Published in final edited form as:
J Pediatr. 2013 November ; 163(5): . doi:10.1016/j.jpeds.2013.06.081.

Parent Support Improves Weight Loss in Adolescents and Young Adults with Down Syndrome

Carol Curtin, MSW[1], **Linda G. Bandini, PhD**[1,2], **Aviva Must, PhD**[3], **James Gleason, MS, PT**[1], **Keith Lividini, MS, MPH**[5], **Sarah Phillips, MS, MPH**[3], **Misha Eliasziw, PhD**[3], **Melissa Maslin, MEd**[1], and **Richard K. Fleming, PhD**[6]

[1]University of Massachusetts Medical School/E.K. Shriver Center, Waltham, MA

[2]Department of Health Sciences, Boston University, Boston, MA

[3]Department of Public Health and Community Medicine, Tufts University School of Medicine, Boston, MA

[5]Harvest Plus, International Food Policy Research Institute, Washington, DC

[6]Department of Exercise and Health Sciences, University of Massachusetts Boston

Abstract

Objective—To assess whether parent training in behavioral intervention, combined with a 16-session nutrition and activity education program, would improve weight loss relative to nutrition and activity education alone in adolescents and young adults with Down syndrome.

Study design—21 youth with Down syndrome aged 13-26 with a BMI ≥85th percentile were enrolled and randomized to a 6-month nutrition and activity education intervention (n=10) or to nutrition and activity education+behaviorial intervention (n=11), and followed for 6 months after the active intervention period (1-year follow-up). The primary outcome measure was body weight; secondary outcomes included percentage body fat (%fat) by bioelectric impedance; intake of fruits, vegetables, and energy-dense low-nutrient snack food (treats) by 3-day food record; and moderate/vigorous physical activity by accelerometry.

Results—At 6 months, mean body weight in the nutrition and activity education+behaviorial intervention group was 3.2kg lower than in the nutrition and activity education group (95%CI: 1.0, 5.5, p=0.005). Mean group differences were sustained at 1 year (3.6kg 95%CI: 1.4, 5.9, p=0.002). At 6 months, moderate/vigorous physical activity time averaged 18 minutes/day more in nutrition and activity education+behaviorial intervention than at baseline (p=0.01); in nutrition and activity education, moderate/vigorous physical activity declined by 7 minutes/day (p=0.30); these changes were largely maintained at 1 year, but were not statistically significant. Vegetable intake in nutrition and activity education+behaviorial intervention exceeded intake in nutrition and activity education by a mean of 1.6 servings at 1 year (p=0.009), but not at 6 months. No group differences were observed for %fat or consumption of fruits or treats.

Corresponding author: Carol Curtin, MSW, Research Assistant Professor, Family Medicine & Community Health, University of Massachusetts Medical School/E.K. Shriver Center, 200 Trapelo Road, Waltham, MA 02452, 781.642.0256, Carol.Curtin@umassmed.edu.

The authors declare no conflicts of interest.

NIH-PA Author Manuscript
NIH-PA Author Manuscript

Conclusions—Parent-supported behavioral intervention appears to be a successful adjunct to a 6-month nutrition education intervention in achieving weight loss in youth with Down syndrome.

Keywords

weight loss; Down syndrome; parenting

Childhood obesity has increased dramatically over the last 20 years in the US, with almost one in five children estimated to be obese.[1] Obesity prevalence is also high in children with intellectual and developmental disabilities,[2] particularly those with Down syndrome. One study of 81 adolescents with Down syndrome estimated the prevalence of obesity at 31%.[3] Data on the consequences of obesity in youth with Down syndrome are lacking, but they are likely to experience similar health risks to the general population.[4]

Research is needed on weight loss interventions that address the cognitive and literacy limitations of adolescents and young adults with Down syndrome. Family-based interventions, which have been shown to be efficacious in randomized controlled trials (RCTs) with typically developing children, use individualized diet and physical activity plans for gradual weight loss, and behavioral training that teaches parents to use diet and activity monitoring, stimulus control, goal setting, and positive reinforcement.[5] To our knowledge, no such weight loss programs for youth with Down syndrome have been tested.[6] Although youth with Down syndrome live in the same obesogenic environment as the general population, their unique needs and challenges may render them more susceptible to the adverse effects of typical obesity risk factors. They may also be vulnerable to additional risk factors not shared by children in the general population by virtue of their limited cognitive abilities, altered body composition, and challenges with motor coordination and balance.

We conducted a pilot RCT of a family-based weight loss intervention with adolescents and young adults with Down syndrome living at home. Our primary aim was to determine whether parent training in behavioral intervention, combined with a 16-session nutrition and activity education program, improved weight loss compared with nutrition and activity education alone. Our secondary aim was to evaluate associated changes in percentage body fat (%fat), moderate to vigorous physical activity, fruit/vegetable, and high energy-dense/low nutrient-dense food intake.

Methods

This pilot RCT was conducted between October 2007 and March 2010 at the University of Massachusetts Medical School (UMMS), *Eunice Kennedy Shriver* Center. Participants were recruited through mailed flyers, postings by disability-related organizations, and physician referrals. Participants with Down syndrome met the following inclusion criteria: age 13-26, body mass index (BMI) ≥ 85^{th} percentile,[7] IQ 45-70; written physician approval; and a parent willing to attend sessions. The relatively large age range was selected to facilitate recruitment and to collect pilot data on participants with Down syndrome that spanned the important transition years of adolescence to young adulthood. Exclusion criteria included use of appetite-altering medications, chronic gastrointestinal illness, untreated thyroid disorders, uncontrolled seizure disorders, or orthopedic or cardiac conditions that would preclude physical activity participation. Families were phone-screened and then attended an enrollment visit (IQ testing, parent and child interview) to determine eligibility. Eligible participants with Down syndrome provided informed assent; parents provided informed consent. The protocol was approved by the UMMS Institutional Review Board.

Participants and parents were interviewed by a registered dietitian who obtained a diet history and developed a diet plan for each participant that specified a 250 kcal/day deficit, designed to yield a ½-1 pound weekly weight loss. This conservative caloric goal was based on the American Academy of Pediatrics recommendations for adolescents, which we deemed developmentally appropriate for the participant age range. Parents were taught to use the diet plans with instruction and given an accompanying instructional guide. Pictures provided a simple visual approach to daily diet planning, and a system of “tickets” and “coins” helped participants choose a daily allowance of discretionary calories.

A physical therapist evaluated participants’ ability to perform exercises in the program’s physical activity plan. The plan, provided in a notebook with simple messaging and illustrations, prescribed flexibility exercises, aerobic activity (eg, brisk walking, dancing) for 5 days/week, and strength training (exercise balls/bands) for 2 days/week. On the rare occasion that a participant was unable to perform exercises as prescribed, they were given a modified version of the exercise.

Participants were randomized to one of the two intervention groups, with block size equal to the number of subjects in each wave[8]; group assignment was made in the order of enrollment by the research coordinator working from a printed list of assignments. Parents were not blinded to group assignment. Immediately following assignment, three families who reported schedule conflicts were permitted to join the other intervention group. These participants were flagged to evaluate the effect of this reassignment in the analyses.

Both interventions were conducted in 16 90-minute sessions delivered in the first 6 months of the intervention period. This active intervention period began with 10 weekly sessions in the first 3 months, followed by 3 months of tapered intensity (4 bi-weekly sessions, followed by 2 sessions that met every third week). Participants were tracked during a no-intervention follow-up in months 6-12. Figure 1 (available at www.jpeds.com) shows the 3 separate waves that were designed to maintain group sizes of 4-5 participants.

Nutrition and activity education taught basic nutritional concepts and exercises through simple verbal instruction, demonstrations, activities (e.g., games), and taste tests. Sessions were conducted by a dietitian and a therapeutic recreation specialist. Eight sessions covered nutrition, seven also addressed physical activity, and the final session was a potluck celebration dinner. Participants were taught to make food choices associated with their diet plans, emphasizing fruit, vegetable, and low-fat dairy consumption; correct portion sizes; and healthy snacking. Physical activity sessions taught exercises from the participants’ plans. All 15 sessions provided 40 minutes of instruction with parents present, a 10-minute break, and 40 minutes of practice and taste tests with adolescent and young adult participants only. Parents attended the first 40 minutes and met separately as a group for informal support/discussion for the last 40 minutes.

Nutrition and activity education+behaviorial intervention included the same nutrition and activity education activities (first 40 minutes) as indicated above, followed by 40 minutes of group training with parents, conducted by a behavioral specialist who provided instruction on behavioral strategies such as diet/activity monitoring, modification of “stimulus control” conditions at home, daily/weekly goal setting, and positive reinforcement. These strategies are used in family-based intervention research with typically developing children.[5, 9] Although not required to make personal changes, parents were encouraged to model, facilitate, and reinforce healthy eating/activity for their offspring. Each full-group session began with participants sharing their goal accomplishments from the prior week.

Outcome data were assessed during the sessions; those taking the measurements were not blinded to group assignment, but training stressed objectivity. All outcome measures were

recorded at baseline, 10 weeks, 6 months, and 12 months, with additional weight and %fat assessments at 2, 4, 6, 8, 11, and 13 weeks. The primary outcome was weight (kg). Secondary outcome variables included %fat, physical activity (minutes of moderate/vigorous physical activity), fruit intake (servings/day), vegetable intake (servings/day), and treat intake (kcal/day). The treat category included items such as candy, chips, non-diet soda, cake, cookies, ice cream, etc. Participants were measured in light clothing without shoes. Height was measured via stadiometer to 0.1 cm. Weight and body fat were determined via a bioelectrical impedance analyzer (Tanita© Segmental Body Composition Analyzer and Scale, Model BC-418), using equations developed in NHANES.[10] Minutes of moderate/vigorous physical activity were obtained from Actical® accelerometers (Mini-Mitter Co., Bend, OR) worn by participants during waking hours over 7 consecutive days at the aforementioned intervals. Parents completed a log to capture time worn and unusual occurrences. The accelerometer needed to be worn for ≥ 600 minutes/day on at least 3 weekdays and 1 weekend day that were "typical" (e.g., no reported illnesses, regular school attendance, etc.) to be considered valid. Activity counts in 30-second epochs were used to estimate minutes spent in moderate/vigorous physical activity using validated equations for participants ≤18 years of age[11] and >18 years of age.[12]

Parents completed 3-day food records at each measurement interval and these were entered into the Nutrition Data System for Research to provide estimates of the servings/day of fruits and vegetables and daily caloric intake of treats (University of Minnesota, 2007). Parents were trained to estimate portion size with visual aids such as food models and were asked to record how food was prepared and where it was eaten. Parents were also asked to provide recipes for mixed dishes.

Attendance was recorded at each session. Satisfaction was assessed at 6 months with a series of items and a Likert-type response scale that queried parent perceptions of their child's weight loss, enjoyment, learning, socialization, quality of eating, and levels of activity. Parents in nutrition and activity education+behaviorial intervention also rated their satisfaction with the behavioral strategies. Treatment fidelity was assessed only in the third wave of the study, when the intervention was conducted by a new team at a different site. The dietitian and behavior specialist from the first two waves made fidelity observations of 20% of the sessions. They made simultaneous yet independent observations of the new staff delivering the intervention, using a recording form that operationalized the presence/absence the intervention components for that session, e.g., review of prior week's goals, presentation of information/activities per the intervention manual, assignment of parent homework, etc. Percent agreement was calculated by dividing the number of agreements between the two observers by the total number of components observed. Fidelity checks were not conducted in the first two waves, during which intervention protocol adherence was closely monitored through frequent observations and feedback by study investigators.

Statistical Analyses

The study was designed to have 80% power at alpha of 0.05 to detect a weight loss of ≥4% in nutrition and activity education+behaviorial intervention vs. nutrition and activity education, based on data in typically developing children.[13] Missing data for weight and variables that were used to calculate %fat (height, resistance) were imputed using the most recent prior measurement for intermittent missing values.[14] For the 3 dropouts, an increase of 1 kg/year of weight was assumed, starting from their last available measurement. Because they were >20 years and assumed not to be growing, the mean value from all other time points was used to impute their measurements for height and resistance for the calculation of %fat.

A linear mixed model (SAS 9.2 PROC MIXED) estimated the overall impact of the intervention on each outcome variable and within-group changes over time. This modeling approach was used to incorporate the repeated follow-up measurements and the unequal number of measurements per group. Participant was modeled as a random effect and treatment group as a fixed effect. A treatment-by-visit interaction term was included to assess a differential treatment effect over time. The baseline value for each outcome variable was included as a covariate. An autoregressive (order 1) covariance structure was used to characterize the correlation between the repeated measurements over time. The results are summarized as adjusted means with standard errors (SEs) and 95% confidence intervals (CIs) about the treatment group differences.

The primary analysis compared the two groups on mean change between baseline and each time point for each outcome variable (2, 4, 6, 8, 10, 11, 13, 26, and 52 weeks for weight and %fat; 10, 26, and 52 weeks for moderate/vigorous physical activity and fruit, vegetables, and treat consumption). We repeated our modeling of weight omitting the three participants who were not randomized and compared the results with the model that included them. In addition, we repeated all analyses with and without the imputed values. Because results of these analyses were virtually the same, the results presented are based on the entire sample including imputed values. Results with a p-value ≤0.05 are considered statistically significant.

Results

Of the 57 parents who responded to recruitment advertisements, 45 completed a phone screen to determine initial eligibility; 12 of the 45 did not meet inclusion criteria, and 4 others declined participation due to scheduling or transportation concerns. The remaining 29 participants met initial criteria for inclusion and were invited to a full screening and enrollment visit. Of the 29 invitees, 7 declined participation, due to scheduling or transportation. All 22 participants and parent(s) who attended the screening and enrollment visit qualified for the study. One participant dropped out due to transportation issues and 21 were randomized to the nutrition and activity education (N=10) or nutrition and activity education+behaviorial intervention (N=11) group.

Participants had a mean (SD) age of 20.5 (3.2) years, 81% were female, and, with the exception of one Hispanic participant, all were white (Table I). Three participants dropped out of the study. In nutrition and activity education, one family withdrew after week 10 and one was unable to schedule the 12-month measurement. In nutrition and activity education +behaviorial intervention, one family stopped attending sessions without explanation after week 6. Session attendance was 93%. Mean parent ratings of their child's enjoyment, learning, use of materials, and participation with peers were in the 4 to 5 range (agree to strongly agree) for both nutrition and activity education and nutrition and activity education +behaviorial intervention. Parent satisfaction with their child's progress was higher in nutrition and activity education+behaviorial intervention than nutrition and activity education for child weight loss (mean=3.6 vs. 2.4), healthier eating (mean=4.5 vs. 3.6) and increased physical activity (mean=4.0 vs. 2.6). Fidelity checks revealed 100% adherence to the intervention protocol with the new treatment team in Wave 3. There were no adverse events.

Outcome Evaluation

Mean changes in weight, %fat, minutes per day of moderate/vigorous physical activity, and consumption of fruits, vegetables, and treats over the 6-month active intervention period and at 1-year follow-up are shown in Table II and Figures 2 and 3. Comparing the two groups, the difference in mean weight change diverged over the first 12 weeks and then remained

fairly constant over time (Figure 1, group by time interaction, p=0.005). At 6 months, nutrition and activity education+behaviorial intervention participants lost 2.7kg on average, whereas participants in nutrition and activity education gained an average 0.5kg (p=0.005), resulting in a difference of 3.2kg (95%CI: 1.0, 5.5). At 1 year, nutrition and activity education+behaviorial intervention participants lost an average 1.9kg, whereas participants in nutrition and activity education gained an average 1.7kg (p=0.002), a difference of 3.6kg (95%CI: 1.4, 5.9).

Mean %fat levels showed similar initial declines in both groups during the active intervention period, but began to diverge at 10 weeks, with greater decreases in %fat in the nutrition and activity education+behaviorial intervention group. Subsequently, the mean change between groups was fairly constant to the end of the follow-up period (Figure 2). However, this pattern of decline and divergence did not reach statistical significance (group by time interaction, p=0.52). No significant differences in %fat were observed between the groups at 10 weeks, 6 months, or 1 year (Table II). Body fat percentage did not change significantly over time in the nutrition and activity education group. In contrast, %fat in the nutrition and activity education+behaviorial intervention group declined at the 10-week and 6-month time points (both p=0.009).

On average, the daily moderate/vigorous physical activity at baseline was about 74 minutes for participants in both groups combined. There was an overall significant difference between groups in the mean change in daily moderate/vigorous physical activity (Figure 2, A, p=0.006), which remained constant over time (group by time interaction term, p=0.63). In comparison with baseline, nutrition and activity education+behaviorial intervention participants increased time spent in moderate/vigorous physical activity, whereas participants in nutrition and activity education decreased time spent in moderate/vigorous physical activity (Figure 2, A). At 6 months, participants in the nutrition and activity education+behaviorial intervention group increased their mean time in moderate/vigorous physical activity by about 18 minutes, and those in the nutrition and activity education group decreased their mean time by 7 minutes (p=0.01). A similar finding was observed at the 1-year follow-up, but the difference was not statistically significant (Table II).

At baseline, fruit intake averaged 0.6 servings/day for participants in both groups combined. There was no statistically difference in fruit intake overall between the two groups (p=0.13), nor was there a significant group-by-time interaction (p=0.69; Figure 2, B). No significant between-group mean differences at 6 months or 1 year were observed (Table II). Mean change in fruit intake did not differ over time within the nutrition and activity education +behaviorial intervention group, but increased from baseline at 10, 26, and 52 weeks in the nutrition and activity education group (p=0.001, p=0.04, p=0.04, respectively).

Vegetable intake averaged 2.2 servings/day at baseline for participants in both groups combined. Mean change in daily servings differed by group over time (of borderline significance, p=0.07). A greater increase in vegetable intake was observed in the nutrition and activity education+behaviorial intervention group compared with the nutrition and activity education group at 10-weeks (p=0.01), but was not apparent at 6 months (p=0.24). However, by 12 months nutrition and activity education+behaviorial intervention participants had increased, on average, their consumption by about 1 serving, and participants in the nutrition and activity education had decreased consumption by about ½ of a serving (p=0.009).

At baseline, participants consumed an average of 284 kcals of treats daily for participants in both groups combined. Mean change in daily kcals from treats did not differ between groups (p=0.78) nor did the groups differ over time (p=0.57) (Table II). However, a significant

within-group mean decrease of 143 kcals was observed at 12 months in the nutrition and activity education+behaviorial intervention group ($p < 0.01$).

Discussion

Changes favoring nutrition and activity education+behaviorial intervention over nutrition and activity education were likely due to the addition of parent training and support. Although these results are promising, participants' weight loss was less than initially expected. This may reflect the conservative 250 kcal/day deficit prescribed; recent research suggests less weight loss than expected with caloric deficits due to longer term compensatory decreases in energy output.[16]

The strategies used in both nutrition and activity education and nutrition and activity education+behaviorial intervention were modeled on those used for the general pediatric population but were modified to accommodate the cognitive needs of youth and young adults with Down syndrome. For example, verbal presentation of information was kept at a minimum in favor of hands-on activities involving the use of food models and games. Parents were sometimes counseled to select initially modest diet-related goals to address their children's restricted eating patterns. Strategies were well received by participants and parents; however, families sometimes struggled to incorporate new information each week, and in nutrition and activity education+behaviorial intervention, to implement behavior change strategies at home. Sixteen sessions may not have provided enough instruction and support to promote generalized behavior change.

Unique differences in the participants' diet and physical activity behaviors were encountered, suggesting some protocol modifications. For example, although the diet plans were designed to simplify food choices, parents had many questions, such as how to accommodate participants' restricted eating patterns that limited food choices. Individual diet counseling, not offered in this study, would allow interventionists to address such questions. Monthly individual counseling is recommended in future trials.

The physical activity plans for this study taught strength, flexibility, and aerobic exercises, but session time proved insufficient for participants to master these exercises. Given the primary goal of weight loss, a focus on aerobic activities (e.g., brisk walking, swimming, dancing) is likely more feasible and may offer the added benefit of decreasing sedentary time.[15]

Finally, goal setting for participants was often individualized to meet unique dietary and activity patterns. For example, parents of children with restricted eating patterns often pursued goals to try new healthier foods (eg, vegetables, fruits). Although important, such goals may have overshadowed the more fundamental goals that might lead to greater weight loss, e.g., reductions in energy-dense snacks and increases in aerobic activity. A set of common goals, achievable by all families and designed to establish weight loss, should be included in future investigations.

These results, in combination with the high level of adherence as evidenced by excellent session attendance, parents' positive ratings of their children's acceptance of the program, and parents' own satisfaction, particularly with the nutrition and activity education +behaviorial intervention intervention, suggest that the pilot intervention was feasible and acceptable to participants. The tailored materials and activities that were devised for the youth and young adults enabled them to be actively included in the intervention, a unique approach that complemented the behavioral strategies employed by their parents.

Acknowledgments

We thank Renee Scampini, MS, RD (Mary Mount College, Milwaukee, Wisconsin), for her many contributions to the study, including participation in the development of several nutrition-and-activity sessions that were part of the protocol and her work to expand the healthy eating plans and parent guide that were used with participants and their families. We also would like to thank Elizabeth Reverri, Leslie Song, and Elise Stokes for their assistance with development of instructional materials.

Supported by the National Institutes of Health (DK070627, DK046200, and HDP30HD004147) and the John W. Alden Trust.

Registered with ClinicalTrials.gov: NCT01256112.

References

1. Ogden CL, Carroll MD, Kit BK, Flegal KM. Prevalence of obesity and trends in body mass index among US children and adolescents, 1999-2010. JAMA. 2012; 307(5):483–490. [PubMed: 22253364]
2. De S, Small J, Baur LA. Overweight and obesity among children with developmental disabilities. J Intellect Dev Disabil. 2008; 33(1):43–47. [PubMed: 18300166]
3. Rimmer JH, Yamaki K, Lowry BM, Wang E, Vogel LC. Obesity and obesity-related secondary conditions in adolescents with intellectual/developmental disabilities. J Intellect Disabil Res. 2010; 54(9):787–794. [PubMed: 20630017]
4. Must A, Strauss RS. Risks and consequences of childhood and adolescent obesity. Int J Obes Relat Metab Disord. 1999; 23(suppl 2):S2–S11. [PubMed: 10340798]
5. Epstein LH, Paluch RA, Roemmich JN, Beecher MD. Family-based obesity treatment, then and now: twenty-five years of pediatric obesity treatment. Health Psychol. 2007; 26(4):381–391. [PubMed: 17605557]
6. Hamilton S, Hankey CR, Miller S, Boyle S, Melville CA. A review of weight loss interventions for adults with intellectual disabilities. Obes Rev. 2007; 8(4):339–345. [PubMed: 17578383]
7. Centers for Disease Control and Prevention (CDC). [Accessed Sept 26, 2012] Overweight and Obesity: Basics about Childhood Obesity. http://www.cdc.gov/obesity/childhood/basics.html.
8. Dallal, GE. [Accessed Sept 26 2007] Randomization.com.http://www.randomization.com/Mar 1 2008, Mar 1 2009
9. Robinson TN. Behavioural treatment of childhood and adolescent obesity. Int J Obes Relat Metab Disord. 1999; 23(suppl 2):S52–S57. [PubMed: 10340806]
10. Chumlea WC, Guo SS, Kuczmarski RJ, et al. Body composition estimates from NHANES III bioelectrical impedance data. Int J Obes Relat Metab Disord. 2002; 26(12):1596–1609. [PubMed: 12461676]
11. Puyau MR, Adolph AL, Vohra FA, Zakeri I, Butte NF. Prediction of activity energy expenditure using accelerometers in children. Med Sci Sports Exerc. 2004; 36(9):1625–1631. [PubMed: 15354047]
12. Heil DP. Predicting activity energy expenditure using the Actical activity monitor. Res Q Exerc Sport. 2006; 77(1):64–80. [PubMed: 16646354]
13. Epstein LH, Wing RR, Steranchak L, Dickson B, Michelson J. Comparison of family-based behavior modification and nutrition education for childhood obesity. J Pediatr Psychol. 1980; 5(1): 25–36. [PubMed: 7452420]
14. Ebbeling CB, Leidig MM, Feldman HA, Lovesky MM, Ludwig DS. Effects of a low-glycemic load vs low-fat diet in obese young adults: a randomized trial. JAMA. 2007; 297(19):2092–2102. [PubMed: 17507345]
15. Epstein LH, Paluch RA, Gordy CC, Dorn J. Decreasing sedentary behaviors in treating pediatric obesity. Arch Pediatr Adolesc Med. 2000; 154(3):220–226. [PubMed: 10710017]
16. Hall KD, Heymsfield SB, Kemnitz JW, Klein S, Schoeller DA, Speakman JR. Am J Clin Nutr. 2012; 95(4):989–94. [PubMed: 22434603]

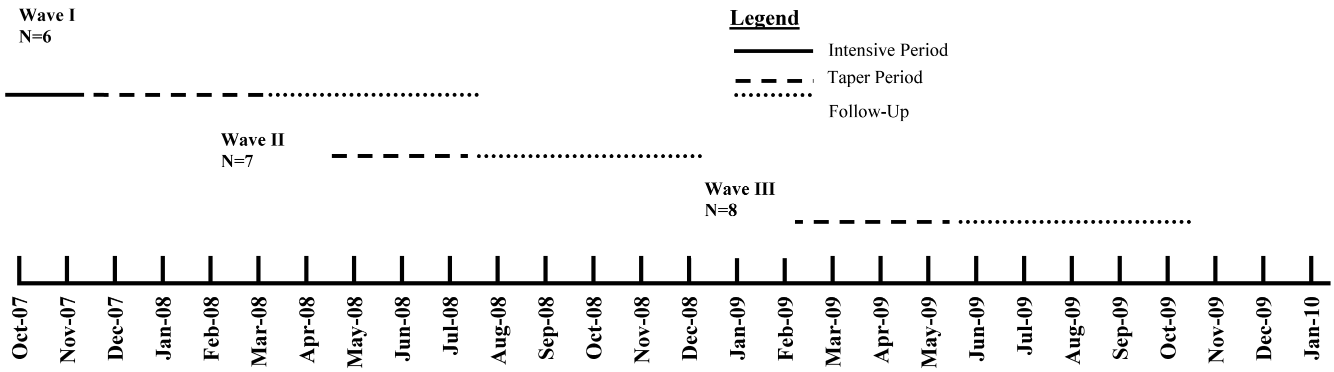
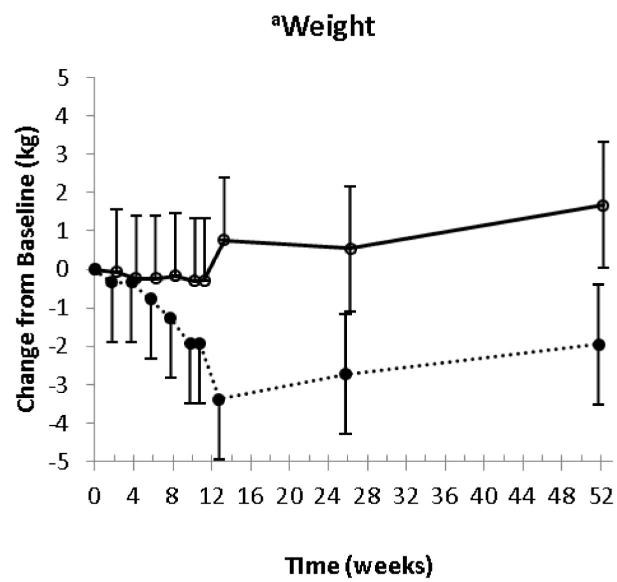


Figure 1. Trial Design



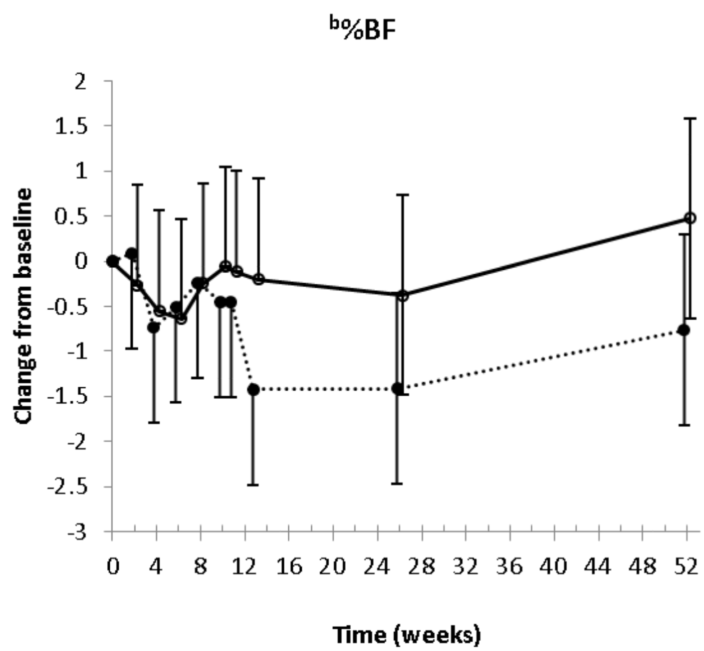


Figure 2a&b. Least Squares Mean Change from Baseline in Weight or Percentage Body Fat at Pre-Specified Follow-up Visits by Treatment Group with Corresponding 95% Confidence Intervals

nutrition and activity education + behaviorial intervention (…●…), nutrition and activity education (—○—) [a] Linear mixed model *p-values*: group = 0.07; time = 0.09; group-by-time interaction = 0.005. At 52 weeks, mean weight decreased 1.95 in nutrition and activity education+behaviorial intervention and increased 1.67kg in nutrition and activity education (mean group difference = −3.62 kg, 95% CI: −5.88, −1.36, p-value = 0.002). [b] Linear mixed model *p-values*: group = 0.48; time = 0.009; group-by-time interaction = 0.52. At 52 weeks, mean PBF decreased 0.76 in nutrition and activity education+behaviorial intervention and

increased 0.48 in nutrition and activity education (mean group difference = −1.24, 95% CI: −2.78, 0.31, p-value = 0.12).

NIH-PA Author Manuscript
NIH-PA Author Manuscript

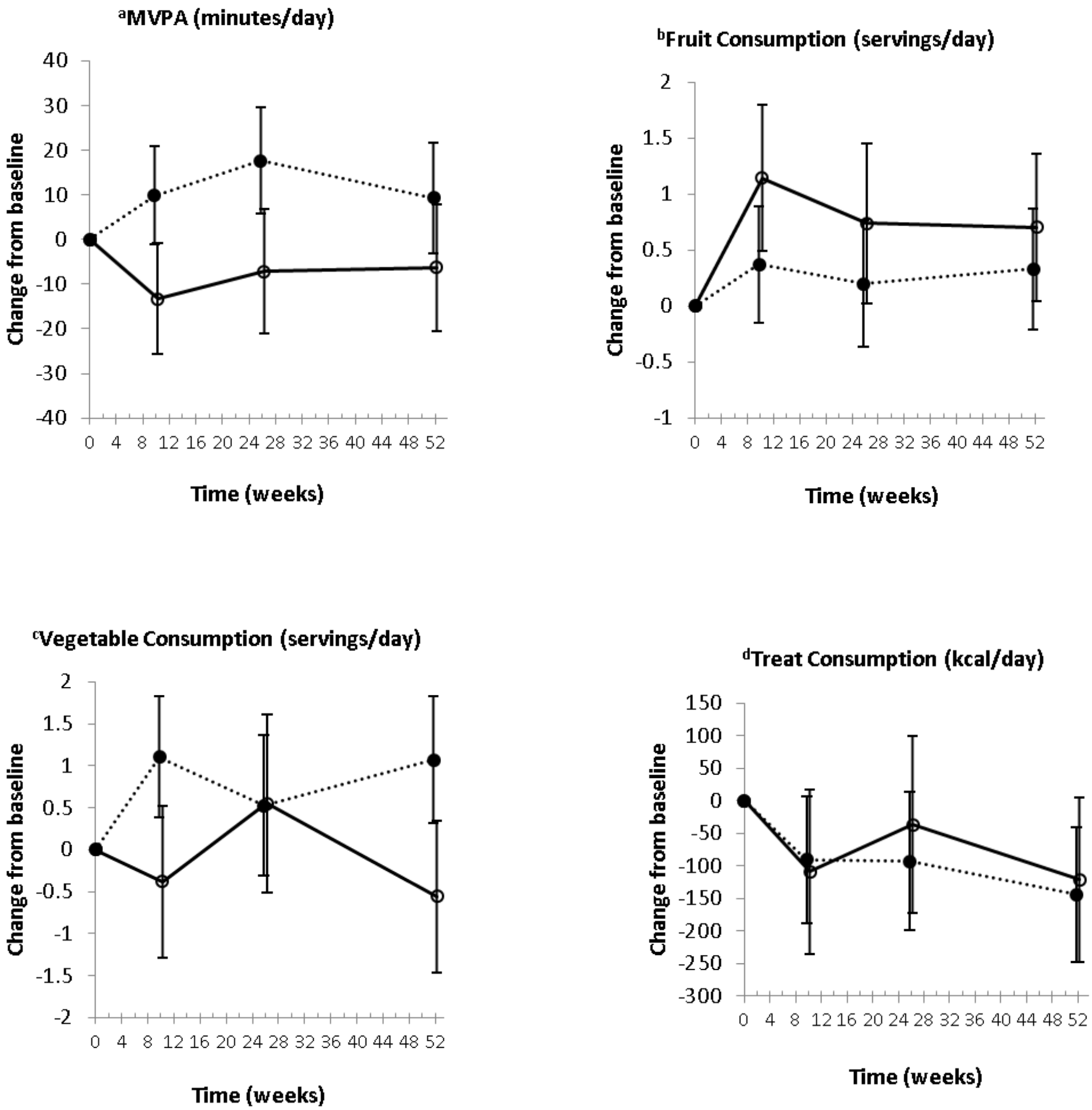


Figure 3a-d. Least Squares Mean Change from Baseline in Physical Activity, Fruit Consumption, Vegetable Consumption, or Treat Consumption at Pre-Specified Follow-up Visits by Treatment Group with Corresponding 95% Confidence Intervals

nutrition and activity education + behaviorial intervention (…●…), nutrition and activity education (—○—) [a] Linear mixed model *p-values*: group = 0.006; time = 0.32; group-by-time interaction = 0.63. At 52 weeks, mean moderate/vigorous physical activity increased 9.26 min/day in nutrition and activity education+behaviorial intervention and decreased 6.29 min/day in nutrition and activity education (mean group difference = −15.55 min/day, 95% CI: −34.49, 3.39, p-value = 0.10). [b] Linear mixed model *p-values*: group = 0.13; time = 0.36; group-by-time interaction = 0.69. At 52 weeks, mean fruit consumption increased 0.33 servings/day in nutrition and activity education+behaviorial intervention and increased servings/day 0.70 in nutrition and activity education (mean group difference = −0.37, 95% CI: −1.23, 0.49, p-value = 0.38).[c] Linear mixed model *p-values*: group = 0.02; time = 0.76;

group-by-time interaction = 0.07. At 52 weeks, mean vegetable consumption increased 1.07 servings/day in nutrition and activity education+behaviorial intervention and decreased 0.56 servings/day in nutrition and activity education (mean group difference = 1.63, 95% CI: 0.44, 2.82, p-value = 0.009).[d] Linear mixed model *p-values*: group = 0.78; time = 0.16; group-by-time interaction = 0.57. At 52 weeks, mean treat consumption decreased 143.49 kcal/day in nutrition and activity education+behaviorial intervention and decreased 120.7 servings/day in nutrition and activity education (mean group difference = −22.78, 95% CI: −194.46, 148.9, p-value = 0.79).

Table 1

Demographic Characteristics† of Study Participants (*N* = 21)

	Intervention Type	
	Nutrition Activity Education (NAE) (*n* = 10)	**Nutrition Activity Education + Behavioral Intervention (NAE + BI) (*n* = 11)**
Age	20.5 (4.1)	20.5 (2.4)
Sex, No. (%)		
Male	1 (10)	3 (27.3)
Female	9 (90)	8 (72.7)
Race/Ethnicity, No. (%)		
White	10 (100)	10 (90.9)
Hispanic	0	1 (9.1)
IQ (KBIT)		
Verbal	54.1 (8.6)	51.6 (12.0)
Non-verbal	53.8 (12.6)	46.0 (5.6)
Composite	49.1 (9.3)	44.8 (6.3)
Weight (kg)	77.3 (16.5)	79.2 (14.9)
Height (cm)	145.3 (6.8)	148.4 (5.5)
Body Mass Index (BMI)	36.5 (6.9)	35.8 (5.4)
% Body Fat	46.6 (7.0)	44.2 (4.6)
Parent BMI ≥ 30, No. (%)		
Neither	5 (50)	6 (54.5)
Either or Both	5 (50)	5 (45.5)
Max Parent Education Level, No. (%)		
High/Trade School	1 (10)	4 (36.4)
Some College	1 (10)	2(18.2)
Bachelors' Degree	2 (20)	2 (18.2)
Advanced Degree	6 (60)	3 (27.3)
Moderate/Vigorous Physical Activity (minutes/day)	60.7 (59.6)	83.1 (47.7)
Fruit Intake (servings/day)	0.39 (0.59)	0.67 (0.7)
Vegetable Intake (servings/day)	2.6 (2.1)	1.9 (1.1)
Treat Intake (kcal/day)	173.5 (116.1)	355.2 (205.5)

Table 2

Changes in Indices of Weight, Body Fatness, Physical Activity, and Diet[†]

	Group Means (SE)		Group Differences	
	NAE (n=10[a])	NAE+BI (n=11)	Difference (95%CI)	p-value
Weight (kg)				
Baseline	78.3 (6.9)			
Change at 10 weeks	−0.3 (0.8)	−1.9 (0.8)	−1.6 (−3.9, 0.6)	0.16
Change at 6 months	0.5 (0.8)	−2.7 (0.8)	−3.2 (−5.5, −1.0)	0.005
Change at 1 year	1.7 (0.8)	−1.9 (0.8)	−3.6 (−5.9, −1.4)	0.002
Percentage Body Fat				
Baseline	45.3 (2.6)			
Change at 10 weeks	−0.06 (0.6)	−0.4 (0.5)	−0.4 (−1.9, 1.2)	0.63
Change at 6 months	−0.4 (0.6)	−1.4 (0.5)	−1.0 (−2.6, 0.5)	0.19
Change at 1 year	0.5 (0.6)	−0.8 (0.5)	−1.2 (−2.8, 0.3)	0.12
MVPA (minutes/day)				
Baseline	73.7 (22.7)			
Change at 10 weeks	−13.3 (6.0)	9.8 (5.3)	−23.1 (−39.8, −6.4)	0.009
Change at 6 months	−7.1 (6.7)	17.6 (5.8)	−24.8 (−43.2, −6.3)	0.01
Change at 1 year	−6.3 (6.8)	9.3 (5.9)	−15.5 (−34.5, 3.4)	0.10
Fruit (servings/day)				
Baseline	0.6 (0.3)			
Change at 10 weeks	1.1 (0.3)	0.4 (0.3)	−0.8 (−1.6, 0.07)	0.07
Change at 6 months	0.7 (0.3)	0.2 (0.3)	−0.5 (−1.5, 0.4)	0.24
Change at 1 year	0.7 (0.3)	0.3 (0.3)	−0.4 (−1.2, 0.5)	0.38
Vegetables (servings/day)				
Baseline	2.2 (0.8)			
Change at 10 weeks	−0.4 (0.4)	1.1 (0.3)	1.5 (0.3, 2.7)	0.01
Change at 6 months	0.6 (0.5)	0.5 (0.4)	−0.03 (−1.4, 1.3)	0.96
Change at 1 year	−0.6 (0.4)	1.1 (0.4)	1.6 (0.4, 2.8)	0.009
Treats (kcal/day)				
Baseline	284.5 (85.7)			
Change at 10 weeks	−108.7 (61.5)	−90.5 (47.5)	18.2 (−148.3, 184.7)	0.82
Change at 6 months	−36.3 (66.1)	−92.6 (51.8)	−56.3 (−236.2, 123.6)	0.53
Change at 1 year	−120.7 (61.5)	−143.5 (50.3)	−22.8 (−194.5, 148.9)	0.79

[†]Adjusted means (standard error) and mean differences (95% confidence interval) from linear mixed models with the baseline value included as a covariate.

[a]sample size in the NAE group for MVPA=8; sample size in the NAE group for food variables (fruits, vegetables, and treats)=7