Family-Based Treatment of Severe Pediatric Obesity: Randomized, Controlled Trial

WHAT'S KNOWN ON THIS SUBJECT: Family-based, behavioral weight management programs are associated with moderate weight losses and health benefits for school-aged children, but few studies have focused on severely obese children.

WHAT THIS STUDY ADDS: Intervention was associated with short-term reductions in obesity and improvements in medical parameters. Sustained decreases in overweight were observed only among children with better session attendance. Chronic care models are indicated to optimize health outcomes for severely obese children.

abstract

OBJECTIVE: We evaluated the efficacy of family-based, behavioral weight control in the management of severe pediatric obesity.

METHODS: Participants were 192 children 8.0 to 12.0 years of age (mean ± SD: 10.2 ± 1.2 years). The average BMI percentile for age and gender was 99.18 (SD: 0.72). Families were assigned randomly to the intervention or usual care. Assessments were conducted at baseline, 6 months, 12 months, and 18 months. The primary outcome was percent overweight (percent over the median BMI for age and gender). 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, particularly session attendance.

RESULTS: Intervention was associated with significant decreases in child percent overweight, relative to usual care, at 6 months. Intent-to-treat analyses documented that intervention was associated with a 7.58% decrease in child percent overweight at 6 months, compared with a 0.66% decrease with 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 ≥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 and conferred longer-term weight change benefits for children who attended ≥75% of sessions. *Pediatrics* 2009;124:1060–1068

AUTHORS: Melissa A. Kalarchian, PhD,[a] Michele D. Levine, PhD,[a] Silva A. Arslanian, MD,[b] Linda J. Ewing, PhD, RN,[a] Patricia R. Houck, MS,[a] Yu Cheng, PhD,[c] Rebecca M. Ringham, PhD,[a] Carrie A. Sheets, MS,[a] and Marsha D. Marcus, PhD[a]

Departments of [a]Psychiatry and [b]Pediatrics University of Pittsburgh School of Medicine, and Department of [c]Statistics, University of Pittsburgh, Pittsburgh, Pennsylvania

KEY WORDS

behavioral intervention, childhood obesity, obesity treatment, weight management

ABBREVIATIONS

CHQ-PF50—Child Health Questionnaire, Parent Version

ITT—intent-to-treat

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Address correspondence to Marsha D. Marcus, PhD, Western Psychiatric Institute and Clinic, 3811 O'Hara St, Pittsburgh, PA 15213. E-mail: marcusmd@upmc.edu

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Pediatric obesity (defined as ≥95th percentile of BMI for age and gender)[1] is a major public health concern, with data from the National Health and Nutrition Examination Survey documenting that 17.1% of children 2 to 19 years of age 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 of ≥99th percentile for age and gender,[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 initial interventions and are 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 focused on moderately overweight youths.[9] Weight losses in behavioral weight management programs typically are modest, ranging from 5% to 20% of excess body weight or 1 to 3 BMI units.[9] Nevertheless, we reasoned that it was important to evaluate the impact of a comprehensive weight management program for severe pediatric obesity, in comparison with the usual care provided to these children, and to evaluate factors associated with treatment outcomes. 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 and 6, 12, and 18 months (only weight and height data were collected at 18 months). Children received physical examinations at each assessment. After baseline assessments, participants were assigned randomly to study conditions (1:1) through permuted block randomization with stratification according to race, with a block size of 2, 4, or 6. An overview of study design, recruitment, and retention is presented in Fig 1.

Study Participants

Eligibility criteria included (1) child age between 8.0 and 12.0 years, (2) child BMI of ≥97th percentile, and (3) adult willing to participate in the program with the child. Child exclusion criteria included (1) mental retardation, pervasive developmental disorder, or psychosis; (2) psychiatric symptoms requiring alternative 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

The intervention consisted of 20 group meetings (60 minutes each) during months 0 to 6. Adult and child groups met separately and were presented with complementary material. Immediately before or after group meetings, the adult and child were weighed and together met with a lifestyle coach to review self-monitoring records and to set weekly goals. Six booster sessions (3 group sessions and 3 telephone calls) were provided between month 6 and month 12. There was no contact between the 12-month and 18-month assessments.

The intervention was adapted from the program developed by Epstein et al,[7,10–13] which has been studied extensively. Participants were provided with a modified version of the Stoplight Eating Plan[14] and were given a daily energy range on the basis of body weight (≤68 kg: 5040–5880 kJ [1200–1400 kcal]; 69–113 kg: 5880–6720 kJ [1400–1600 kcal]; >113 kg: 6720–7560 kJ [1600–1800 kcal]). Families were taught behavioral strategies to increase physical activity and to decrease sedentary behaviors, such as watching television and playing computer games, with a goal of limiting those behaviors to <15 hours/week. Behavior modification techniques included self-monitoring, environmental changes, stepwise 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 to 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 2 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 the intervention after completion of the 18-month assessment.

Assessments

Participants self-reported demographic information. Children and adults were weighed in street clothes, without shoes, by using a digital scale (Scale-Tronix 5002; Scale-Tronix, White Plains, NY). A stationary stature board was used for height assessments. Child percent overweight, calculated as percent over the median BMI for age and gender,[15] was the primary study outcome, because it has been recommended for reporting changes in adi-

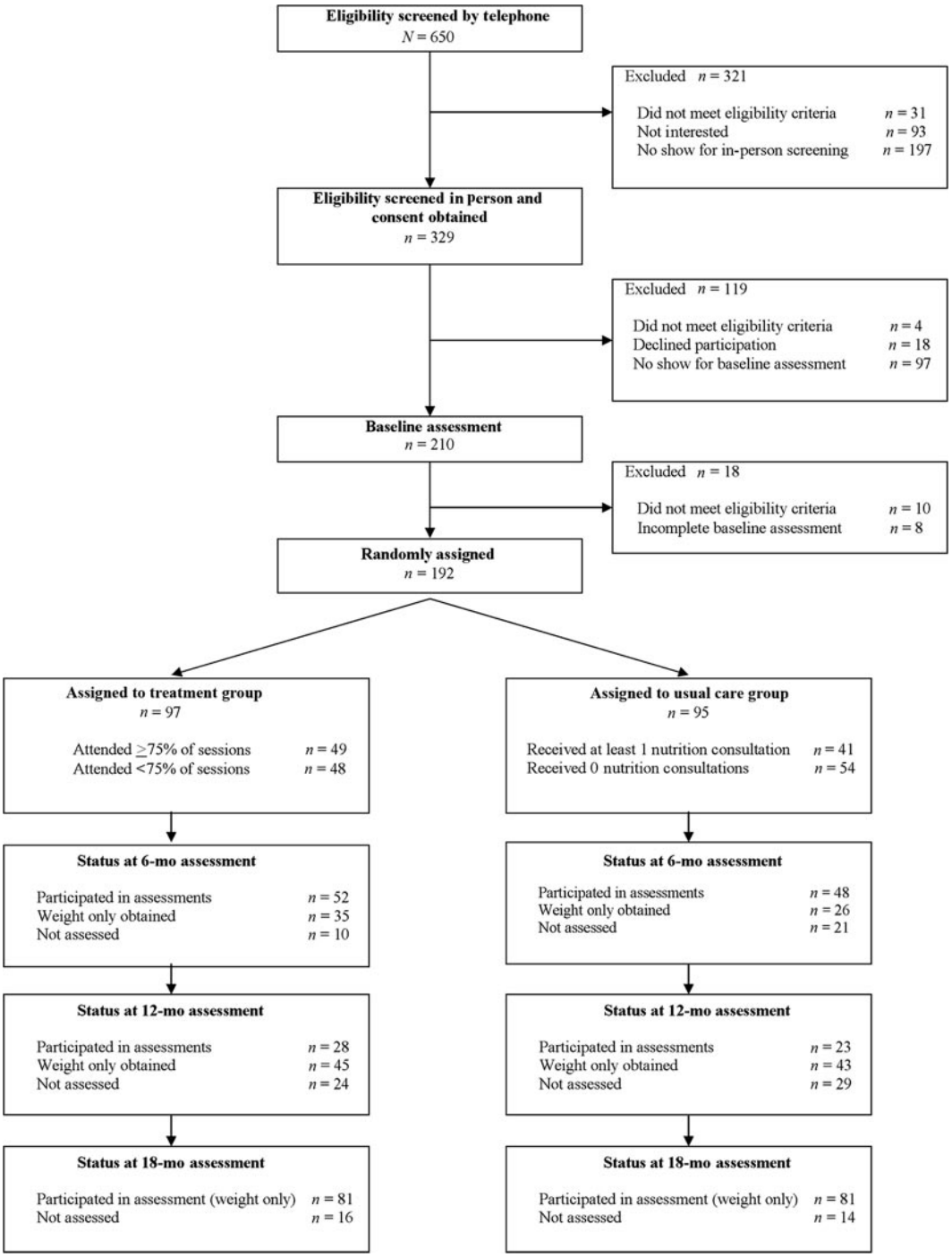

FIGURE 1
Study design and recruitment.

posity in children.[16] Adult BMI was calculated as weight (in kilograms)/(height in meters × height in meters). Adults also completed the general health perceptions and global health subscales of the Child Health Questionnaire, Parent Version (CHQ-PF50),[17] for assessment of health-related quality of life.

Medical assessments were performed at the Pediatric Clinical and Translation Research Center (previously the General Clinical Research Center) at Children's Hospital of Pittsburgh, at baseline, 6 months, and 12 months. Waist circumference was measured at the midpoint between the lowest rib and the iliac crest.[18] Duplicate measurements were

made for a subset of children ($n = 16$) to document reliability, with a Pearson correlation coefficient of 0.90 ($P < .001$). Body composition was determined through dual-energy x-ray absorptiometry with a GE Lunar Prodigy system (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; 3 readings were taken 5 minutes apart while the children were resting. Assessors did not provide the intervention but were not blinded to the treatment condition.

Sample Size and Statistical Analyses

Power computations were performed by using PASS 6.0 (NCSS, Kaysville, UT) and assumed a 2-tailed significance level of .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 dropout rates of 30% projected over the course of the trial.

Descriptive statistics were used to summarize participant demographic characteristics. Independent *t* tests or χ^2 analyses (or Fisher's exact tests) were used to test for differences between treatment conditions at randomization and to compare baseline characteristics of participants lost to follow-up monitoring and participants retained. The proportions of children lost to follow-up monitoring were compared at each time point by using separate χ^2 tests. All hypothesis tests used a 2-tailed level of significance of .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 with usual care, we fit a series of longitudinal models by using SAS mixed models (SAS Institute, Cary, NC) with fixed effects including time (0, 6, 12, and 18 months), group (intervention or usual care), and group-time interaction. For all other end points, 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 or usual care), and group-time interaction. Planned contrasts were set to compare the 2 conditions with respect to 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 by using Cohen's *d*.[19]

The mixed model is an ITT approach, because the analysis includes all subjects with varying numbers of assessments, with the assumption that the incomplete data are missing at random. To examine the missing-at-random assumption and the stability of results, we performed a series of sensitivity analyses that included models with demographic variables, including gender, race (black, white, or other), adult participant education (high school graduate or less, some college, or college graduate or more), and household income (less than $30 000 or $30 000 or more), and excluded children who began to take medications known to affect body weight after random assignment. To evaluate the impact of missing data further, we used models in which subject data were weighted by a function of the probability of being missing. Because the overall pattern of results from sensitivity analyses and weighted models was similar to that from the primary ITT analyses, we report the results of the primary analyses only.

A secondary study objective was to identify factors associated with treatment outcomes. 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 children in the intervention group who obtained an adequate dose of treatment (defined as ≥75% of sessions attended) with those of children in the usual care group. Next, we fit a multivariate linear regression restricted to the intervention group only, to consider session attendance simultaneously with other conceptually relevant covariates. By using backward variable selection, we examined child percent overweight at 6 months (after 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 ($N = 192$) 10.2 ± 1.2 years of age, with an average BMI percentile of 99.18 (SD: 0.72), were assigned randomly to intervention or usual care. Baseline characteristics for child and adult participants are presented in Tables 1 and 2, respectively. Baseline child and adult characteristics did not vary significantly according to group.

The proportions of children lost to follow-up monitoring at 6 months differed according to group (intervention: 13.4%; usual care: 26.3%; $\chi^2 = 5.04$; $P = .02$). However, baseline characteristics of those who did and did not complete the 6-month assessment did not differ. The proportions of noncompleters did not differ according to group at 12 months (intervention: 26.8%; usual care: 36.8%; $\chi^2 = 2.23$; $P = .14$) or at 18 months (intervention: 22.7%; usual care: 17.9%; $\chi^2 = 0.68$; $P = .41$). However, 18-month assessment completers differed from noncompleters with respect to baseline child BMI (31.7 vs 34.0 kg/m^2; $t = -2.14$; $P = .037$), percent overweight (87.4% vs 101.8%; $t = 2.36$; $P =$

TABLE 1 Baseline Characteristics of Study Participants

Characteristic	Intervention	Usual Care	Total	Between-Group *P*
Age, mean ± SD, mo	10.07 ± 1.19	10.30 ± 1.21	10.19 ± 1.20	.18
Weight, mean ± SD, kg	70.17 ± 18.44	72.74 ± 16.63	71.44 ± 17.57	.31
BMI, mean ± SD, kg/m^2	31.71 ± 5.21	32.54 ± 4.67	32.12 ± 4.95	.25
BMI percentile, mean ± SD	99.17 ± 0.60	99.19 ± 0.84	99.18 ± 0.72	.85
Percent overweight, mean ± SD, %	88.61 ± 29.24	92.02 ± 25.90	90.30 ± 27.62	.39
Ethnicity, %				.98
Hispanic	1.05	1.09	1.07	
Non-Hispanic	98.95	98.91	98.93	
Race, %				.61
American Indian/Alaska native	0.00	0.00	0.00	
Native Asian	1.03	0.00	0.52	
Black	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	.76
Systolic blood pressure, mean ± SD, mm Hg	111.2 ± 9.44	113.05 ± 9.87	112.11 ± 9.67	.19
Diastolic blood pressure, mean ± SD, mm Hg	69.18 ± 7.58	69.70 ± 8.73	69.44 ± 8.15	.66
Waist circumference, mean ± SD, cm	70.25 ± 18.44	72.58 ± 16.75	71.40 ± 17.62	.36
Percent fat, mean ± SD, %	45.95 ± 3.92	45.94 ± 3.42	45.95 ± 3.67	.98
Total fat mass, mean ± SD, kg	31.04 ± 8.92	32.19 ± 8.17	31.60 ± 8.56	.37
Total lean mass, mean ± SD, kg	34.08 ± 6.97	35.62 ± 6.89	34.83 ± 6.96	.13
Global health score, parent rating, mean ± SD	71.3 ± 20.1	73.4 ± 17.2	72.3 ± 18.7	.44
General health perceptions score, parent rating, mean ± SD	66.3 ± 17.5	67.4 ± 15.3	68.8 ± 16.4	.62

TABLE 2 Baseline Characteristics of Participating Parents/Guardians and Households

Characteristic	Intervention	Usual Care	Total	Between-Group *P*
Participating parent/guardian age, mean ± SD, y	40.91 ± 6.55	41.27 ± 8.93	41.09 ± 6.53	.63
Parent/guardian BMI, mean ± SD, kg/m^2	35.60 ± 9.20	34.76 ± 8.93	35.08 ± 8.98	.57
Female participating parent, %	91.75	92.63	92.19	.82
Participating parent education, %				.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, %				.94
$0–30 000	26.80	26.32	26.56	
$30 001 or more	73.20	73.68	73.44	
No. of people in household, mean ± SD	4.03 ± 1.18	4.01 ± 1.18	4.02 ± 1.18	.91

.023), and number of people in the household (4.11 vs 3.67 persons; $t = 2.13$; $P = .035$).

Primary Analyses (ITT)

Results for children, including observed and modeled means, are shown in Fig 2. Percent overweight values remained relatively stable in the usual care group, compared with a decrease in the intervention group. Results for medical outcomes, including systolic blood pressure, diastolic blood pressure, percent body fat, and waist circumference, are shown in Fig 3.

For total body fat, there were significant effects of group ($F_{1,167} = 5.90$; $P = .016$), time ($F_{2,614} = 16.71$; $P = .003$), and group-time interaction ($F_{2,614} = 5.75$; $P = .039$) (data not shown). For total fat-free mass, there were effects of group ($F_{1,196} = 4.38$; $P = .038$) and time ($F_{2,343} = 53.85$; $P < .0001$). For the CHQ-PF50 general health subscale, there were effects of time ($F_{2,227} = 6.58$; $P = .002$) and group-time interaction ($F_{2,227} = 3.97$; $P = .02$). For participating adult BMI, there were significant effects of time ($F_{2,196} = 6.67$; $P = .002$) and group-time interaction ($F_{2,196} = 7.62$; $P = .0007$).

Planned contrasts indicated that differences in percent overweight were significant at 6 months only (Table 3). Significant effects for other outcomes, except for CHQ-PF50 global health scores, persisted through 12 months.

Secondary Analyses

Among children assigned randomly to the intervention group, the mean number of sessions attended was 12.6 (SD: 5.6 sessions), and 50% of children ($n =$

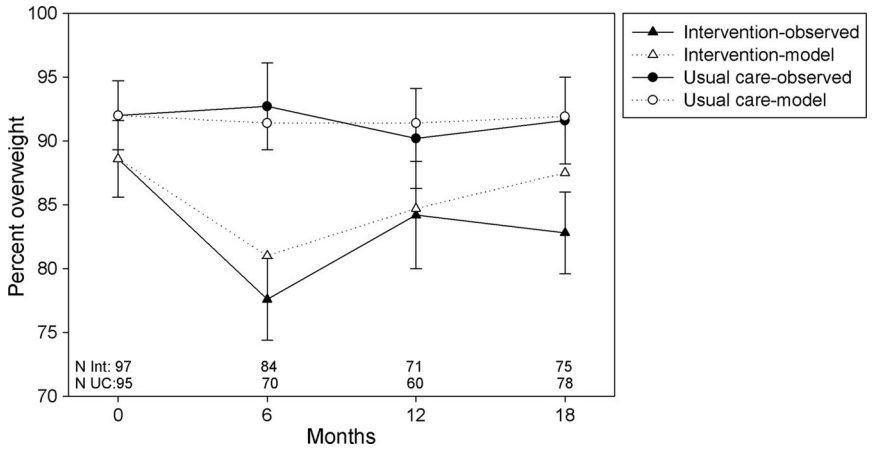

FIGURE 2
Changes in child percent overweight over time (ITT analysis). Int indicates intervention; UC, usual care. Note. There were significant effects for time ($F_{3, 405} = 6.61$, $P = .0002$) and group by time ($F_{3, 405} = 4.61$, $P = .004$).

49) received an adequate dose of treatment, defined as attendance at 15 (75%) of 20 sessions. Weight trajectories of children in the intervention group who received an adequate dose of treatment, compared with children in the usual care group, are presented in Fig 4. Planned contrasts indicated that differences in percent overweight were significant at 6 months ($P = .0001$), 12 months ($P = .0004$), and 18 months ($P = .02$).

Finally, we examined factors associated with 6-month outcomes 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 ($\beta = 0.91 \pm 0.04$; $P < .001$), higher income ($\beta = -5.57 \pm 2.43$; $P = .025$), more treatment sessions attended ($\beta = -0.82 \pm 0.2$; $P < .001$), and decrease in adult BMI during treatment ($\beta = 1.68 \pm 0.57$; $P = .004$).

DISCUSSION

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 care of severely obese, school-aged children. Overall, our results documented favorable 6-month (posttreatment) changes in percent overweight and 12-month improvements in medical risk parameters among study participants. Specifically, children in the intervention group showed a 7.58% decrease in percent overweight at the completion

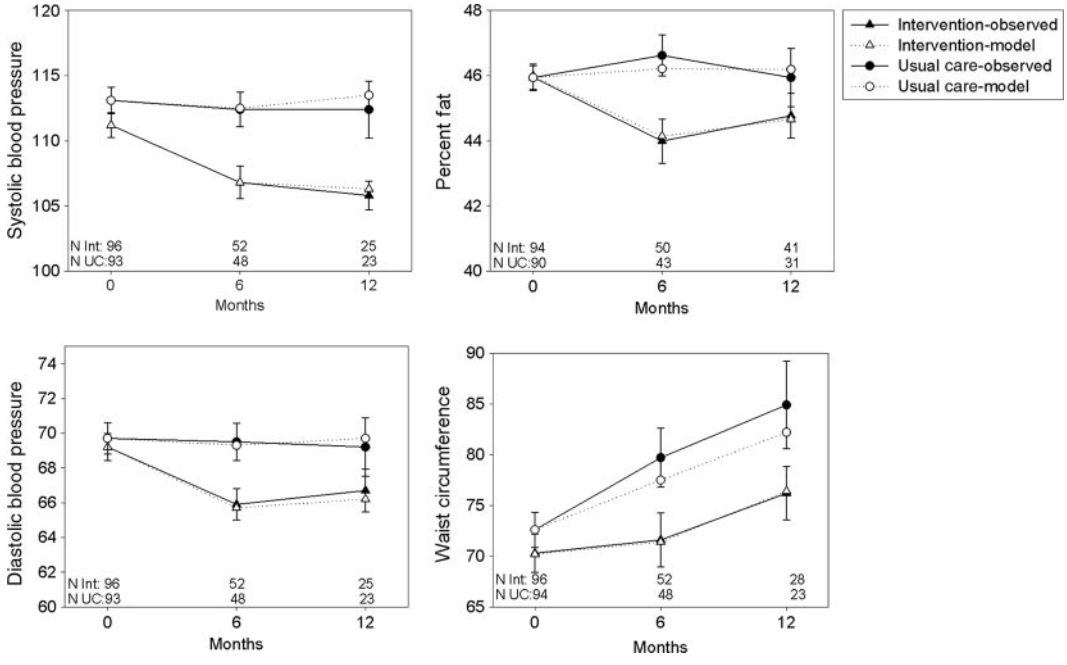

FIGURE 3
Changes in child medical outcomes over time. BP indicates blood pressure; DEXA, dual-energy x-ray absorptiometry; Int, intervention; UC, usual care. Notes. For systolic blood pressure there were effects for group ($F_{1, 202} = 13.25$, $P = .0003$), time ($F_{2, 182} = 3.82$, $P = .024$) and group by time ($F_{2, 182} = 3.07$, $P = .049$) and diastolic blood pressure an effect for group ($F_{198} = 5.61$, 1, $P = .019$). For total body fat, there was also a significant effect group ($F_{1, 167} = 5.90$, $P = .016$), time ($F_{2, 6.14} = 16.71$, $P = .003$) and group by time ($F_{2, 6.14} = 5.75$, $P = .039$). For waist circumference, there was a significant effect for time ($F_{2, 145} = 68.51$, $P < .0001$) and group by time ($F_{2, 145} = 7.53$, $P = .0008$).

TABLE 3 Modeled Changes in Outcomes, According to Group, Over Time

Outcome	Change, Mean ± SE		Treatment Effect, Mean ± SE	Effect Size (Cohen's *d*)	Between-Group *P*
	Intervention	Usual Care			
Weight, kg ($N = 192$)					
6 mo	1.56 ± 0.68	4.76 ± 0.57	−3.20 ± 0.89	0.51	.0003
12 mo	6.92 ± 0.72	9.22 ± 0.59	−2.30 ± 0.94	0.34	.014
18 mo	11.77 ± 0.70	13.35 ± 0.55	−1.58 ± 0.89	0.25	.077
BMI, kg/m^2 ($N = 192$)					
6 mo	−0.68 ± 0.29	0.54 ± 0.21	−1.22 ± 0.36	0.48	.0007
12 mo	0.48 ± 0.30	1.09 ± 0.23	−0.61 ± 0.38	0.22	.11
18 mo	1.50 ± 0.30	1.72 ± 0.21	−0.21 ± 0.36	0.08	.56
Percent overweight, % ($N = 192$)					
6 mo	−7.58 ± 1.59	−0.66 ± 1.17	−6.92 ± 1.98	0.49	.0005
12 mo	−3.91 ± 1.69	−0.62 ± 1.24	−3.29 ± 2.10	0.22	.12
18 mo	−1.16 ± 1.66	−0.17 ± 1.12	−0.99 ± 2.01	0.07	.62
Parent BMI, kg/m^2 ($N = 188$)					
6 mo	−1.19 ± 0.24	−0.01 ± 0.25	−1.18 ± 0.35	0.47	.001
12 mo	−0.67 ± 0.28	0.62 ± 0.29	−1.29 ± 0.40	0.45	.002
Waist circumference, cm ($N = 192$)					
6 mo	1.11 ± 0.82	4.94 ± 0.65	−3.83 ± 1.04	0.51	.0003
12 mo	6.18 ± 1.05	9.59 ± 0.87	−3.41 ± 1.36	0.35	.014
Systolic blood pressure, mm Hg ($N = 190$)					
6 mo	−4.47 ± 1.34	−0.59 ± 1.43	−3.87 ± 1.96	0.29	.049
12 mo	−4.88 ± 1.79	0.42 ± 1.93	−2.96 ± 5.30	0.29	.045
Diastolic BP, mm Hg ($N = 190$)					
6 mo	−3.48 ± 1.08	−0.37 ± 1.34	−3.12 ± 1.72	0.25	.072
12 mo	−2.96 ± 1.44	−0.01 ± 1.80	−2.96 ± 2.30	0.18	.20
Percent fat, % ($N = 186$)					
6 mo	−1.86 ± 0.45	0.27 ± 0.43	−2.13 ± 0.63	0.49	.0008
12 mo	−1.33 ± 0.49	0.25 ± 0.49	−1.58 ± 0.69	0.33	.024
Total fat mass, kg ($N = 186$)					
6 mo	−0.41 ± 0.87	2.50 ± 0.35	−2.91 ± 0.94	0.43	.021
12 mo	1.73 ± 0.95	4.20 ± 0.39	−2.46 ± 1.03	0.34	.051
Total lean mass, kg ($N = 186$)					
6 mo	1.85 ± 0.60	2.51 ± 0.38	−0.66 ± 0.71	0.13	.36
12 mo	3.66 ± 0.66	4.21 ± 0.43	−0.54 ± 0.78	0.10	.49
Global health score, parent rating ($N = 192$)					
6 mo	6.55 ± 2.10	−0.28 ± 2.39	6.84 ± 3.17	0.30	.032
12 mo	4.13 ± 2.49	0.48 ± 2.84	3.65 ± 3.77	0.14	.33
General health perceptions score, parent rating ($N = 192$)					
6 mo	6.88 ± 1.54	0.46 ± 1.71	6.42 ± 2.30	0.39	.006
12 mo	5.71 ± 1.81	1.83 ± 1.96	3.87 ± 2.67	0.20	.15

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 for other randomized, controlled trials. For example, a meta-analysis of 14 randomized, controlled trials of lifestyle interventions for pediatric obesity[20] documented an average decrease in percent overweight of 8.2% after 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 moderately overweight.[9] A recent investigation did focus on an older group (~12 years, compared with 10 years in the present study) of severely obese youths.[21] In that study, children were assigned randomly to a weight management program that included behavioral modification sessions and supervised exercise or to usual clinical management. Duration and intensity were greater than in the present investigation, in that participants attended twice-weekly sessions for 6 months and biweekly sessions for an additional 6 months. At month 6, treatment was associated with significant decreases in BMI (−2.1 kg/m^2, compared with −0.7 kg/m^2 in the current study) and insulin resistance.[21] Therefore, available data indicate that severely obese youths achieve short-term changes in BMI that are comparable to those observed with other behavioral interventions.

The changes in percent overweight were not well maintained in the period after intervention in the current study. Child participants in the intervention group exhibited increases in percent overweight and BMI in the 1-year period after weekly intervention, whereas children in the

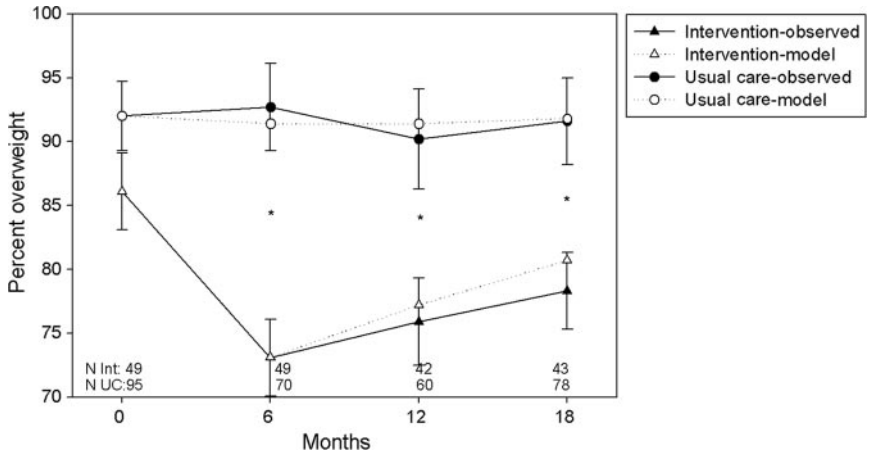

FIGURE 4

Changes in child percent overweight over time (completers). Int indicates intervention; UC, usual care. Note. There were significant effects for group ($F = 9.34$, df = 1, 123, $p = .0027$), time ($F_{3, 235} = 14.25$, $P = .001$ and group by time ($F_{3, 235} = 11.40$, $P = .0001$).

usual care group maintained a stable degree of overweight, such that the study groups did not differ significantly in percent overweight at the 12- and 18-month assessments. This finding is in contrast to results reported in the literature,[20] where, on average, the effects of family-based interventions were sustained over follow-up periods ranging from 1 month to 5 years after treatment. Weight loss maintenance in severely obese children is of particular importance, given their level of medical risk. Results of the study by Savoye et al[21] also raise concerns about weight loss maintenance in severely obese children. In that investigation, the BMI among participants in the treatment group also increased during the second 6 months, despite ongoing biweekly intervention sessions.

Although the impact on percent overweight was modest, the intervention had positive effects on other health-related parameters that were sustained at 12 months. Specifically, children who received family-based, weight management, compared with 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 youths.[18] Therefore, the effects of the 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; therefore, we cannot attribute outcomes to the specific components of the family-based intervention. Next, the prevalence of severe pediatric obesity varies according to gender and race/ethnicity, with highest rates being observed among Hispanic boys and black girls.[2] Because there were no Hispanic youths in the current study, results may be most applicable to white and black boys and girls. Furthermore, youths 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, which suggests that replication is needed before firm conclusions about medical outcomes can be drawn.

CONCLUSIONS

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 the changes in percent overweight were modest, given the severity of obesity, the significant health benefits of the 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 relationship between attendance and weight control, the present findings suggest the potential importance of strategies to promote and to facilitate program adherence. Larger reductions in adult BMI were associated with more-successful outcomes, which indicates that working 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; therefore, families with financial strain may benefit from strategies to reduce intervention cost burden. Finally, children with 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 monitoring at 18 months, which suggests 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 difficult. 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 to sustain weight control efforts and to mitigate health risk. Family-based intervention should 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 changes.

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