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Outcomes of a 1-year randomized controlled trial to evaluate a behavioral 'stepped-down' weight loss intervention for adolescent patients with obesity

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Summary

Background—Stepped-care approaches to weight loss have shown some success among adults. A 'stepped-down' version of the stepped-care approach to adolescent weight loss has never been evaluated.

Objectives—We conducted a one-year randomized controlled trial to compare a stepped-down weight loss intervention versus enhanced usual care (EUC).

Methods—Study participants were obese adolescents age 11–13 (N = 106, 51% girls, and 82% Hispanic) recruited from primary care clinics in San Diego, California. The stepped-down intervention was delivered through clinician and health educator counseling (in-person and by phone) and mailed content. The intervention consisted of four-month 'steps' beginning with the most intensive contact followed by reduced contact if treatment goals were met. The EUC group received an initial physician visit, one session with a health counselor, and monthly mailed materials. Body mass index (BMI kg/m^2) was measured at baseline, 4, 8, and 12 months. Mixed-model regression analyses were stratified by sex.

Results—Results indicated a clinically significant treatment effect for boys on BMI ($p < 0.001$) but not girls. No between group differences were found for adiposity and biometric outcomes. Only 13% of intervention participants succeeded in stepping down from step 1 to step 2 or step 3.

Conclusions—A stepped-down approach to weight loss showed some evidence of efficacy for weight loss in boys but not girls. The findings suggest the program as designed was not intensive enough to result in weight loss in this population segment.

Keywords

Adolescents; obesity; primary-care intervention; stepped-down

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Introduction

Obesity in adolescence is a significant and growing health problem in the United States. According to the Centers for Disease Control and Prevention (CDC), in 2007–2008 an estimated 18% of US adolescents age 12–19 with obesity, a prevalence almost four times greater than the reported 5% in 1976–1980 (1). Furthermore, research suggests both insufficient physical activity (PA) and unhealthy diet increase with age in adolescence (2,3). Adolescents with obesity are more likely to become adults with obesity and are at greater risk for premature morbidity and mortality (4).

Despite the higher prevalence of obesity and greater risk of cardiovascular disease among Hispanic adolescents compared with adolescents of other racial/ethnic groups (5), Hispanics are less frequently represented in obesity intervention studies targeting youth (6). Interventions targeting overweight adolescents, particularly Hispanics, are therefore imperative.

Although several obesity interventions targeting adolescents have been evaluated (7–10), many of these interventions showed small treatment effects, did not meet all treatment goals, showed high attrition rates and showed decline in participant interest. Nevertheless, studies with adults have shown that early weight loss can lead to long-term success (11), intensive treatment has better weight loss outcomes than non-intensive treatment (12), and long-term interventions are more effective for weight change than short-term interventions (13). Therefore, obesity interventions of long duration (i.e. at least 1 year) and with a beginning phase intensive enough to produce significant early weight loss may be needed for adolescents with obesity.

A ‘stepped-down’ approach to interventions modifies the more common ‘stepped-up’ approach to clinical interventions. A stepped-up approach is when ‘dose’ of the intervention increases if a positive response is not produced after the initial low dose. In stepped-down interventions, patients begin with the most intensive step followed by less intensive steps as patients demonstrate self-efficacy and self-management skills necessary to improve behaviour. The stepped-up approach has shown positive weight management results for overweight adults (14) and has been recommend for the management of childhood obesity (15). A stepped-down approach for obesity has been tested only among adults where significant weight loss among participants was observed (16).

We present findings from a randomized controlled trial (RCT) evaluating the stepped-down approach to weight loss, targeting changes in body mass index (BMI), adiposity, blood pressure, fasting blood glucose and lipids among adolescents with obesity. It was hypothesized the treatment would decrease body weight and blood pressure and improve obesity-related metabolic parameters among adolescents (17). Because of the severity of the problem of adolescent obesity in Hispanic populations (5), we conducted the study in paediatric practice settings that served this community.

Methods

Study sample

Adolescents with obesity (BMI > 95 percentile for age and gender) aged 11–13 years were recruited through their primary care providers within three sites of the Children's Primary Care Medical Group in Chula Vista, California. Chula Vista is the second largest city in San Diego County located south of the city of San Diego and 7 miles from the United States–Mexico international border. The racial and ethnic distribution in Chula Vista is approximately 58% Hispanic, 20% white and 14% Asian (2010 US Census).

Participants were literate in English, planned to be a San Diego County resident for the next year, had a parent or guardian willing to participate, were willing to return to the physician office for counselling sessions and could attend measurement visits. Parents were eligible if they were literate in English or Spanish. Adolescents were excluded if they were without reliable transportation, taking weight-altering medications within 6 months prior to study initiation, unable to do moderate-to-vigorous PA, more than 300 lb, in foster care, receiving special needs education, a previous participant in our weight loss studies, currently enrolled in a weight loss programme, or diagnosed with obesity-related disorders requiring immediate weight loss management or diseases affecting absorption or processing of nutrients.

Recruitment occurred from June 2008–November 2009. Participants were primarily recruited at the recommendation of their paediatricians during routine care visits. Study information was also distributed through recruitment flyers placed in office waiting rooms and through physician-generated letters mailed to patients' homes. Upon completion of an initial phone screening for eligibility with the adolescent and parent, a 2-week run-in screening programme was conducted. During the 2-week run-in programme, the adolescent–parent dyads were asked to perform some of the activities that would be required of them if they were to be enrolled in the intervention trial (independent of randomization assignment). These tasks included (i) attending a measurement visit; (ii) scheduling and completing a phone call with a study staff member; (iii) locating a food item at home, reading the food label, and describing the nutrition content; (iv) tracking basic food intake and PA in a written diary over 4 days and (v) scheduling and attending a follow-up appointment. Only adolescent–parent dyads that performed these five run-in activities within the designated period were invited to enter the RCT.

At the beginning of the baseline measurement visit, informed consent and assent was obtained. Adolescents were randomized at baseline into the stepped-down care (SDC) or the enhanced usual care (EUC) group. Simple randomization to study arm was determined by a computer using a permutated block algorithm and was stratified within the primary care provider site. At baseline, 4-and 8-month assessments, adolescents in both study groups received $15, and at 12 months they received a $25 incentive for completing measurements. Parents received a $15 incentive for completing measures at each assessment and $20 at each measurement point to compensate for transportation costs. Ethical approval for the study was obtained from participating healthcare organizations and from the University of California, San Diego (UCSD) Human Subjects Review Board.

Intervention and comparison conditions

The SDC intervention was based on a combination of the Chronic Care Model (CCM) (18) and social cognitive theory (19). CCM provided a conceptual framework for the healthcare delivery for adolescents with obesity of chronic illness management in a primary care setting. CCM emphasizes interdisciplinary team input, case management to coordinate healthcare delivery, self-management support and disease decision support. Within the CCM framework, social cognitive theory constructs of behaviour self-management were applied and included: building self-efficacy, goal-setting, feedback, identifying barriers and social support.

The intervention followed modified recommendations from the American Academy of Pediatrics for treatment of childhood obesity (20) and consisted of three 4-month steps (Fig. 1). The goal was for adolescents to lose at least 4 lb every 4 months. If the participant did not meet the goal, then the step was repeated. If a 4-lb weight loss was achieved, the participant was 'stepped-down' to the next level of reduced intensity. The assumption guiding the stepped-down approach was achievement of 4-lb weight loss over a 4-month step indicated adherence to the programme and mastery of necessary skills for improving diet and PA.

The number and frequency of treatment elements varied for each intervention step. At the start of the programme, the physician provided brief counselling on healthy dietary and PA behaviours. If progress is not made, then follow-up physician visit occurred at month 8 and focused on weight management strategies. Face-to-face health educator visits occurred monthly in step 1 and bi-monthly in step 2, and included discussing weight management concepts, identifying barriers to healthy eating and PA, and brainstorming problem-solving strategies to overcome barriers. These meeting were available to the child and parent, but the parent was not required to attend. Phone calls, which were biweekly in steps 1 and 2, and monthly in step 3, were used to review progress as the last clinical interaction, help adolescents set new goals and discuss barriers and solutions, and speak to parent to reinforce parental involvement and emphasize importance of healthy changes in the home environment to encourage goal attainment. Diet and PA education materials were distributed to adolescents and their parents at health education visits at the paediatric clinics. The adolescent and parent were asked to keep self-monitoring logs for steps and weight that could be e-mailed or mailed to their health counsellor for feedback. Pedometers (New Lifestyle NL-800) were distributed at the initial health educator visit to monitor PA and help participants set appropriate PA goals.

The EUC participants received an initial counselling visit by the physician, one visit with a health educator, materials on how to improve weight-related behaviours, and monthly follow-up mailings on weight-related issues. This condition was labelled 'enhanced' because participants received more than the current standard of practice in the Children's Primary Care Medical Group for adolescents with obesity with no medical comorbidities. These adolescents also received the NL-800 pedometer at the initial health educator visit.

The research team had extensive experience with training providers on behavioural counselling with adolescents. Primary care providers (20 physicians, 2 nurse practitioners)

were trained on how to read web-based assessment summaries and provide brief diet and PA behavioural counselling to patients. Staff members were trained on measurement and interviewing skills. Health educators had prior work experience and/or educational background in diet, health education and/or weight management. Measurement procedures were standardized and validated.

Measures

Body weight and height were determined at baseline, 4-, 8- and 12-month assessments. Body fat, fasting blood lipids and blood pressure measurements were taken during baseline and 12-month assessments at the UCSD National Institutes of Health-supported General Clinical Research Center (GCRC). Height (without shoes) was measured using a stadiometer and weight was measured using a calibrated digital scale while the participant was wearing light clothing. BMI was calculated as kg m^{-2}. CDC Vital and Health Statistics were used to calculate BMI *z*-scores and percentiles using age- and sex-specific median, standard deviation and power of the Box–Cox transformation (21). Percentage over median BMI was calculated as the adolescent's percentage over median BMI for age and sex ((child's BMI – median BMI for age and sex) / median BMI for age and sex × 100). Percentage of body fat was determined from dual-energy x-ray absorptiometry (DXA), using the Hologic Discovery W and APEX 4.0.1 software. Scans were conducted by technicians at the GCRC using the minimal radiation dose considered safe and appropriate for a paediatric population (<1/100th of the equivalent radiation exposure of a chest x-ray). Iliac waist circumference was based on the average of two measurements by research staff following standardized procedures.

Blood lipid profile including total, high-density lipoprotein (HDL) cholesterol and triglycerides were measured from fasting blood samples. Low-density lipoprotein (LDL) cholesterol was calculated as total cholesterol minus HDL. Blood draws and blood assays were conducted by GCRC staff using established clinical assay protocols. Blood pressure measurements were taken by trained staff using a portable Critikon Dinamap 8100 non-invasive monitor. After a 5-min rest, five consecutive measurements of systolic and diastolic blood pressures were taken at 1-min increments, with the third through fifth readings averaged for data analysis. Measurements were taken with the appropriate cuff size (two cuff sizes were available), and while the participant was sitting with their left forearm supported on a table.

Demographic information was collected through a survey completed by the parent at the baseline assessment. Acculturation was measured with the Short Acculturation Scale for Hispanics – Youth (SASH-Y) (22). Twelve items were rated on a 5-point Likert scale and averaged to compute a composite score with higher scores reflecting more Anglo-acculturation.

Statistical analysis

Demographic characteristics, baseline outcome measures, and study completion status were compared between intervention groups using Student's *t*-test for continuous variables and chi-square tests for categorical variables. To determine the intervention effect on outcome

measures, repeated measures mixed linear model analyses using maximum likelihood estimation were conducted. Estimated marginal means and 95% confidence intervals of outcomes were computed for each time point. Analyses were stratified by sex given previous research findings (2,23). Intent-to-treat analyses were conducted using available data and assuming data were missing at random. Models were specified with a between-subject factor of treatment group, a within-subject factor of time, and a group × time interaction. Statistical significance of the group × time interaction effect in the model indicated differential between-group change in the outcome from baseline to 12 months. Non-normally distributed outcomes were log or square root transformed. Reported *P*-values are for two-sided tests with statistical significance at $P < 0.05$. Analyses were conducted using the Statistical Package for the Social Sciences (SPSS) version 19 (SPSS, Inc., Chicago, IL, USA).

Sample size was determined based on BMI outcomes from previous studies (24,25) with a 1.0–1.5-point between-group difference in BMI considered a clinically meaningful change. An effect size of $d = 0.72$ was anticipated (BMI change of 1.3, with $\sigma = 1.63$). A sample size of 53 per group provided 90% power to detect this effect size anticipating attrition of 25%. We had 70% power with 25 per group for analyses stratified by sex.

Results

Figure 2 shows the flow of participants from recruitment through the final assessment at 12 months. Following an initial telephone call to determine study interest and eligibility, 231 adolescent–parent dyads began the study run-in programme. Of those completing the run-in programme ($n = 128$), 106 participants were randomized into the study (Fig. 2). Comparisons between successful completers and non-completers of the run-in programme did not reveal differences according to demographic, home and neighbourhood environment, and acculturation measures. Demographic characteristics are displayed in Table 1. Baseline characteristics did not differ by treatment group and sex. Intervention steps were reassessed at 4 and 8 months. Sixty-six percent ($n = 35$, 12 boys, 23 girls) of the 53 intervention participants stayed in step 1, 11% ($n = 6$, 4 boys, 2 girls) progressed to step 2, 2% ($n = 1$ girl) progressed to step 3, 8% ($n = 4$, 3 boys, 1 girl) regressed to step 1 after going to step 2, and 13% ($n = 7$, 4 boys, 3 girls) dropped from the study while in step 1.

The hypothesized standard deviation effect size difference between study groups of 0.72, which is equivalent to a 1.0–1.5-point change in BMI, was achieved in boys. Boys in the SDC group had a reduction in BMI of −0.7, while boys in the EUC group had an increase of BMI of 0.6, equivalent to a total BMI difference of 1.3 and a standardized effect size of 0.70.

Table 2 displays model estimated means and treatment effects for the anthropometric outcomes in girls and boys. Significant treatment effects on BMI, BMIz and percentage over BMI were observed, but only for boys. Of the 13 (12%) adolescents who lost at least 5% of their body weight after 12 months of treatment, 9 (69%) of them were boys, with 7 of them in the SDC group compared with 2 in the EUC ($P = 0.04$). Change in BMI and change in DXA measured percentage of body fat were strongly correlated ($r = 0.71$ [boys 0.84, girls

0.64]). Treatment effects were not found for DXA or waist circumference measures for girls or boys. For the DXA model, boys in both groups lost 4.20 (standard error [SE] = 1.03) percentage points of body fat by 12 months ($P < 0.001$), with boys in the SDC group losing an additional 1.81 (SE = 1.52) percentages points, but this interaction effect was not statistically significant ($P = 0.264$). Most boys lost some body fat over 12 months with five EUC group boys and three SDC group boys gaining body fat. All boys gained body weight over 12 months. However, all but five SDC group boys lost BMI points, while 14 SDC group boys gained BMI points. Decreased body fat percentage was associated with decreased body weight ($r = 0.704$) and increased height ($r = -0.393$). Study groups did not differ on change in boys' weight. However, SDC group boys, on average, grew 2 cm more than EUC group boys, although this difference was not statistically significant ($P = 0.161$).

Treatment effects were not observed on blood pressure, plasma glucose, cholesterol (total or LDL), or triglycerides in girls or boys (Table 3). However, girls in the EUC group had a significantly greater decrease in LDL cholesterol than girls in the SDC group, 99.4–80.9 vs. 94.1–86.1 ($P = 0.04$).

Discussion

We found some evidence that an obesity intervention with a stepped-down approach can lead to a clinically significant decrease in BMI (1.0–1.5-point change in BMI) in boys. The standardized effect size of 0.70 found for boys exceeds the average standardized effect size of 0.48 found in a meta-analysis of trials of childhood weight loss interventions with education-only control groups (26), and is consistent with weight change effect sizes found for studies identified as 'low-intensity' interventions (15). However, we did not demonstrate BMI changes in girls or in other measures of body fat or cardio-metabolic parameters in either boys or girls over the 12-month study period.

The between-group difference in BMI for boys seemed to be due to the treatment group boys growing slightly taller (7.25 vs. 6.78 cm) and gaining less weight (4 vs. 7 kg) than the control group boys. Consistent with the direction of change in body weight, treatment group boys lost 5.9 percentage points of body fat while control group boys lost 4.25 percentage points, but this difference was not statistically different. It seems that treatment groups boys were 'growing' into a more normal weight range and this change was not as pronounced in the change in body fat.

It is not clear why the SDC programme was not effective for decreasing BMI in girls. One possible explanation is that girls may need a longer length of treatment, more support, and encouragement for weight management compared with boys (27). Girls may also need additional behavioural counselling to help address barriers to PA and healthy diet, such as body image and self-esteem issues, which have been associated with female adolescent sports participation and weight management success (28).

Because two-thirds of participants remained in step 1 (i.e. the most intensive phase), changes in treatment outcomes, progress, or goal attainment from step to step could not be tested. The fact that most remained in the most intensive phase suggests losing weight is

difficult for adolescents with obesity, and perhaps they need an intervention with greater intensity. In fact, following Whitlock *et al.*'s methodology (15), we estimated the intensity of step 1 to be about 19 net hours of contact placing it in their category of 'low intensity' interventions (i.e., 10–25 contact hours). Whitlock *et al.* identified three moderate to high-intensity studies that were between 35 and 98 net hours of contact (15). Greater intensity might include more frequent counselling calls and/or additional in-person clinic visits, and even organized PA sessions. Whether additional personnel resources are required also must be considered. For example, current recommendations suggest referral to a tertiary care centre (with the additional resources of a dietician, exercise specialist, and behavioural interventionalist) may be required for adequate management of adolescents with obesity (20). Feasibility of providing such resources within the confines of a primary care clinic needs to be evaluated.

Overall, the results suggest adolescents with obesity needed a more intensive intervention than what was provided in step 1. It may be the case that a stepped-down approach might be more applicable to populations that are overweight rather than obese. When adolescents had success reducing their BMI, it was mostly due to gaining height and gaining less weight, rather than losing body weight. The step-down approach might function better for adolescents if it is based on BMI change rather than weight loss.

Study limitations should be noted. The study sample was not representative of many regions of the United States outside of Southern California, and thus, findings may not be generalizable to other adolescent populations. The run-in programme was conducted to minimize participant attrition, but may have resulted in a more motivated sample of participants and parents compared with non-run-in trial cohorts.

Implications for research and practice

To our knowledge, this is the first study evaluating the efficacy of a stepped-down approach for weight management focusing on adolescents with obesity. The post-intervention decrease in BMI among adolescent boys using this approach is promising and supports recent recommendations for implementing tailored youth obesity interventions delivered through primary care based on behavioural theory (7,20,29). Further research is needed to evaluate stepped-care approaches for obesity treatment in adolescence and the influence of sex differences on intervention outcomes. A more intensive first step is likely needed to achieve adolescent weight loss compared with reducing weight gain. Further study is also needed to determine proximal family influences and distal community environmental factors that may be specific to facilitating or hindering weight loss for Hispanic adolescents (6,30).

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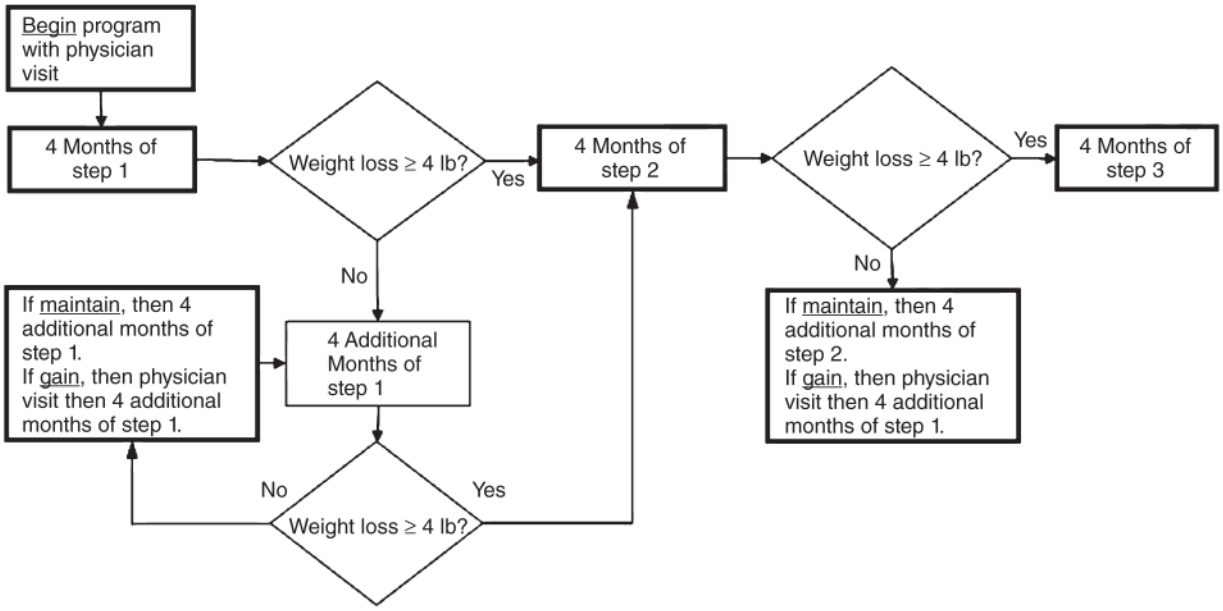

Figure 1.

The goal of the stepped-down care model for the intervention programme was for adolescents to lose at least 4 lb every 4 months. If the participant gained or maintained weight during a given 4-month period, the step was repeated. If the participant achieved 4-lb weight loss during the 4-month period, the participant was 'stepped-down' to the next lower level of reduced intensity.

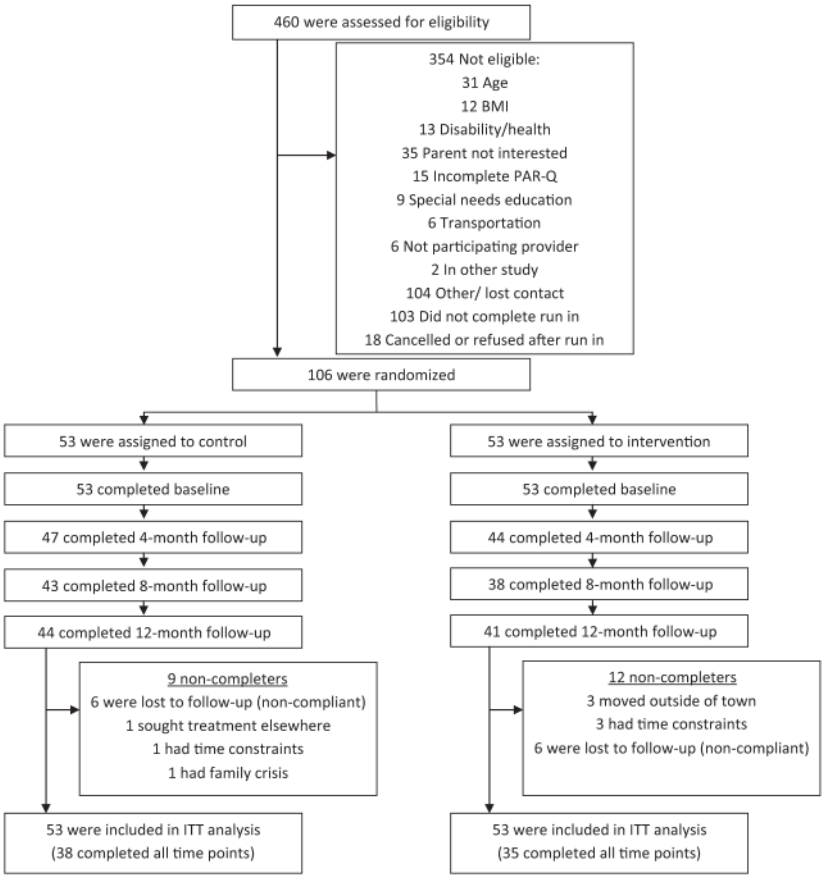

Figure 2.

This study flow diagram shows the final sample size of 106 adolescents. ITT, intention-to-treat.

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Table 1

Baseline sample demographic characteristics by sex and group of adolescents enrolled in the stepped-down weight loss intervention

	Girls (*n* = 54)		Boys (*n* = 52)		Overall (*n* = 106)
	Enhanced usual care (*n* = 25)	Stepped care (*n* = 29)	Enhanced usual care (*n* = 28)	Stepped care (*n* = 24)	
Age (mean, SD)	11.8 (1.0)	12.0 (0.9)	11.7 (0.9)	12.0 (0.8)	11.9 (0.9)
Race/ethnicity (*N*, %)					
African American	0 (0%)	2 (7%)	1 (4%)	1 (4%)	4 (4%)
Asian/Pacific Islander	0 (0%)	0 (0%)	1 (4%)	1 (4%)	2 (2%)
Hispanic	23 (92%)	24 (83%)	23 (81%)	17 (71%)	87 (82%)
White non-Hispanic	0 (0%)	2 (7%)	2 (7%)	4 (17%)	8 (7%)
Multi-ethnic or other	2 (8%)	1 (3%)	1 (4%)	1 (4%)	5 (5%)
Parent marital status (*N*, %)					
Married/living with partner	22 (88%)	20 (69%)	22 (79%)	18 (75%)	82 (77%)
Single	3 (12%)	9 (31%)	6 (21%)	6 (25%)	24 (23%)
Parent highest education (*N*, %)					
≤High school degree	7 (28%)	13 (44%)	10 (37%)	7 (29%)	38 (36%)
Some college/associates degree	14 (56%)	8 (28%)	7 (26%)	10 (42%)	39 (37%)
≥Bachelors degree	4 (16%)	8 (28%)	10 (37%)	7 (29%)	29 (27%)
Parent annual income (*N*, %)					
<$35 000	9 (36%)	10 (39%)	12 (43%)	7 (31%)	43 (41%)
$35 000–49 900	8 (32%)	8 (30%)	4 (14%)	5 (23%)	25 (23%)
$50 000–74 900	6 (24%)	2 (8%)	7 (25%)	4 (19%)	19 (18%)
≥$75 000	2 (8%)	6 (23%)	5 (18%)	6 (27%)	19 (18%)
Acculturation (mean, SD)*	40.1 (9.4)	42.2 (8.0)	45.5 (8.5)	45.6 (9.7)	43.4 (9.0)
BMI Percentile (mean, SD)	97.3 (2.4)	97.3 (2.5)	97.8 (1.8)	98.1 (1.3)	97.6 (2.1)

*Range 12–60 with higher scores indicating more Anglo-acculturation.

BMI, body mass index; SD, standard deviation.

Table 2

Estimated means from repeated measures mixed models for change in anthropometric outcome measures from baseline to 12 months by sex and intervention group

Variable	Girls		*P*-value*	Boys		*P*-value*
	Stepped care	Enhanced usual care		Stepped care	Enhanced usual care	
BMI						
Baseline	29.8 (28.4, 31.3)	28.9 (27.4, 30.4)	0.15	29.4 (27.8, 31.0)	28.9 (27.4, 30.4)	0.003
4 months	30.1 (28.7, 31.6)	29.0 (27.4, 30.6)		29.2 (27.6, 30.8)	29.1 (27.6, 30.6)	
8 months	30.4 (28.9, 32.0)	29.1 (27.8, 30.7)		29.0 (27.3, 30.6)	29.3 (27.8, 30.8)	
12 months	30.7 (29.1, 32.4)	29.1 (27.4, 30.9)		28.8 (27.1, 30.4)	29.5 (27.9, 31.0)	
BMIz						
Baseline	2.1 (1.9, 2.1)	2.0 (1.9, 2.2)	0.42	2.1 (2.0, 2.3)	2.1 (2.0, 2.2)	0.008
4 months	2.0 (1.9, 2.2)	2.0 (1.8, 2.1)		2.1 (2.0, 2.2)	2.1 (2.0, 2.2)	
8 months	2.0 (1.8, 2.1)	1.9 (1.8, 2.1)		2.0 (1.9, 2.2)	2.1 (2.0, 2.2)	
12 months	2.0 (1.8, 2.1)	1.9 (1.7, 2.1)		2.0 (1.8, 2.1)	2.1 (1.9, 2.2)	
Percent over median BMI						
Baseline	63.7 (55.6, 71.8)	59.8 (51.2, 68.5)	0.18	63.8 (54.9, 72.6)	63.5 (55.3, 71.8)	0.002
4 months	63.2 (55.0, 71.5)	58.3 (49.4, 67.2)		60.3 (51.5, 69.1)	62.4 (54.3, 70.6)	
8 months	62.8 (54.2, 71.4)	56.8 (47.6, 66.0)		56.9 (48.0, 65.7)	61.4 (53.2, 69.6)	
12 months	62.4 (53.3, 71.4)	55.3 (45.6, 64.9)		53.4 (44.4, 62.5)	60.3 (51.9, 68.6)	
DXA percentage body fat						
Baseline	43.7 (41.6, 45.7)	46.3 (44.2, 48.3)	0.11	45.1 (42.4, 47.8)	45.3 (42.8, 47.8)	0.26
12 months	42.8 (40.3, 45.3)	43.9 (41.4, 46.3)		39.2 (35.5, 42.9)	41.1 (37.6, 44.5)	
Waist circumference (cm)						
Baseline	99.3 (95.3, 103.4)	98.7 (94.4, 103.1)	0.55	98.1 (94.0. 102.1)	97.1 (93.4, 100.8)	0.48
12 months	99.6 (95.0, 104.2)	97.6 (92.9, 102.3)		97.7 (93.0, 102.4)	98.0 (93.6, 102.4)	

* $P < 0.05$. 95% confidence intervals are shown in parenthesis.

BMI, body mass index; DXA, dual-energy x-ray absorptiometry.

Table 3

Estimated means from repeated measures mixed models for change in cardiometabolic outcome measures from baseline to 12 months by sex and intervention group

	Girls		*P*-value*	Boys		*P*-value*
	Stepped care	Enhanced usual care		Stepped care	Enhanced usual care	
Systolic blood pressure						
Baseline	117.0 (112.6, 121.4)	119.0 (114.2, 123.7)	0.35	118.9 (114.3, 123.5)	121.1 (116.8, 125.3)	0.15
12 months	118.1 (114.1, 122.1)	117.3 (113.2, 121.3)		122.9 (118.0, 127.8)	120.4 (115.9, 125.0)	
Diastolic blood pressure						
Baseline	68.8 (64.1, 73.5)	69.8 (64.7, 74.8)	0.74	67.9 (64.0, 71.8)	66.3 (62.7, 69.9)	0.23
12 months	67.5 (64.9, 70.0)	67.4 (64.8, 70.0)		65.8 (61.3, 70.2)	68.1 (64.0, 72.3)	
Plasma glucose						
Baseline	87.7 (85.2, 90.2)	88.9 (86.2, 91.6)	0.43	89.3 (86.1, 92.6)	91.5 (88.5, 94.4)	0.95
12 months	85.4 (82.7, 88.0)	85.1 (82.3, 87.9)		87.4 (84.5, 90.4)	89.4 (86.8, 92.1)	
Cholesterol						
Baseline	157.5 (148.8, 166.2)	163.6 (154.1, 173.2)	0.19	164.7 (152.9, 176.5)	169.5 (158.5, 180.6)	0.17
12 months	152.6 (141.5, 163.8)	150.0 (138.4, 161.7)		143.7 (132.2, 155.1)	158.7 (148.2, 169.2)	
HDL cholesterol						
Baseline	41.1 (37.2, 45.0)	41.6 (37.2, 45.9)	0.90	39.7 (36.1, 43.3)	42.8 (39.4, 46.1)	0.30
12 months	45.5 (41.5, 49.5)	45.7 (41.5, 49.9)		44.5 (40.6, 48.5)	45.8 (42.2, 49.4)	
LDL cholesterol						
Baseline	94.1 (87.1, 101.1)	99.4 (91.7, 107.2)	0.04	99.8 (89.6, 110.1)	104.8 (95.0, 114.5)	0.20
12 months	86.1 (77.8, 99.5)	80.9 (72.2, 89.5)		79.8 (70.7, 88.8)	93.2 (85.0, 110.1)	
Triglycerides†						
Baseline	100.7 (84.7, 119.7)	120.2 (84.3, 123.3)	0.67	111.2 (69.7, 140.6)	97.3 (78.0, 121.4)	0.26
12 months	93.3 (75.5, 115.1)	99.3 (79.6, 123.3)		87.3 (69.7, 109.4)	90.2 (73.5, 110.9)	

95% confidence intervals are shown in parenthesis. *P*-value is for group × time interaction from longitudinal mixed model stratified by gender.

*$P < 0.05$.

†Log transformed for analyses, exponentiated means, and confidence intervals.

HDL, high-density lipoprotein; LDL, low-density lipoprotein.