)	3 (7.0%)	4 (9.8%)	6 (8.2%)	0 (0%)	1 (2.5%)
	1	20 (28%)	8 (19%)	8 (20%)	21 (29%)	15 (33%)	10 (25%)
	2	23 (32%)	9 (21%)	8 (20%)	22 (30%)	13 (28%)	8 (20%)
	3	12 (17%)	11 (26%)	12 (29%)	11 (15%)	5 (11%)	8 (20%)

4	5 (7.0%)	6 (14%)	3 (7.3%)	6 (8.2%)	9 (20%)	8 (20%)
5	1 (1.4%)	5 (12%)	5 (12%)	4 (5.5%)	3 (6.5%)	2 (5.0%)
6	5 (7.0%)	1 (2.3%)	1 (2.4%)	3 (4.1%)	1 (2.2%)	3 (7.5%)
Unknown	4	32	34	2	29	35

eTable 7. Evaluation of treatment related differences in eating behaviors over post-treatment, 6- and 12-month assessments

	Servings	Effect of gshFBT vs FBT	L95	U95	p
Children					
	Sugar Sweetened Beverages	-0.21	-1.44	0.91	0.74
	Fruit	0.76	-0.82	2.37	0.34
	Vegetables	0.39	-1.37	2.20	0.66
Parents					
	Sugar Sweetened Beverages	-0.14	-1.08	0.81	0.75
	Fruit	0.59	-0.56	1.78	0.31
	Vegetables	-0.21	-1.41	0.95	0.72

Note: All ordered logistic regression models used a cumulative link and joint imputation with adjustment for planned covariates and corresponding baseline values. L95 = Lower bound of the 95th Credible Interval. U95 = Upper bound of the 95th Credible Interval. p = probability that 0 is under the estimated posterior distribution.