Effects of a Weight Management Program on Body Composition and Metabolic Parameters in Overweight Children

A Randomized Controlled Trial

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Context Pediatric obesity has escalated to epidemic proportions, leading to an array of comorbidities, including type 2 diabetes in youth. Since most overweight children become overweight adults, this chronic condition results in serious metabolic complications by early adulthood. To curtail this major health issue, effective pediatric interventions are essential.

Objective To compare effects of a weight management program, Bright Bodies, on adiposity and metabolic complications of overweight children with a control group.

Design One-year randomized controlled trial conducted May 2002-September 2005.

Setting Recruitment and follow-up conducted at Yale Pediatric Obesity Clinic in New Haven, Conn, and intervention at nearby school.

Participants Random sample of 209 overweight children (body mass index [BMI] >95th percentile for age and sex), ages 8 to 16 years of mixed ethnic groups were recruited. A total of 135 participants (60%) completed 6 months of study, 119 (53%) completed 12 months.

Intervention Participants were randomly assigned to either a control or weight management group. The control group (n=69) received traditional clinical weight management counseling every 6 months, and the weight management group (n=105) received an intensive family-based program including exercise, nutrition, and behavior modification. Intervention occurred biweekly the first 6 months, bimonthly thereafter. The second randomization within the weight management group assigned participants (n=35) to a structured meal plan approach (dieting), but this arm of the study was discontinued while enrollment was ongoing due to a high dropout rate.

Main Outcome Measures Change in weight, BMI, body fat, and homeostasis model assessment of insulin resistance (HOMA-IR) at 6 and 12 months.

Results Six-month improvements were sustained at 12 months in weight management vs control, including changes in the following (mean [95% confidence interval]): weight (+0.3 kg [–1.4 to 2.0] vs +7.7 kg [5.3 to 10.0]); BMI (–1.7 [–2.3 to –1.1] vs +1.6 [0.8 to 2.3]); body fat (–3.7 kg [–5.4 to –2.1] vs +5.5 kg [3.2 to 7.8]); and HOMA-IR (–1.52 [–1.93 to –1.01] vs +0.90 [–0.07 to 2.05]).

Conclusion The Bright Bodies weight management program had beneficial effects on body composition and insulin resistance in overweight children that were sustained up to 12 months.

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THE PREVALENCE OF OVERweight among children and adolescents increased significantly from 1999-2004, with 17% overall defined as overweight and with an even higher prevalence among African American youth (18%-26%).[1] Attention has focused on the increase of type 2 diabetes in adolescents that has accompanied the epidemic of childhood obesity, which is due to a combination of severe insulin resistance and progressive beta-cell failure, and is more common in African American and Hispanic youth.[2,3] However, an even greater proportion of obese children have impaired glucose tolerance,[4] as well as hypertension, dyslipidemia, and other components of the metabolic syndrome.[3,5] Since an overweight child has a high probability of becoming an overweight adult,[6] the grave concerns for the long-term health of obese children are well justified.

While intensive lifestyle programs can have positive clinical outcomes in adults,[7] few studies have reported successful interventions in children and

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adolescents. Treatment modalities for children present a unique challenge as nutrition education, physical activity, and behavior modification must be presented to both the parent or caregiver and child, with the parent or caregiver being the major agent of change in the family.[8] Comprehensive family-based programs that have reported positive long-term outcomes had limited participation of minority youth.[9-11]

The Yale Bright Bodies Weight Management Program (www.brightbodies.org) is a family-based, intensive lifestyle intervention that has been specially tailored for the needs of inner-city minority children. In a nonrandomized pilot study, we showed that this intervention could achieve a sustained decrease in body mass index (BMI) for 2 years.[12] In that study, adolescents who were educated about better food choices of moderate portion sizes were more successful long-term than teenagers who were given a structured meal plan diet.[12]

The current randomized clinical trial was undertaken to further evaluate the efficacy of the weight management program in comparison to routine care provided by our pediatric obesity clinic. While the major aim of the study was to compare changes in BMI, body composition, insulin sensitivity, blood pressure, and lipid profiles, a secondary aim was to compare nutrition components by randomizing families in the weight management group to either the better food choices or structured meal plan approaches. However, due to a high dropout rate in participants randomized to the structured meal plan approach, that arm was eliminated halfway through enrollment.

METHODS

Participants

Participants were recruited from the Yale Pediatric Obesity Clinic. Criteria for participation included a BMI above the 95th percentile based on the Centers for Disease Control and Prevention (CDC) growth chart,[13] age 8 to 16 years old, and English-speaking ability. Participants had to show an interest in the weight management program and have a caregiver (eg, father, mother, or grandparent) who was willing to participate in the educational component of the program. Participants were excluded if they had diabetes, a psychiatric disorder (eg, schizophrenia, severe autism or mental retardation, or psychosis), or other serious medical condition that would preclude participation in the program. Participants taking medications that potentially cause significant weight gain (eg, risperidone, olanzapine, clozopine) were also excluded, as well as participants using medications for weight loss or involved in a coexisting weight management program. Participants randomized to the control group were guaranteed participation in the weight management program after completion of the 12-month randomized study period. Coinvestigators classified individuals' race/ethnic groups based on participant's responses. Race/ethnicity was assessed in the study because of interest in program efficacy on minority population. The study was approved by the Yale Human Investigation Committee and written informed assent and consent were obtained from participants and parents.

Research Design

This study was a parallel-group, randomized controlled trial to compare the effects of the Bright Bodies weight management program with conventional clinic management. Participants were randomized (2:1) to either the weight management program or control groups. Initially, a second randomization (1:1) occurred within the weight management group to explore differences in the type of diet intervention children received (ie, structured meal plan vs better food choices). However, randomization to the structured meal plan group was discontinued due to a 83% dropout rate at 6 months in the first 35 participants in this group (data not shown). Thereafter, we continued to randomize 2:1 between the weight management and control groups but discontinued the second randomization.

Study Groups

Bright Bodies Weight Management Group. Participants randomized to the weight management group attended the program twice a week for 6 months and then every other week for an additional 6 months. During the first 6 months, the program consisted of exercise twice (50 minutes each) and nutrition/behavior modification once (40 minutes each) per week. Participants and caregivers attended all classes, including nutrition-related topics, together, but behavior modification classes for participants and caregivers were held separately. Participants were weighed every 1 to 2 weeks during the first 6 months and every 2 weeks for the last 6 months. Caregivers were also encouraged to be weighed.

The behavior modification component of the weight management program was facilitated by the registered dietitian or social worker. Topics were provided from the *Smart Moves Workbook*, a curriculum developed for overweight children and used in our pilot study.[12] Sample topics included "Ready, Set, Goal!," "Risky Business: Identifying High-risk Situations," "Environmental Engineering," "Mirror, Mirror on the Wall," "Bullies, Teasers, and Other Annoying People," and "Oops I Slipped—Understanding a Relapse." Techniques included self-awareness, goal setting, stimulus control, coping skills training (CST), cognitive behavior strategies, and contingency management. Behavior modification classes for caregivers included topics that reflected the challenges parents verbalized. Coping skills training was the primary technique used as it has been used for the treatment of other chronic conditions, including diabetes.[14] These classes emphasized the importance of the parents' role in modeling healthy behavior change. A pilot study using CST with overweight parents of children in our weight management program showed positive outcome trends for parents when comparing those with and without CST.[15]

The exercise component of the weight management program was facilitated by exercise physiologists. Each class consisted of a warm-up, high-intensity aerobic exercise, and a cool-down. The high-intensity exercise consisted of a large variety of games such as Swim Fish Swim, obstacle courses, basketball, flag football, sprinting games, and basic sport drills. The program also used Dance Dance Revolution (Konami, Redwood City, Calif, using Sony Playstation, Sony Corporation of America, New York, NY), in which children followed dance patterns and competed with each other. The main objective of the high-intensity exercise was to sustain 65% to 80% of the age-adjusted maximal heart rate for the duration of the exercise. To ensure this, a heart rate monitor (Polar USA, Dartmouth, Mass) was worn by all participants and Borg's Perceived Exertion Scale[16] was used to monitor exertion. Participants were also encouraged to exercise 3 additional days at home per week and to decrease sedentary behaviors. The minimum activity that each participant completed was 100 minutes per week (two 50-minute sessions) for the first 6 months and 100 minutes twice per month for the last 6 months. Motivational tools were used to encourage regular attendance. One example was a game in which the children accumulated points for each exercise class or activity attended throughout the program.

The nutrition education component of the weight management program used a nondiet approach that emphasized low-fat, nutrient-dense foods of moderate portion sizes. Topics included "Determining Portion Sizes," "Better Food Choices: A Non-Diet Approach," "Making Sense of a Food Label," "Bag It!—The Pros to Bringing Lunch to School," and "Recipes Dear to Our Heart: Ingredient Substitutions for Traditional Recipes." The registered dietitians used the *Smart Moves Workbook,* which provided consistent structure for all class topics.

Control Group. The control group participants were seen in the pediatric obesity clinic every 6 months and received diet and exercise counseling by registered dietitians and physicians along with brief psychosocial counseling by a social worker. Nutrition counseling included decreasing intake of juice, switching to diet beverages, switching from whole to low-fat milk, and bringing lunch to school vs choosing hot lunch. Exercise counseling included decreasing sedentary activities (computer and video games) and finding an activity the participant enjoyed enough to engage in on a regular basis. The participant and caregiver were both involved in setting the nutrition and activity goals to ensure that the clinic plan was realistic and accepted by both.

Outcomes

Outcome measures were obtained at baseline, 6, and 12 months in both the weight management and control groups in the obesity clinic facility using the same scales and instruments.

Weight was measured (with participant in socks with no shoes and wearing a light gown) in kilograms to the nearest 0.1 kg using a medical weight scale (model CN20, Detecto, a division of Cardinal Scale Manufacturing Co, Webb City, Mo), zeroed and calibrated before each weight. A stadiometer (Harpenden, Cambridge, Md), calibrated in 0.1-cm intervals, was used to determine height. Body mass index was calculated as the weight in kilograms divided by height in meters squared. Percent body fat was determined by a body fat analyzer (Tanita, TBF 300, Tanita Corp of America, Inc, Arlington Heights, Ill). This method for estimating percentage of body fat has a high correlation with dual-energy x-ray absorptiometry in children,[17] including African American and Hispanic children (Caprio Research Group, Yale University School of Medicine, ongoing validation, unpublished data). Total body fat was calculated by multiplying the percent body fat by actual weight in kilograms.

Blood pressure was measured automatically with a sphygmomanometer (Model 01-752, American Diagnostics, Hauppauge, NY) 3 times after participants sat still for at least 5 minutes; second and third measurements were averaged for analysis.

Blood samples were obtained after a 10-hour overnight fast for measurement of plasma glucose, insulin, total cholesterol, high-density lipoprotein cholesterol, low-density lipoprotein cholesterol, and triglyceride levels. Plasma glucose levels were measured with a chemistry analyzer (YSI 2700 STAT Analyzer, Yellow Springs Instruments, Yellow Springs, Ohio) and plasma insulin levels were measured by radiommunoassay (Linco Laboratories, St Charles, Mo). Plasma lipid levels were measured with an autoanalyzer (AutoAnalyzer, model 747-200, Roche-Hitachi, Indianapolis, Ind).

The homeostasis model assessment of insulin resistance (HOMA-IR) was used to measure change in insulin sensitivity and was calculated using the following formula: fasting plasma insulin [in μIU/mL] + fasting plasma glucose [in mmol/L] ÷ 22.5.[18]

Sample Size and Statistical Analysis

For the purpose of sample size estimation, the primary outcome of this study was change in BMI between baseline and 6 months. Our database of over 600 overweight children between the ages of 8 and 16 years estimates an SD for BMI of 6.8. Conservatively assuming a correlation of 0.75 between BMI at baseline and 6 months, a 2-sided .017 significance level and an SD of 7, a sample size of 58 participants per group would provide 80% power to detect a treatment difference of 3. We planned to enroll 70 participants per group to account for a 20% dropout. Dropping the structured meal plan arm of the weight management group allowed us to increase the sample size of the better food choices arm of this group.

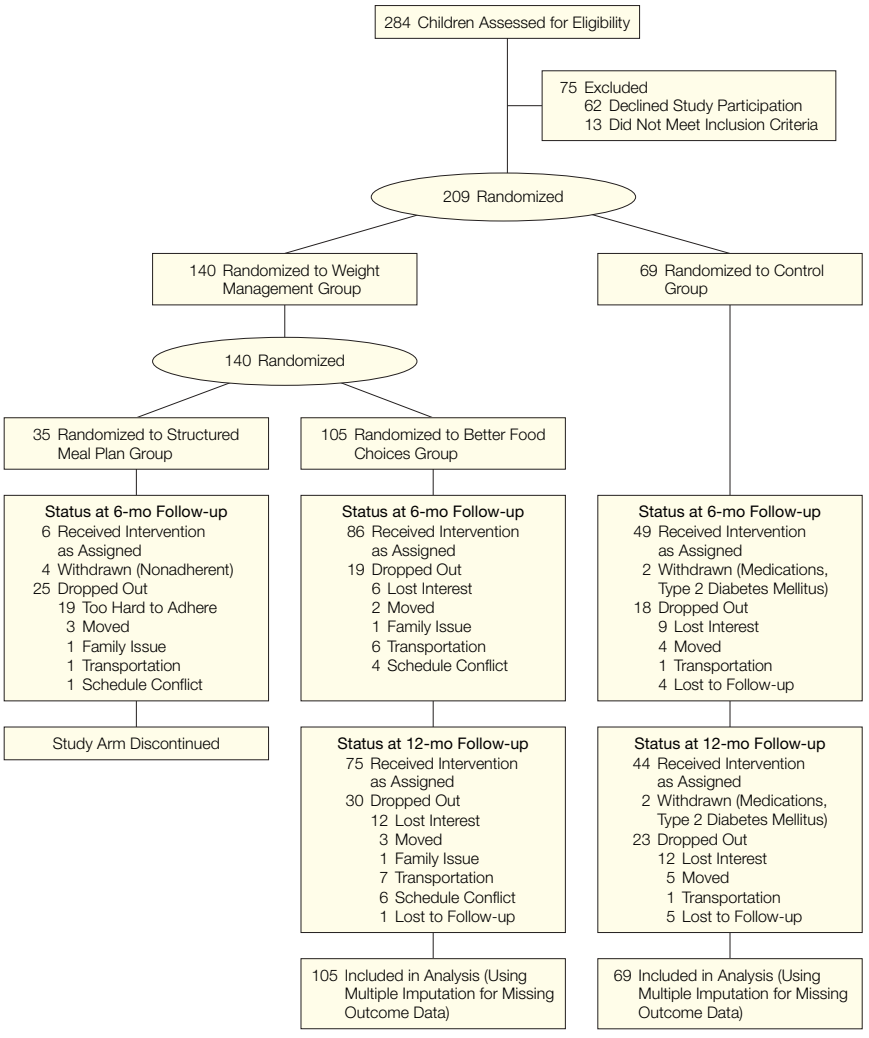
An intent-to-treat analysis was performed. Changes in outcomes were compared between treatments using a mixed effects model with covariate adjustment for baseline outcome. Treatment assignment and time (6 and

12 months) and treatment × time interaction were included as fixed effects. For positively skewed variables, log transformations were used prior to analysis. Mean changes and 95% confidence intervals (CIs) derived from the mixed models are presented.

Multiple imputation with data augmentation under the multivariate normal model using PROC MI from SAS[19] was performed to impute missing outcome data. The details of this process are described by Allison.[20 (pp27-50)] The imputation was conducted on continuous missing data with log transformations applied for normality where necessary. Baseline, 6-, and 12-month outcome measures were included in the imputation model along with age, sex, race, and treatment. Five imputations using a sequential chain of iterations with a burn in of 200 iterations followed by 100 iterations between successive imputations were performed. Following imputation, each "filled-in" data set was analyzed separately using a mixed model and parameter estimates were averaged across data sets. Variance estimates included both a within-imputation and an across-imputation component.

At 6 and 12 months, values were imputed for 39 (22%) and 55 (32%) participants, respectively. The assumption of this multiple imputation process is that data are missing at random, ie, missing observations may depend on values of observed data but are conditionally independent of unobserved values. Similar models were evaluated without multiple imputation using either all participants with at least 1 postrandomization assessment (weight management group, n=86; control group, n=49), participants who completed both 6-month and 12-month assessments (weight management group, n=75; control group, n=44), or participants with single imputation by last observation carried forward (LOCF). These separate analyses had little effect on treatment estimates and therefore only results from the multiple imputation analysis are presented. $P<.05$ was considered statistically significant.

Figure 1. Flowchart for Enrollment, Randomization, and Follow-up of Study Participants



RESULTS

Participants

Of the 284 children assessed for eligibility (FIGURE 1), 8 were taking medications known to result in weight gain, 1 was taking a thyroid medication, and 4 were already involved in a weight management program. Sixty-two families declined to participate. The remaining 209 participants were randomized 2:1 to the weight management or control group.

Participants in the weight management group were further randomized 1:1 to the structured meal plan or better food choices groups. This second randomization was discontinued due to a high dropout rate in the structured meal plan group; only 6 of the 35 structured meal plan participants completed the first 6 months of the study. Only those participants randomized to the control group (n=69) or weight management plus better food choices group (n=105) were included in this analysis. The number of participants in each group completing 6 and 12 months of the study are shown in Figure 1. There was no statistical significance in dropout rates among ethnic groups, although minority participants had a somewhat greater retention than white participants.

As shown in TABLE 1, randomization produced similar distributions of baseline characteristics in the 2 groups and there were no significant differences in these variables in the participants who completed the 12 months of the study. Children in the control group weighed slightly more but were also taller than children in the weight management group. Among all randomized participants, baseline total cholesterol and glucose levels were higher in the weight management vs control group, but the differences did not achieve statistical significance. The middle 50% of participants' BMIs were between 31.3 and 39.9.

Effects of Treatment

Changes in BMI, body weight, and body fat are shown in TABLE 2 and FIGURE 2. Although mean body weight was essentially unchanged from baseline after 12 months in the weight management group (+0.3 [95% CI, –1.4 to 2.0] kg), BMI change was –1.7 (95% CI, –2.3 to –1.1] due to continued growth in height. It should be noted there were no differences in changes in height between the control and weight management groups at 6 and 12 months. Percent body fat and total body fat were also reduced in the weight management group. In contrast, BMI, body weight, and percent and total body fat increased in the control group. The difference between the 2 groups in changes in BMI (–3.3), body weight (–7.4 kg), body fat (–9.2 kg), and percent body fat (–6.0%) after 12 months were significantly different ($P<.001$).

Circulating concentrations of total cholesterol decreased in the weight management group and increased in the control group ($P=.05$ at 6 months and $P=.005$ at 12 months) (Table 2). However, there were no significant differences in changes in other lipid levels or blood pressure between the weight management and control groups.

As shown in Table 2, there was a small, not significantly different, reduction in fasting glucose concentrations in both groups during the study. Mean fasting plasma insulin concentration fell by 6.5 µIU/mL at 6 months and 6.1 µIU/mL at 12 months in the weight management group but increased in the control group. The differences in changes in HOMA-IR between weight management and control participants at 6 (–1.51 vs +0.33) and 12 months (–1.52 vs +0.90) were significant ($P<.001$).

Table 1. Baseline Characteristics of Children Randomized to Weight Management and Control Groups*

	All Randomized Participants			Completers		
Characteristics	Weight Management Group (n = 105)	Control Group (n = 69)	*P* Value	Weight Management Group (n = 75)	Control Group (n = 44)	*P* Value
Race/ethnic group, No. (%)						
Non-Hispanic white	40 (38.1)	24 (34.8)	.89	25 (33.8)	16 (36.4)	.95
Non-Hispanic black	40 (38.1)	27 (39.1)		27 (36.5)	16 (36.4)	
Hispanic	25 (23.8)	18 (26.1)		22 (29.7)	12 (27.3)	
Sex, No. (%)						
Female	59 (56.2)	47 (68.1)	.11	42 (56.8)	27 (61.4)	.62
Male	46 (43.8)	22 (31.8)		32 (43.2)	17 (38.6)	
Age, y	11.9 (2.5)	12.4 (2.3)	.19	12.0 (2.4)	12.2 (2.1)	.71
Weight, kg	87.0 (25.1)	91.2 (23.3)	.26	87.9 (26.1)	88.9 (22.0)	.82
Height, cm	155.2 (11.6)	157.7 (11.6)	.17	155.3 (10.1)	157.4 (11.1)	.30
BMI	35.8 (7.6)	36.2 (6.2)	.73	35.9 (7.9)	35.4 (5.3)	.68
Body fat, %	47.0 (8.7)	45.8 (7.2)	.35	47.6 (9.0)	46.2 (7.9)	.40
Body fat mass, kg	42.1 (18.1)	42.4 (14.9)	.91	43.2 (19.9)	41.8 (15.3)	.69
Blood pressure, mm Hg						
Systolic	123 (13.6)	122 (14.0)	.75	123 (14.7)	122 (14.8)	.68
Diastolic	66 (9.5)	67 (11.1)	.67	65 (9.7)	65 (11.5)	.88
Cholesterol, mg/dL						
Total	167 (34.5)	158 (35.5)	.07	170 (38.2)	164 (37.2)	.43
HDL	44 (10.8)	43 (16.5)	.78	42 (9.9)	43 (18.5)	.83
LDL	98 (33.4)	92 (27.9)	.15	100 (36.5)	96 (30.6)	.45
Triglycerides, mg/dL†	104 (1.8)	101 (1.6)	.78	110 (1.8)	108 (1.7)	.89
Fasting glucose, mg/dL	92 (8.3)	90 (8.5)	.09	92 (8.0)	90 (8.1)	.25
Fasting insulin, µIU/mL†	23 (1.8)	24 (1.7)	.77	24 (1.7)	25 (1.6)	.90
HOMA-IR†	5.07 (1.87)	5.23 (1.7)	.73	5.46 (1.79)	5.37 (1.69)	.87

Abbreviations: BMI, body mass index, calculated as weight in kilograms divided by height in meters squared; HDL, high-density lipoprotein; HOMA-IR, homeostasis model assessment of insulin resistance; LDL, low-density lipoprotein.
SI conversion factors: To convert total, HDL, and LDL cholesterol to mmol/L, multiply by 0.0259; triglycerides to mmol/L, multiply by 0.0113; and glucose to mmol/L, multiply by 0.0555.
*Data are presented as mean (SD) unless otherwise indicated.
†Data are presented as geometric means with geometric SDs.

There were no differences in any outcome measures between ethnic groups and sexes.

COMMENT

As illustrated by the outcomes in the control group in this study, simple education about health risks of obesity and routine counseling regarding diet and exercise are insufficient to prevent the seemingly inexorable increases in BMI, body weight, and body fat observed in traditionally treated overweight children.[21] Cross-sectional data indicate that 9- to 12-year-old children at the 95th percentile of body weight will gain 5 to 7 kg annually,[22] which is very similar to what was observed in our control participants.

The Bright Bodies program was developed to meet the challenge of managing overweight children, and several of its components were tested in pilot studies in our overweight clinic population.[12,15,23] Because the majority of our patients are low-income, inner-city minority youth, educational materials, behavior modification techniques, and exercise components were developed to be accessible to all members of our multiethnic population. The ability of the Bright Bodies program to lower BMI over 2 years was demonstrated in a nonrandomized pilot study.[12] However, a randomized trial was needed to fully evaluate the beneficial effects of this program.

When viewed in isolation, the impact of the Bright Bodies program on body weight, BMI, and body composition was highly favorable: essentially no weight gain over 12 months, a 4% (3.7 kg) reduction in body fat, and a modest fall in BMI. When viewed in comparison with the increases in all of these parameters in the control group, the benefits of the program are even more impressive. Improvements from the Bright Bodies program achieved during the first 6 months of intensive follow-up were sustained during the

Table 2. Changes in Body Composition, Cardiovascular, and Insulin Sensitivity Parameters for Weight Management and Control Groups at 6 and 12 Months*

		Mean (95% Confidence Interval)			
Outcome	Month	Weight Management Group	Control Group	Treatment Effect (Intervention – Control)†	Between-Group *P* Value
Weight, kg	6	–2.6 (–4.2 to –0.9)	5.0 (2.9 to 7.2)	7.6 (4.3 to 10.8)	<.001‡
	12	0.3 (–1.4 to 2.0)	7.7 (5.3 to 10.0)	7.4 (4.2 to 10.6)	<.001‡
BMI	6	–2.1 (–2.6 to –1.5)	1.1 (0.4 to 1.8)	3.1 (2.1 to 4.2)	<.001‡
	12	–1.7 (–2.3 to –1.1)	1.6 (0.8 to 2.3)	3.3 (2.1 to 4.3)	<.001‡
Body fat, %	6	–3.2 (–4.3 to –2.1)	2.0 (0.6 to 3.5)	5.2 (3.5 to 7.0)	<.001‡
	12	–4.0 (–5.2 to –2.8)	2.0 (0.5 to 3.5)	6.0 (4.2 to 7.8)	<.001‡
Estimated body fat mass, kg	6	–4.1 (–5.7 to –2.6)	4.4 (2.2 to 6.5)	8.5 (5.7 to 11.3)	<.001‡
	12	–3.7 (–5.4 to –2.1)	5.5 (3.2 to 7.8)	9.2 (6.4 to 12.0)	<.001‡
Blood pressure, mm Hg					
Systolic	6	–2.2 (–4.6 to 0.3)	0.3 (–2.7 to 3.2)	–2.4 (–1.8 to 6.6)	.25
	12	–2.0 (–4.4 to 0.3)	–0.4 (–3.7 to 2.9)	–1.6 (–2.6 to 5.8)	.45
Diastolic	6	–1.7 (–3.8 to 0.4)	1.9 (–0.8 to 4.7)	–3.6 (–0.3 to 7.5)	.07
	12	1.4 (–0.8 to 3.6)	2.8 (–0.4 to 6.0)	–1.4 (–2.5 to 5.3)	.47
Cholesterol, mg/dL					
Total	6	–7.5 (–12.3 to –2.7)	1.5 (–4.7 to 7.6)	–9.0 (–0.09 to 18.0)	.05‡
	12	–9.2 (–14.8 to –3.5)	3.7 (–3.9 to 11.3)	–12.8, (3.8 to 21.9)	.005‡
HDL	6	2.2 (0.3 to 4.2)	0.0 (–2.4 to 2.5)	2.2 (–5.8 to 1.4)	.23
	12	3.2 (1.3 to 5.2)	1.4 (–1.4 to 4.2)	1.8 (–5.4 to 1.8)	.32
LDL	6	–3.3 (–7.2 to 0.7)	2.0 (–2.7 to 6.7)	–5.3 (–1.6 to 12.2)	.13
	12	–2.4 (–6.9 to 2.2)	1.5 (–4.8 to 7.9)	–3.9 (–3.0 to 10.8)	.26
Triglycerides, mg/dL§	6	–17.9 (–25.3 to –9.9)	–4.2 (–16.0 to 8.5)	–13.7 (–3.6 to 33.9)	.12
	12	–21.3 (–28.4 to –13.6)	–8.1 (–20.9 to 7.4)	–13.2 (–2.3 to 33.4)	.11
Fasting glucose, mg/dL	6	–2.2 (–3.8 to –0.5)	–1.3 (–3.5 to 0.9)	0.9 (–2.3 to 4.1)	.57
	12	–3.4 (–5.2 to –1.8)	–1.8 (–4.3 to 0.8)	1.7 (–1.5 to 4.9)	.30
Fasting insulin, μIU/mL§	6	–6.5 (–8.2 to 4.5)	1.7 (–1.6 to 5.7)	8.2 (3.9 to 10.0)	<.001‡
	12	–6.1 (–8.1 to 4.0)	4.5 (0.2 to 9.6)	10.6 (5.7 to 12.1)	<.001‡
HOMA-IR§	6	–1.51 (–1.92 to 1.06)	0.33 (–0.43 to 1.22)	1.84 (0.85 to 3.10)	<.001‡
	12	–1.52 (–1.93 to –1.01)	0.90 (–0.07 to 2.05)	2.42 (1.29 to 3.76)	<.001‡

Abbreviations: BMI, body mass index, calculated as weight in kilograms divided by height in meters squared; HDL, high-density lipoprotein ; HOMA-IR, homeostasis model assessment of insulin resistance; LDL, low-density lipoprotein.
SI conversion factors: To convert total, HDL, and LDL cholesterol to mmol/L, multiply by 0.0259; triglycerides to mmol/L, multiply by 0.0113.
*Control group (n = 69) and weight management group (n = 105) at 6 and 12 months.
†Treatment effect defined as the change in the weight management group – the change in the control group.
‡Statistically significant difference between changes in weight management and control group.
§Data are presented as geometric means (95% confidence intervals).

second 6-month maintenance phase and the gap between the 2 groups widened due to continued excessive weight gain in the control group. The duration of this study was 12 months, but in our previous nonrandomized pilot study, weight management participants who received education regarding better food choices were able to show a continuing decline in BMI at 2 years.[12] The benefits of the Bright Bodies program extend beyond changes in anthropometrics. A previous study that examined the effects of the supervised exercise component of the Bright Bodies program demonstrated that physical fitness also improved.[23]

The Diabetes Prevention Program demonstrated that an intensive lifestyle program that reduced weight by 7% delayed or prevented the development of type 2 diabetes in adults with impaired glucose tolerance.[7] In our own study, obese adolescents with impaired glucose tolerance who were able to limit increases in BMI to less than 1.0 reverted to normal glucose tolerance 2 years later. In contrast, those participants who had a change in BMI of more than 3.0 developed type 2 diabetes.[24] Thus, the differences in changes in weight and BMI between the weight management and control groups in this study are likely to be clinically—as well as statistically—significant if sustained over the long term.

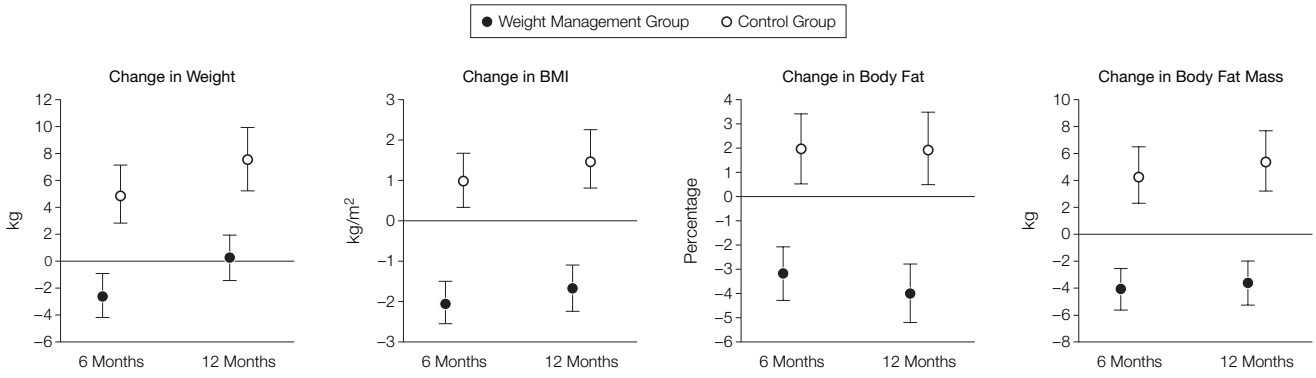
In view of the intensity of the program and the substantial commitment in time and effort by the participants, it is noteworthy that 71% of the weight management group (Bright Bodies plus better food choices) completed the entire 12 months of this intervention. Somewhat surprisingly, there was a slightly greater dropout rate in the control group, even though participation in the study involved very little burden on these control participants. Such observations speak to the perceived benefits of the program by our families.

Another comprehensive weight management program[25] targeting similarly aged youths of mixed ethnicity that showed results comparable to ours (–4.9 units BMI in 1 year) used a much more restrictive diet component, ranging from a protein-sparing modified fast to 1200 calories per day. However, the extremely high dropout rate in our structured meal plan group and the results of other studies[26,27] indicate that calorically restrictive diets are generally not successful in most overweight children. Furthermore, our own pilot study[12] and the experience of others[9,10] suggest that the better food choices approach is more likely to be effective over the long term. In an effort to stress a nondiet approach, we did not ask the children to keep food records, which is characteristic of dieting. This is, perhaps, a limitation of our study since we have no measurable change in calories or macronutrients.

Since insulin resistance is considered to be a major pathophysiological factor underlying many of the clinical complications of childhood obesity[28] and is increasing in prevalence,[29] we measured changes in HOMA-IR in the 2 groups as a surrogate risk factor for such complications. As with the anthropometric parameters, HOMA-IR increased in the control group and decreased in the weight management group, so that the differences in changes in HOMA-IR (–1.84 at 6 months and –2.42 at 12 months) were substantial. There was also a modest lowering of systolic blood pressure, total cholesterol, low-density lipoprotein cholesterol, and triglyceride levels in the weight management group, but only the change in total cholesterol differed significantly from the control group. The relatively normal baseline blood pressure and lipid levels in these participants may have limited our ability to show more substantial change.

In contrast to conventional wisdom regarding the futility of changing the lifestyle of overweight children, we have shown that a family-based program that uses nutrition education, behavior modification, and supervised exercise can lower BMI, improve body composition, and increase insulin sensitiv-

Figure 2. Changes in Body Composition Outcomes for Weight Management and Control Groups at 6 and 12 Months



At 6 and 12 months: weight management group (n=105), control group (n=69). $P<.001$ for all 4 outcomes for the weight management group at 6 and 12 months (between-group comparison). BMI indicates body mass index, calculated as weight in kilograms divided by height in meters squared. Error bars represent 95% confidence intervals.

ity. The net −9.2 kg differences in changes in body fat between the weight management and control groups in this study compares very favorably with the results of treatment of adults with type 2 diabetes with exenatide and rimonabant, which have been touted for their weight loss effects.[30] Moreover, pharmacological treatment of overweight children will not encourage healthier lifestyles or enhance physical fitness.

The success of the Bright Bodies program undoubtedly relates, in part, to the frequent contacts between families and the professional staff. While the program was very successful in treating overweight children, the expense incurred in operating such a program is substantial. Future work for our group includes cost-benefit analyses, as this would be helpful for pediatric clinicians or health management organizations that are considering offering similar services to overweight children and adolescents.

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