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Family-based treatment of severe pediatric obesity: A randomized controlled trial

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Abstract

Objective—We evaluated the efficacy of family-based behavioral weight control in the management of severe pediatric obesity.

Patients and Methods—Participants were 192 children aged 8.0 to 12.0 years ($M = 10.2$, $SD = 1.2$). Average BMI percentile for age and sex was 99.18 ($SD = 0.72$). An adult living with the child also participated. Families were randomized to INTERVENTION or USUAL CARE. INTERVENTION consisted of 20 weekly group sessions and 6 monthly booster sessions. USUAL CARE consisted of 2 nutrition consultations. Assessments were conducted at baseline, 6-, and 12-months; only weight and height were assessed at 18-months. Primary outcome was percent overweight (percent over the median BMI for age and sex). Changes in blood pressure, body composition, waist circumference, and health-related quality of life also were evaluated. Finally, we examined factors associated with changes in child percent overweight, in particular, session attendance.

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Results—INTERVENTION was associated with significant decreases in child percent overweight relative to USUAL CARE at 6-months. Intention to treat analyses documented that INTERVENTION was associated with a 7.58% decrease in child percent overweight at 6 months, versus a 0.66% decrease in USUAL CARE, but differences were not significant at 12- or 18-months. Small, significant improvements in medical outcomes were observed at 6- and 12-months. Children who attended $\geq 75\%$ of INTERVENTION sessions maintained decreases in percent overweight through 18-months. Lower baseline percent overweight, better attendance, higher income, and greater parent BMI reduction were associated with significantly greater reductions in child percent overweight at 6-months among INTERVENTION participants.

Conclusions—INTERVENTION was associated with significant short-term reductions in obesity and improvements in medical parameters. Additionally, INTERVENTION conferred longer-term weight change benefits for children who attended $\geq 75\%$ of sessions. Development of chronic care treatment models is indicated to enhance compliance and optimize health outcomes in severely obese children.

Keywords

behavioral intervention; childhood obesity; Obesity treatment; Weight management

Pediatric obesity (defined as $\geq 95^{\text{th}}$ percentile of BMI for age and sex)¹ is a major public health concern, with data from the National Health and Nutrition Examination Survey documenting that 17.1 % of children aged 2–19 years were obese in 2003–2004.² Of note, the greatest increases in prevalence have occurred among the heaviest children,³ and as many as 4% of US children now have a BMI $\geq 99^{\text{th}}$ percentile for age and sex,⁴ a threshold associated with multiple medical risk factors, and severe adult obesity.

Despite the morbidity associated with severe pediatric obesity, conservative approaches such as family-based behavioral weight management are indicated as the initial intervention and will be crucial for long-term weight control.⁵ Although numerous investigations have documented the efficacy of family-based behavioral weight management programs,^{6–8} most studies have focused on moderately overweight youth.⁹ Weight losses in behavioral weight management programs typically are modest, ranging from 5–20% of excess body weight or 1–3 units of BMI.⁹ Nevertheless, we reasoned that it was important to evaluate the impact of a comprehensive weight management program for severe pediatric obesity in comparison to the usual care provided to these children, and to evaluate factors associated with treatment outcome. We hypothesized that relative to USUAL CARE, INTERVENTION would be associated with favorable changes in BMI and medical risk factors.

METHODS

Design

This study was a randomized, controlled trial conducted at the University of Pittsburgh Medical Center from March 2001 through May 2006. The protocol was approved by the University of Pittsburgh Institutional Review Board; parents or guardians provided informed consent, and children provided assent. Assessments were conducted at baseline, 6-, 12 and 18-months (only weight and height were collected at month 18). Children received physical examinations at each assessment. After baseline assessments, participants were randomly assigned to study conditions (1:1) by permuted block size randomization stratified by race, with a block size of 2, 4 or 6. An overview of study design, recruitment, and retention is presented in Figure 1.

Study Participants

Eligibility criteria included: 1. child between 8.0 and 12.0 years of age; 2. child BMI $\geq$ 97th percentile; and 3. adult willing to participate in the program with the child. Child exclusion criteria were 1. mental retardation, pervasive developmental disorder or psychosis; 2. psychiatric symptoms requiring alternate treatment; 3. genetic obesity syndrome; 4. current obesity treatment; 5. inability to engage in prescribed daily activity; 6. medical conditions contraindicating USUAL CARE; and 7. use of medication known to affect body weight (stable doses of stimulant or antidepressant medication were allowed).

Family-based Intervention

INTERVENTION consisted of 20 60-minute group meetings during months 0–6. Adult and child groups met separately, and were presented with complementary material. Immediately prior to or after group meetings, the adult and child were weighed, and together met with a lifestyle coach to review self-monitoring records and set weekly goals. Six booster sessions (three group sessions and three telephone calls) were provided between 6- and 12-months post-treatment. There was no contact between the 12- and 18-month assessments.

INTERVENTION was adapted from the program developed by Epstein and colleagues, which has been studied extensively.^{7, 10–13} Participants were provided with a modified version of the Stoplight Eating Plan¹⁴ and given a daily calorie range based on body weight (≤ 68 kg = 1200 – 1400 kcal; 69 – 113 kg = 1400 – 1600 kcal; > 113 kg = 1600 – 1800 kcal). Families were taught behavioral strategies to increase physical activity and decrease sedentary behaviors, such as watching television and playing computer games, with a goal of limiting these to less than 15 hours per week. Behavior modification techniques included self-monitoring, changing the environment, step-wise goal setting, stimulus control, and positive reinforcement for meeting prescribed goals. We also included instruction in setting realistic expectations, promoting body image, minimizing emotional eating, and coping with teasing.⁵ Participating adults were instructed to set goals for and model healthy changes in eating and physical activity. Overweight adults were encouraged, but not required, to lose weight.

Usual Care

Adults and children in the USUAL CARE condition were offered two nutrition consultation sessions to develop an individual nutrition plan based on the Stoplight Eating Plan. There was no additional contact between assessments. USUAL CARE participants were offered INTERVENTION after completion of the 18-month assessment.

Assessments

Participants self-reported demographic information. Children and adults were weighed in street clothes without shoes using a digital scale (Scale-Tronix 5002). A stationary stature board was used for height assessment. Child percent overweight, calculated as percent over median BMI for age and sex,¹⁵ was the primary study outcome as it has been recommended for reporting changes in adiposity in children.¹⁶ Adult BMI was calculated by formula [weight (kg) /height (m^2)]. Adults also completed the General Health Perceptions and Global Health subscales of the Child Health Questionnaire, Parent Version (CHQ-PF50),¹⁷ to assess the health-related quality of life.

Medical assessments were performed at the Pediatric Clinical and Translation Research Center (PCTRC; previously General Clinical Research Center) at Children's Hospital of Pittsburgh, at baseline, 6- and 12-months. Waist circumference was measured at the midpoint between the lowest rib and the iliac crest.¹⁸ Duplicate measurements were taken on a subset of children ($n = 16$) to document reliability, with a Pearson correlation of .90 ($p < .001$). Body composition

was determined by dual energy x-ray absorptiometry (DEXA) using GE Lunar Prodigy (GE Medical Systems Lunar, Madison WI). Percent body fat, total body fat and fat free mass were determined. Resting blood pressure was measured with an automated mercury sphygmomanometer with a cuff suitable for obese children, with 3 readings taken 5 minutes apart while the children were resting. Assessors did not provide INTERVENTION, but were not blind to treatment condition.

Sample Size and Statistical Analysis

Power computations were done using PASS 6.0 (NCSS, Kaysville, UT), and assumed a two-tailed significance level of 0.05. We planned to enroll 100 participants per study condition to have power of 0.8 to detect approximate treatment effect sizes of 0.5 with 30% dropout projected over the course of the trial.

Descriptive statistics were used to summarize participant demographic characteristics. Independent t-tests or chi-square analyses (or Fisher's exact tests) were utilized to test for differences between treatment conditions at randomization, and compare baseline characteristics of those lost to follow-up with those retained. The proportion of children lost to follow-up was compared at each time point using separate chi-square tests. All hypothesis tests utilized a two-tailed level of significance of 0.05.

Primary outcomes were evaluated with an intent-to-treat (ITT) analysis. To test the hypothesis that the INTERVENTION would have a positive impact on percent overweight in comparison to USUAL CARE, we fit a series of longitudinal models using SAS mixed models with fixed effects including time (0, 6, 12 and 18 months), group (INTERVENTION, USUAL CARE), and group by time interaction. For all other endpoints, which had no 18-month assessments, we fit a similar series of mixed models with terms for time (0, 6, and 12 months), group (INTERVENTION, USUAL CARE), and group by time interaction. Planned contrasts were set to compare the two conditions on the changes in weight outcomes from baseline to the 6-, 12- and 18-month assessments, and the changes in other outcomes from baseline to the 6- and 12- month assessments. Effect sizes were calculated using Cohen's *d*.¹⁹

The mixed model is an ITT approach as the analysis includes all subjects with varying numbers of assessments assuming the incomplete data are missing at random (MAR). To examine the MAR assumption and the stability of results, we ran a series of sensitivity analyses that included models with demographic variables [sex (male, female); race (black, white or other); participating adult education (high school graduate or less, some college, college graduate or more); and household income (< 30,000, ≥ 30,000)], and excluding children who started medications known to affect body weight after randomization. To evaluate the impact of missing data further, we utilized models where subjects were weighted by a function of the probability of being missing. As the overall pattern of results from sensitivity analyses and weighted models was similar to the primary ITT analysis, we report the primary analyses only.

A secondary study objective was to identify factors associated with treatment outcome. We were particularly interested in evaluating the impact of session attendance as an indicator of adherence. Accordingly, we first examined the impact of dose of treatment by comparing the weight trajectories of INTERVENTION children who obtained an adequate dose of treatment (defined as ≥75% of sessions attended) to that of USUAL CARE children. Next, we fit a multiple linear regression restricted to the INTERVENTION group only to consider session attendance simultaneously with other conceptually relevant covariates. Using backward variable selection, we examined child percent overweight at 6 months (post-treatment) as a function of baseline percent overweight, demographic variables, number of treatment sessions attended, and adult BMI change in treatment.

RESULTS

Sample characteristics

Children (N = 192) aged 10.2 years (SD = 1.2), with an average BMI percentile of 99.18 (SD = 0.72), were randomized to INTERVENTION or USUAL CARE. Baseline characteristics for child and adult participants are presented in Table 1 and Table 2, respectively. Baseline child and adult characteristics did not vary significantly by group.

The proportion of children lost to follow-up differed by group at 6 months (13.4 % in INTERVENTION vs. 26.3% in USUAL CARE group, $X^2 = 5.04$, $p = 0.02$). However, baseline characteristics of those who did and did not complete the 6-month assessment did not differ. The proportion of non-completers did not differ by group at 12 months (26.8% in INTERVENTION vs. 36.8% in USUAL CARE, $X^2 = 2.23$, $p = 0.14$), or at 18 months (22.7% in INTERVENTION vs. 17.9% in USUAL CARE, $X^2 = 0.68$, $p = 0.41$). However, 18-month assessment completers differed from non-completers in baseline child BMI (31.7 vs. 34.0, $t = -2.14$, $p = 0.037$), percent overweight (87.4 vs. 101.8, $t = 2.36$, $p = 0.023$), and number of people in household (4.11 vs. 3.67, $t = 2.13$, $p = 0.035$).

Primary analyses (Intent to Treat)

Results for children, including observed and modeled means, are shown in Figure 2. Data indicate that percent overweight remained relatively stable in USUAL CARE compared to a decrease in INTERVENTION. Results for medical outcomes, including systolic blood pressure, diastolic blood pressure, percent body fat, and waist circumference, are shown in Figure 3.

Not shown in Figure 3, for total body fat, there were significant effects of group ($F = 5.90$, $df = 1, 167$, $p = .016$), time ($F = 16.71$, $df = 2, 6.14$, $p = .003$) and group by time ($F = 5.75$, $df = 2, 6.14$, $p = .039$). For total fat free mass, there were effects for group ($F = 4.38$, $df = 1, 196$, $p = .038$) and time ($F = 53.85$, $df = 2, 343$, $p < .0001$). For the CHQ-PF50, General Health subscale, there were effects for time ($F = 6.58$, $df = 2, 227$, $p = .002$) and group by time ($F = 3.97$, $df = 2, 227$, $p = .02$). For participating adult BMI, there was a significant effect for time ($F = 6.67$, $df = 2, 196$, $p = .002$) and group by time ($F = 7.62$, $df = 2, 196$, $p = .0007$).

Planned contrasts, reported in Table 3, indicated that differences in percent overweight were significant at 6-months only. Significant effects for other outcomes, except CHQ-PF50 Global Health, persisted through 12 months.

Secondary analyses

Among children randomized to INTERVENTION, the mean number of sessions attended was 12.6 (± 5.6), and 50% ($n = 49$) received an adequate dose of treatment defined as attendance at 15/20 (75%) of sessions. Weight trajectories of INTERVENTION children who received an adequate dose of treatment compared to USUAL CARE children are presented in Figure 4. Planned contrasts indicated that differences in percent overweight were significant at 6- ($p = .0001$), 12- ($p = .0004$) and 18-months ($p = .020$).

Finally, we examined factors associated with 6-month outcome among children in the INTERVENTION group only. Results of the final model indicated that larger 6-month decreases in child percent overweight were associated with lower child percent overweight at study entry ($\beta = 0.91$, $SE = .04$, $p < 0.001$), higher income ($\beta = -5.57$, $SE = 2.43$, $p = .025$), more treatment sessions attended ($\beta = -0.82$, $SE = .2$, $p < 0.001$), and decrease in adult BMI during treatment ($\beta = 1.68$, $SE = 0.57$, $p = .004$).

Comment

To our knowledge, we conducted the first trial to evaluate the efficacy of an evidence-supported, family-based behavioral weight control program^{7, 10–13} in the management of severely obese school-aged children. Overall, our results document favorable 6-month (post-treatment) changes in percent overweight, and 12-month improvements in medical risk parameters among study participants. Specifically, children in the INTERVENTION condition showed a 7.58% decrease in percent overweight at the completion of acute treatment, which was significantly better than the 0.66% decrease observed in the USUAL CARE group.

The present short-term results are comparable to results reported in other randomized controlled trials. For example, a meta-analysis of 14 randomized controlled trials of lifestyle interventions for pediatric obesity²⁰ documented an average decrease in percent overweight of 8.2% at post-treatment, which is comparable to the 7.58% decrease observed in the current study. However, the children in the present investigation were severely obese, whereas children in previous studies were likely to be moderately overweight.⁹ Another recent investigation did focus on an older group (approximately 12 years versus 10 years in the present study) of severely obese youth.²¹ In that study, children were randomized to a weight management program that included behavioral modification sessions and supervised exercise, or usual clinical management. Duration and intensity were greater than in the present investigation in that participants attended twice a week sessions for six months and bi-weekly sessions for an additional six months. At month 6, treatment was associated with significant decreases in BMI (−2.1 versus −0.7 in the current study) and insulin resistance.²¹ Thus, available data indicate that severely obese youth achieve short-term changes in BMI that are comparable to those observed in other behavioral interventions.

The changes in percent overweight were not well-maintained in the period after intervention in the current study. Child participants in INTERVENTION exhibited increases in percent overweight and BMI in the one-year period after weekly intervention while children in USUAL CARE maintained a stable degree of overweight, such that differences between study conditions in percent overweight did not differ significantly 12- or 18-month assessments. This finding stands in contrast to results reported in the literature,²⁰ where, on average, the effects of family-based intervention were sustained over follow-up (ranging from one month to 5 years post-treatment). Weight loss maintenance in severely obese children is of particular importance given their level of medical risk. Results of the Savoye et al.²¹ study also raise concerns about weight loss maintenance in severely obese children. In that investigation, BMI among participants in the treatment group also increased during the second 6-months, despite ongoing bi-weekly intervention sessions.

Although impact on percent overweight was modest, INTERVENTION had positive effects on other health-related parameters that were sustained at 12-months. Specifically, children receiving family-based weight management when compared to those who received USUAL CARE evidenced significant improvements in waist circumference, systolic blood pressure, percent body fat, and total body fat. Waist circumference has been shown to be a significant predictor of abdominal fat and insulin resistance independent of BMI in youth.¹⁸ Thus the effects of INTERVENTION on cardiovascular risk factors are encouraging.

Several factors may affect the generalizability of study results. First, the study design did not control for time and attention, and thus we can not attribute outcomes to the specific components of the family-based intervention. Next, the prevalence of severe pediatric obesity varies by sex and race/ethnicity, with highest observed rates among Hispanic boys and Black girls.² As there were no Hispanic youth in the current study, results may be most applicable to White and Black boys and girls. Further, youth who participate in university-based research

programs may not be representative of those in the community. Finally, there was a significant proportion of missing data in the ITT analyses for medical risk factors, suggesting that replication is needed before firm conclusions about medical outcomes can be drawn.

In summary, a 6-month family-based behavioral weight management program was associated with significant decreases in percent overweight and improvements in medical risk factors in severely obese school-aged children. Although changes in percent overweight were modest given the severity of obesity, the significant health benefits of INTERVENTION suggest that further efforts to optimize the outcomes of family-based intervention programs are warranted. Session attendance was associated with significantly better child weight loss maintenance. Although future work is needed to understand the relation between attendance and weight control, the present findings suggest the potential importance of strategies to promote and facilitate program adherence. Similarly, larger reductions in adult BMI were associated with more successful outcomes, indicating that work to enhance adult role modeling and participation in child weight control programs may improve outcomes. Higher family income also was associated with short-term child decreases in percent overweight, and thus families with financial strain may benefit from strategies to reduce intervention cost burden. Finally, children with a lower percent overweight at study entry, even among an extremely overweight sample, exhibited better short-term decreases in percent overweight, and were less likely to be lost to follow-up at 18 months, suggesting that the heaviest children may require different strategies for engagement and treatment.

Available data suggest that maintenance of weight losses among severely obese children may be problematic. Thus, there is a compelling need to develop chronic care models for this high risk population. Effective longitudinal models are likely to require the sequential application of evidence-supported intervention components implemented over time to enhance and sustain weight control efforts and mitigate health risk. Family-based intervention will be an important component of any chronic care model. Data presented here suggest that future work should be directed at maximizing initial weight losses, promoting program participation, and identifying ways to support family behavior change.

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Figure 1.
Study design and recruitment.

Figure 2.

Changes in child percent overweight over time (ITT).

Note. There were significant effects for time ($F = 6.61$, $df = 3$, 405 , $p = .0002$) and group by time ($F = 4.61$ $df = 3$, 405 , $p = .004$).

Figure 3.
Changes in child medical outcomes over time.

Notes. For systolic blood pressure there were effects for group ($F = 13.25$, $df = 1$, 202 , $p = .0003$), time ($F = 3.82$, $df = 2$, 182 , $p = .024$) and group by time ($F = 3.07$, $df = 2$, 182 , $p = .049$) and diastolic blood pressure and effect for group ($F = 5.61$, 1 , $df = 198$, $p = .019$). For percent body fat, there were effects for group ($F = 4.10$, $df = 1$, 204 , $p = .0441$), time ($F = 3.47$, $df = 2$, 182 , $p = .0333$) and group by time ($F = 6.45$, $df = 2$, 182 , $p = .002$). For waist circumference, there was a significant effect for time ($F = 68.51$, $df = 2$, 145 , $p < .0001$) and group by time ($F = 7.53$, $df = 2$, 145 , $p = .0008$).

Figure 4.

Changes in child percent overweight over time (completers).

Note. There were significant effects for group ($F = 9.34$, $df = 1$, 123 , $p = .0027$), time ($F = 14.25$, $df = 3$, 235 , $p = .0001$) and group by time ($F = 11.40$, $df = 3$, 235 , $p = .0001$).

Table 1

Baseline Characteristics of Study Participants

Characteristics	Intervention Mean (SD)	Usual Care Mean (SD)	Total Mean (SD)	Between group P
Age (months)	10.07 (1.19)	10.30 (1.21)	10.19 (1.20)	0.18
Weight (kg)	70.17 (18.44)	72.74 (16.63)	71.44 (17.57)	0.31
BMI	31.71 (5.21)	32.54 (4.67)	32.12 (4.95)	0.25
BMI percentile	99.17 (0.60)	99.19 (0.84)	99.18 (0.72)	0.85
Percent overweight	88.61 (29.24)	92.02 (25.90)	90.30 (27.62)	0.39
Ethnicity (%)				0.98
Hispanic	1.05	1.09	1.07	
Non-Hispanic	98.95	98.91	98.93	
Race(%)				0.61
American Indian/Alaska	0.00	0.00	0.00	
Native Asian	1.03	0.00	0.52	
Black/African-American	24.74	27.37	26.04	
Native Hawaiian/Other	0.00	0.00	0.00	
Pacific Islander	0.00	0.00	0.00	
White	74.23	72.63	73.44	
Female (%)	55.67	57.89	56.77	0.76
Systolic Blood Pressure (mmHg)	111.2 (9.44)	113.05 (9.87)	112.11 (9.67)	0.19
Diastolic Blood Pressure (mmHg)	69.18 (7.58)	69.70 (8.73)	69.44 (8.15)	0.66
Waist Circumference (cm)	70.25 (18.44)	72.58 (16.75)	71.40 (17.62)	0.36
DEXA Percent fat	45.95 (3.92)	45.94 (3.42)	45.95 (3.67)	0.98
DEXA Total fat (kg)	31.04 (8.92)	32.19 (8.17)	31.60 (8.56)	0.37
DEXA Total lean (kg)	34.08 (6.97)	35.62 (6.89)	34.83 (6.96)	0.13
Global Health – Parent Rating	71.3 (20.1)	73.4 (17.2)	72.3 (18.7)	0.44
General Health Perceptions – Parent Rating	66.3 (17.5)	67.4 (15.3)	68.8 (16.4)	0.62

Table 2

Baseline characteristics of participating parent/guardian and household

Characteristics	Intervention Mean (SD)	Usual Care Mean (SD)	Total Mean (SD)	Between group P
Participating parent/guardian age (years)	40.91 (6.55)	41.27 (8.93)	41.09 (6.53)	0.63
Parent/Guardian BMI	35.60 (9.20)	34.76 (8.93)	35.08 (8.98)	0.57
Female participating parent (%)	91.75	92.63	92.19	
Participating parent education				0.14
High school or less	14.4	25.3	19.8	
Some college/technical	54.6	44.2	49.5	
College or graduate degree (%)	30.9	30.5	30.7	
Family income (%)				0.94
\$0 – \$30,000	26.80	26.32	26.56	
> \$30,001	73.20	73.68	73.44	
Number of people in household	4.03 (1.18)	4.01 (1.18)	4.02 (1.18)	0.91

Table 3

Modeled changes in outcomes by group over time

Outcome (p-value for group effect)	Month	Intervention Mean Change (SE)	Usual Care Mean Change (SE)	Treatment Effect (SE)	Effect Size (Cohen d)	Between Group P
Weight (kg) (N = 192)	6	1.56 (0.68)	4.76 (0.57)	-3.20 (0.89)	0.51	0.0003
	12	6.92 (0.72)	9.22 (0.59)	-2.30 (0.94)	0.34	0.014
	18	11.77 (0.70)	13.35 (0.55)	-1.58 (0.89)	0.25	0.077
BMI (kg/m ²) (N = 192)	6	-0.68 (0.29)	0.54 (0.21)	-1.22 (0.36)	0.48	0.0007
	12	0.48 (0.30)	1.09 (0.23)	-0.61 (0.38)	0.22	0.11
	18	1.50 (0.30)	1.72 (0.21)	-0.21 (0.36)	0.08	0.56
Percent overweight (N = 192)	6	-7.58 (1.59)	-0.66 (1.17)	-6.92 (1.98)	0.49	0.0005
	12	-3.91 (1.69)	-0.62 (1.24)	-3.29 (2.10)	0.22	0.12
	18	-1.16 (1.66)	-0.17 (1.12)	-0.99 (2.01)	0.07	0.62
Parent BMI (kg/m ²) (N = 188)	6	-1.19 (0.24)	-0.01 (0.25)	-1.18 (0.35)	0.47	0.001
	12	-0.67 (0.28)	0.62 (0.29)	-1.29 (0.40)	0.45	0.002
Waist Circumference (cm) (N = 192)	6	1.11 (0.82)	4.94 (0.65)	-3.83 (1.04)	0.51	0.0003
	12	6.18 (1.05)	9.59 (0.87)	-3.41 (1.36)	0.35	0.014
Systolic BP (mmHG) (N = 190)	6	-4.47 (1.34)	-0.59 (1.43)	-3.87 (1.96)	0.29	.049
	12	-4.88 (1.79)	0.42 (1.93)	-2.96 (5.30)	0.29	0.045
Diastolic BP (mmHG) (N = 190)	6	-3.48 (1.08)	-0.37 (1.34)	-3.12 (1.72)	0.25	0.072

Outcome (p-value for group effect)	Month	Intervention Mean Change (SE)	Usual Care Mean Change (SE)	Treatment Effect (SE)	Effect Size (Cohen d)	Between Group P
	12	-2.96 (1.44)	-0.01 (1.80)	-2.96 (2.30)	0.18	0.20
DEXA Percent Fat (N = 186)	6	-1.86 (0.45)	0.27 (0.43)	-2.13 (0.63)	0.49	0.0008
	12	-1.33 (0.49)	0.25 (0.49)	-1.58 (0.69)	0.33	0.024
DEXA Total Fat (kg) (N = 186)	6	-0.41 (0.87)	2.50 (0.35)	-2.91 (0.94)	0.43	0.021
	12	1.73 (0.95)	4.20 (0.39)	-2.46 (1.03)	0.34	0.051
DEXA Total Lean (kg) (N = 186)	6	1.85 (0.60)	2.51 (0.38)	-0.66 (0.71)	0.13	0.36
	12	3.66 (0.66)	4.21 (0.43)	-0.54 (0.78)	0.10	0.49
Global Health Parent Rating (N = 192)	6	6.55 (2.10)	-0.28 (2.39)	6.84 (3.17)	0.30	0.032
	12	4.13 (2.49)	0.48 (2.84)	3.65 (3.77)	0.14	0.33
General Health Perceptions Parent Rating (N = 192)	6	6.88 (1.54)	0.46 (1.71)	6.42 (2.30)	0.39	0.006
	12	5.71 (1.81)	1.83 (1.96)	3.87 (2.67)	0.20	0.15