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Effect of a Stepped-Care Intervention Approach on Weight Loss in Adults

A Randomized Clinical Trial

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Context Given the obesity epidemic, effective but resource-efficient weight loss treatments are needed. Stepped-treatment approaches customize interventions based on milestone completion and can be more effective while costing less to administer than conventional treatment approaches.

Objective To determine whether a stepped-care weight loss intervention (STEP) compared with a standard behavioral weight loss intervention (SBWI) would result in greater weight loss.

Design, Setting, and Participants A randomized clinical trial of 363 overweight and obese adults (body mass index: 25-<40; age: 18-55 years, 33% nonwhite, and 83% female) who were randomized to SBWI (n=165) or STEP (n=198) at 2 universities affiliated with academic medical centers in the United States (Step-Up Study). Participants were enrolled between May 2008 and February 2010 and data collection was completed by September 2011.

Interventions All participants were placed on a low-calorie diet, prescribed increases in physical activity, and attended group counseling sessions ranging from weekly to monthly during an 18-month period. The SBWI group was assigned to a fixed program. Counseling frequency, type, and weight loss strategies could be modified every 3 months for the STEP group in response to observed weight loss as it related to weight loss goals.

Main Outcome Measure Mean change in weight over 18 months. Additional outcomes included resting heart rate and blood pressure, waist circumference, body composition, fitness, physical activity, dietary intake, and cost of the program.

Results Of the 363 participants randomized, 260 (71.6%) provided a measure of mean change in weight over 18 months. The 18-month intervention resulted in weight decreasing from 93.1 kg (95% CI, 91.0 to 95.2 kg) to 85.6 kg (95% CI, 83.4 to 87.7 kg) ($P<.001$) in the SBWI group and from 92.7 kg (95% CI, 90.8 to 94.6 kg) to 86.4 kg (95% CI, 84.5 to 88.4 kg) in the STEP group ($P<.001$). The percentage change in weight from baseline to 18 months was −8.1% (95% CI, −9.4% to −6.9%) in the SBWI group ($P<.001$) compared with −6.9% (95% CI, −8.0% to −5.8%) in the STEP group ($P<.001$). Although the between-group difference in 18-month weight loss was not statistically different (−1.3 kg [95% CI, −2.8 to 0.2 kg]; $P=.09$), there was a significant group × time interaction effect ($P=.03$). The cost per participant was $1357 (95% CI, $1272 to $1442) for the SBWI group vs $785 (95% CI, $739 to $830) for the STEP group ($P<.001$). Both groups had significant and comparable improvements in resting heart rate, blood pressure level, and fitness.

Conclusions Among overweight and obese adults, the use of SBWI resulted in a greater mean weight loss than STEP over 18 months. Compared with SBWI, STEP resulted in clinically meaningful weight loss that cost less to implement.

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EXCESS WEIGHT IS ASSOCIATED WITH chronic disease, making weight loss the most logical first-line treatment for obesity-related conditions.[1] Lifestyle interventions can result in 8% to 10% weight loss within 6 months,[2] but not all patients achieve or sustain this magnitude of lost weight.[3] Most weight loss programs are intensive during the initial weeks of treatment, become less intensive over time, and maintain a fixed contact schedule for participants irrespective of treatment success or failure. Intensive weight loss programs are costly and require substantial time commitments from the participants, making them impractical in many circumstances.

An alternative is a stepped-care approach. It involves an initially low-intensity intervention that is increased if weight loss milestones are not achieved at fixed time points.[4] Stepped care has been effective for treatment of other health conditions.[5-10] In theory, stepped care could result in better weight loss than conventional therapy because treatment intensity is escalated if weight loss goals are not met during the treatment period. Prior stud-

See also pp 2627 and 2641.

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ies of stepped care for obesity treatment were of short duration,[11-13] included limited step progression,[11-13] and did not have control groups with a standard behavioral weight loss approach.[12] If shown to be an effective and a lower cost alternative to traditional in-person programs, a stepped-care approach could prove to be a cost-effective means for obesity treatment.

We hypothesized that a stepped-care weight loss intervention (STEP) would result in greater weight loss compared with a standard behavioral weight loss intervention (SBWI).

METHODS

The Step-Up Study was a randomized clinical trial that included 2 clinical sites (University of Pittsburgh and University of North Carolina at Chapel Hill). Eligible individuals were randomized to SBWI or STEP. Randomization was stratified within each clinical site based on sex and race/ethnicity. Sex and race/ethnicity were self-reported on a questionnaire that was administered prior to randomization using the categories listed in TABLE 1. Randomization occurred using a computer-generated assignment with variable block sizes ranging from 4 to 8. For block sizes of 4, 6, or 8, randomization was evenly split between the STEP and SBWI groups. However, because the design of the study required that more individuals be randomized to the STEP group, block sizes of 5 or 7 resulted in more individuals randomized to the STEP group compared with the SBWI group. The random allocation sequence was generated by the study's statistician (W.L.). Randomization was conducted once the investigators confirmed that a participant was eligible (ie, following completion of baseline assessments).

Recruitment included television and newspaper advertisements. Verbal consent was provided by the potential participant to complete a telephone screening to determine initial eligibility, and the information obtained was confirmed during an in-person visit after written informed consent was obtained. Eligibility included body mass index (BMI; calculated as weight in kilograms divided by height in meters squared) between 25 and less than 40 and age between 18 and 55 years. Ineligibility included history of cardiovascular disease, presence of a metabolic condition that might affect weight, presence of a medical condition that would contraindicate diet and exercise, taking medication that would affect weight or heart rate response to exercise, sustained weight loss of 4.5 kg or greater within the past 6 months, regular participation in physical activity equivalent of 20 minutes per day or longer on 3 or more days per week over the prior 6 months, recent pregnancy (within 6 months), or current or planned pregnancy within the subsequent 18 months. Individuals appearing to be eligible based on the telephone screening were invited to an orientation session. After the orientation session and prior to further data collection, interested individuals provided written informed consent. Individuals completed a medical history and a physical activity readiness questionnaire,[14] and provided clearance from their physician prior to participation. Procedures were approved by the institutional review boards at the University of Pittsburgh and the University of North Carolina at Chapel Hill. Participants were enrolled between May 2008 and Feb-

Table 1. Demographic Characteristics (N = 363)

	Total	SBWI Group	STEP Group	*P* Value[a]
All patients, No. (%)				
Intention-to-treat analysis	363 (100)	165 (100)	198 (100)	
Completed study	260 (71.6)	121 (73.3)	139 (70.2)	
Lost to follow-up	103 (28.4)	44 (26.7)	59 (29.8)	
Female sex, No. (%)				
Intention-to-treat analysis	300 (82.6)	136 (82.4)	164 (82.8)	.92
Completed study	206 (79.2)	96 (79.3)	110 (79.1)	.97
Lost to follow-up	94 (91.3)	40 (90.9)	54 (91.5)	.92
Age, mean (SD), y				
Intention-to-treat analysis	42.20 (9.03)	42.39 (9.22)	42.04 (8.89)	.71
Completed study	42.81 (8.95)	43.28 (8.82)	42.40 (9.07)	.43
Lost to follow-up	40.65 (9.10)	39.95 (9.94)	41.17 (8.47)	.51
Body mass index[b]				
Intention-to-treat analysis	32.95 (3.63)	32.98 (3.61)	32.93 (3.65)	.89
Completed study	32.75 (3.53)	32.72 (3.52)	32.77 (3.55)	.92
Lost to follow-up	33.47 (3.83)	33.69 (3.78)	33.30 (3.88)	.61
Race/ethnicity[c]				
Asian	2; 2	2; 2	0	.34
Black	103; 69	47; 29	56; 40	
Hispanic, Latino, Portuguese, or Cape Verdean	7; 5	1; 1	6; 4	
White	243; 181	110; 86	133; 95	
Other[d]	8; 3	5; 3	3; 0	
Education level[c]				
High school (10-12 y)	24; 15	14; 9	10; 6	.92
Vocational training (beyond high school)	18; 11	8; 5	10; 6	
Some college (<4 y)	105; 75	55; 42	50; 33	
Undergraduate degree	122; 90	47; 35	75; 55	
Graduate degree	92; 68	40; 30	52; 38	

Abbreviations: SBWI, standard behavioral weight loss intervention; STEP, stepped-care weight loss intervention.
[a] For between-group comparisons and were obtained using the χ^2 test for categorical variables and the *t* test for continuous variables.
[b] Calculated as weight in kilograms divided by height in meters squared.
[c] The first number is patients in the intent-to-treat analysis and the second number is patients completing 18 months of the study.
[d] Indicates mixed race or a race not specified in the other categories.

ruary 2010, with data collection completed by September 2011.

Weight and self-reported physical activity were assessed at baseline, 3, 6, 9, 12, 15, and 18 months. Resting heart rate and blood pressure, waist circumference, body composition, fitness, objectively measured physical activity, and dietary intake were measured at baseline, 6, 12, and 18 months. Participants were compensated $10 for completion of assessments at 3, 9, and 15 months, and $25 for completion of assessments at 6, 12, and 18 months. Assessment staff knew that the participants were in an active weight loss intervention program because this study did not include a no-treatment control group. To minimize the potential for bias, the staff did not have access to the prior assessment data when assessments were being conducted.

Weight was assessed to 0.1 kg using a digital scale with the participant clothed in a hospital gown or lightweight clothing. Height was measured to the nearest 0.1 cm. Lean body mass was assessed using bioelectrical impedance,[15] which was used to compute percentage of body fat. Waist circumference was measured in duplicate horizontally at the level of the umbilicus.

Resting blood pressure was measured in duplicate and represented as the mean of 2 measurements in which systolic blood pressure (SBP) differed by 10 mm Hg or less and diastolic blood pressure (DBP) differed by 6 mm Hg or less. Resting heart rate was measured via palpation.

Fitness was assessed using a submaximal graded treadmill test terminated when the participant first achieved or exceeded 85% of age-predicted maximal heart rate (computed as 220 minus the participant's age). A participant with abnormalities on his or her electrocardiogram or possessing contraindications to exercise was referred to his or her primary care physician prior to proceeding with this study. Fitness was defined as the time to achieve 85% of age-predicted maximal heart rate.

Physical activity was measured using a questionnaire[16] and a portable device worn for 1 week (SenseWear Pro Armband, BodyMedia Inc). Data from this device were used to identify minutes from bouts of activity that were 10 minutes or longer in duration performed at 3 or greater metabolic equivalents. A food frequency questionnaire was used to estimate energy intake (kilocalories per day) and macronutrient composition.[17,18]

Costs were assessed from the payer, participant, and societal (sum of payer and participant) perspective. Payer costs include both labor and nonlabor costs. Labor costs consisted of the market value for staff time associated with preparing and delivering the intervention sessions. Nonlabor costs from the payer perspective included an imputed cost for the rental space required to hold the intervention sessions and costs for all intervention materials. This included costs for photocopies and printing, paper and other office supplies, diaries, nutrient data reference books, cards, postage, pedometers, and meal replacement costs for STEP participants who progressed to step 5 or beyond. Participant costs included an imputed (opportunity) cost for the time they spent in intervention sessions and related travel time and costs. Additional details of the methods, assumptions, and costs for each intervention are provided in the eAppendix and eTable at http://www.jama.com.

The SBWI and STEP groups were prescribed identical diet and physical activity recommendations. The diet was prescribed to reduce energy intake and dietary fat consumption. Energy intake was prescribed at 1200 kcal/d for participants weighing 90 kg or less, 1500 kcal/d for participants weighing more than 90 kg, or 1800 kcal/d for participants weighing 113 kg or more. Prescribed kilocalories per day were adjusted downward for participants if the mean weight loss was less than 0.9 kg per week, the participant had a BMI of 25 or greater, and if the participant expressed a desire to continue to lose weight. Prescribed kilocalories per day were adjusted upward in 100 kcal/d increments each week when further weight loss was not indicated (BMI <25) or when the participant expressed to the intervention staff that they no longer desired to lose additional weight. Meal plans were provided to assist with adoption of dietary recommendations. Participants were instructed to self-monitor food intake in a weekly diary, and interventionists provided feedback to the participant in an attempt to maximize adherence to prescribed dietary goals. The SBWI group returned diaries at intervention sessions, whereas the STEP group returned diaries at in-person sessions but otherwise returned diaries via postal mail.

Prescribed physical activity progressed to 300 minutes per week by the end of week 24, with participants encouraged to maintain this dose for the remainder of the 18 months. Intensity was prescribed as moderate to vigorous.[14] Participants were instructed to self-monitor their physical activity in a weekly diary that was reviewed by the interventionists and feedback was provided to the participant in an attempt to maximize adherence to the prescribed physical activity recommendations.

The SBWI participants received group-based intervention sessions throughout the 18-month intervention. Sessions were weekly for months 1 through 6, twice per month during months 7 through 12, and once per month during months 13 through 18. Participants were offered a brief individual make-up session if a group session was missed. Sessions focused on improving knowledge related to adoption and maintenance of eating and activity behaviors to promote weight loss, and strategies to facilitate long-term behavioral change such as barrier identification, problem solving, mastery experiences for self-efficacy, and others.

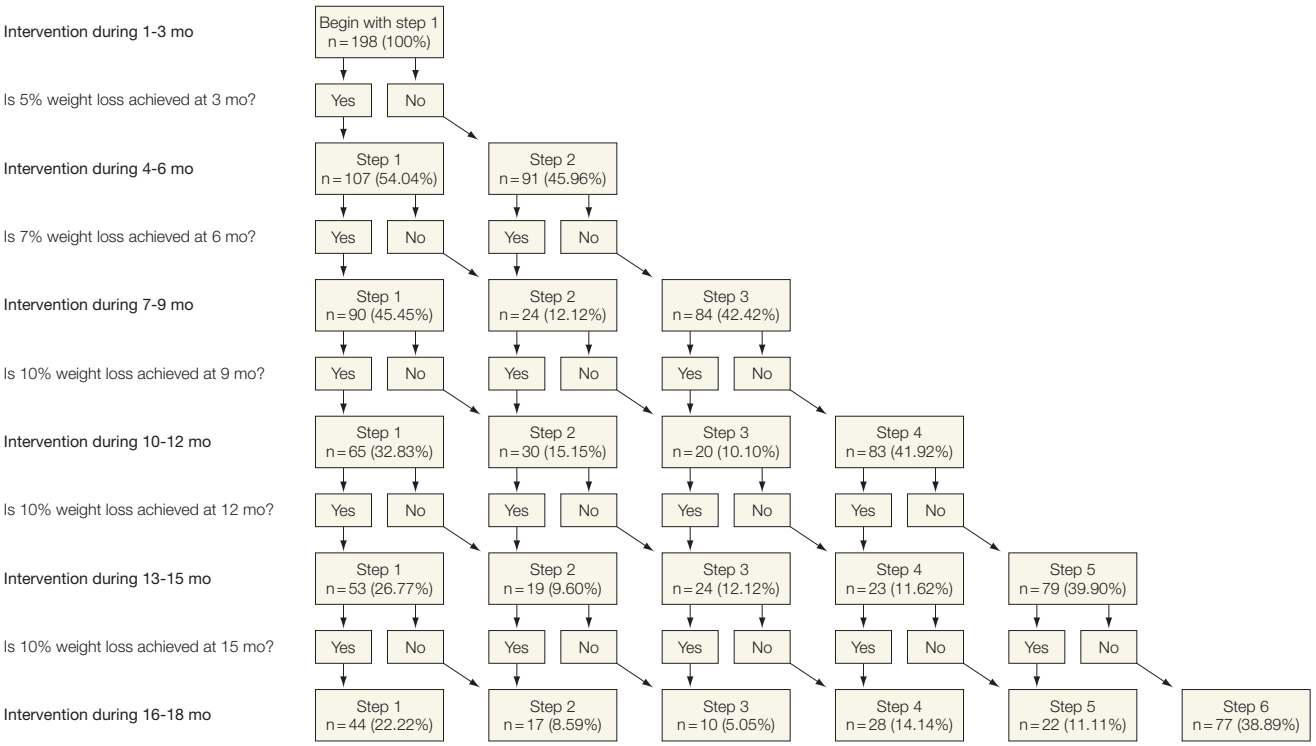
STEP was identical in content to SBWI. However, for the STEP group, contact frequency, contact type, and other weight loss strategies were modified depending on the achievement of

specific weight loss goals at 3-month intervals. Weight loss goals were 5% at 3 months, 7% at 6 months, 10% at 9 months, and remained at 10% at 12, 15, and 18 months. While the goal at 9 months and beyond was to achieve a 10% weight loss, participants were encouraged to continue to lose weight if they desired and there were no contraindications to further weight loss. Participants in the STEP group started at step 1 and progressed to the next intervention step only if the weight loss goal was not achieved. Intervention steps are briefly described below and appear in FIGURE 1.

Step 1: participants were offered a monthly group intervention session. During weeks that a session was not scheduled, lessons that were identical to what was provided to the SBWI group were mailed, and participants submitted their weekly self-monitoring diaries by mail. Step 2: continued with step 1 and received a 10-minute telephone intervention contact once per month. Step 3: continued with step 2 and received a second 10-minute telephone contact each month. Step 4: continued with step 3 and received 1 individual in-person intervention contact per month. Step 5: continued with step 4 and were provided meal replacement shakes and bars to replace 1 meal and 1 snack per day. Step 6: continued with step 5 but replaced 1 of the telephone contacts with a second individual session per month.

An a priori power calculation was computed based on expected differences in body weight at 18 months between the 2 randomized groups. Randomization of 133 participants per group would provide 90% power at a 2-sided α level of .05 to detect approximately a 2.8 kg weight loss difference between the STEP and SBWI groups, equivalent to an effect size of 40%. This magnitude of difference in weight loss may be both statistically significant and clinically meaningful. For example, this magnitude of weight loss closely approximates the 3.5 kg difference in weight loss between the lifestyle intervention compared with the metformin intervention in the Diabetes Prevention Program, and this additional weight loss was associated with a 39% reduction in the onset of type 2 diabetes in overweight and obese adults.[19] Moreover, the hypothesized 2.8 kg dif-

Figure 1. Transition Across Weight Loss Steps in Stepped-Care Weight Loss Intervention (STEP; n=198)



Step descriptions
Step 1: Monthly group session + behavioral lesson delivered via mail
Step 2: Monthly group session + behavioral lesson delivered via mail + 1 telephone counseling session
Step 3: Monthly group session + behavioral lesson delivered via mail + 2 telephone counseling sessions
Step 4: Monthly group session + behavioral lesson delivered via mail + 2 telephone counseling sessions + 1 Individual session
Step 5: Monthly group session + behavioral lesson delivered via mail + 2 telephone counseling sessions + 1 Individual session + meal replacements
Step 6: Monthly group session + behavioral lesson delivered via mail + 1 telephone counseling session + 2 Individual sessions + meal replacements

ference in weight loss would correspond to an improvement in weight loss of approximately 3% between the SBWI and STEP groups relative to the mean baseline weight of the participants in this study, and this magnitude of weight loss has been suggested to be clinically meaningful.[20] However, there is limited evidence in the literature from randomized clinical trials to suggest that a difference in weight loss of less than the 2.8 kg hypothesized difference for this study would result in clinically meaningful improvements in related health outcomes.

The outcomes included intention-to-treat analyses for the 363 participants randomized to the intervention. Missing data were estimated from multiple imputation using SAS version 9.2 (SAS Institute Inc) procedures PROC MI and PROC MIANALYZE. For each outcome, 10 data sets were imputed and the results were then combined.

Analyses were performed with the type I error rate fixed at .05 (2-tailed). Normality of the variables was checked using the Kolmogorov-Smirnov test. Baseline characteristics were checked for imbalance between the STEP and SBWI groups. Categorical variables were tested using the χ^2 test, and other variables were tested using either the *t* test or the Wilcoxon rank sum test.

Separate mixed-effects models using the first-order autoregressive dependence structure were fit to the outcomes based on the number of assessment time points for the variable being analyzed. Each mixed-effects model included covariate adjustment for the following randomization stratification factors: clinical site, sex, and race/ethnicity. Change scores from baseline were calculated and modeled as outcomes with covariate adjustment for the corresponding baseline measure in these models. For example, the mixed-effects model for the primary outcome of weight changes from baseline included a covariate adjustment for baseline weight. Inferences were focused on the treatment effect, time effect, and treatment × time interaction effect. Results from the mixed-model analyses using multiple imputed data are presented as the least square mean (95% confidence interval). The SAS PROC MIXED procedure was used to analyze imputed data.

Distributions of percentage of weight loss were compared between the STEP and SBWI groups using the χ^2 test. Logistic regression models were fitted to 5%, 7%, and 10% weight loss, adjusting for clinical site, sex, race/ethnicity, and baseline weight.

RESULTS

There were no significant differences in demographic characteristics between randomization groups or between participants completing and not completing the study (Table 1). There were 363 participants randomized (SBWI group: n=165; STEP group: n=198) and 260 participants (71.6%) provided a measure of weight at the 18-month assessment (FIGURE 2). After randomization, 21 participants were removed from the study (the reasons appear in

Figure 2. Flow of Patients Through the Step-Up Study

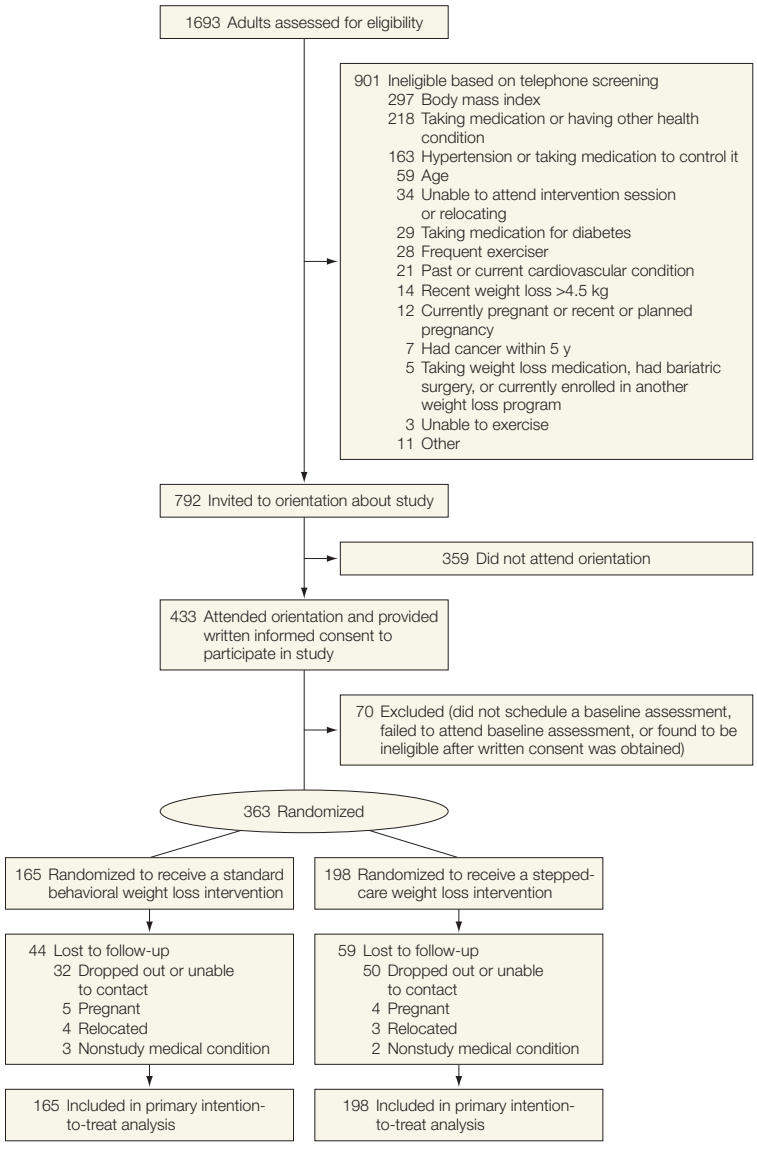


Figure 2). Thus, 342 participants were eligible to complete the study, with 260 of these participants (76.0%) providing a measure of weight at 18 months. Results are presented with analyses of the 363 participants.

When adjusted for baseline body weight, there was a significant group × time interaction ($P = .03$) for weight loss (TABLE 2). This demonstrates that the pattern of weight loss over the 18-month intervention was different between the intervention groups, with overall weight loss favoring the SBWI group. The weight loss at 6 months was –9.6 kg (95% CI, –10.7 to –8.6 kg) in the SBWI group ($P < .001$) compared with –7.6 kg (95% CI, –8.6 to –6.7 kg) in the STEP group ($P < .001$). The percentage change in weight from baseline to 6 months was –10.4% (95% CI, –11.5% to –9.2%) in the SBWI group ($P < .001$) compared with –8.2% (95% CI, –9.2% to –7.2%) in the STEP group ($P < .001$).

The weight loss at 18 months was –7.6 kg (95% CI, –8.7 to –6.5 kg) in the SBWI group ($P < .001$) compared with –6.2 kg (95% CI, –7.3 to –5.2 kg) in the STEP group ($P < .001$)). The percentage change in weight from baseline to 18 months was –8.1% (95% CI, –9.4% to –6.9%) in the SBWI group ($P < .001$) compared with –6.9% [95% CI, –8.0% to –5.8%) in the STEP group ($P < .001$). Although the between-group difference in 18-month weight loss was not statistically different (–1.3 kg [95% CI, –2.8 to 0.2 kg]; $P = .09$), there was a significant group × time interaction effect ($P = .03$).

The effect size for the difference in absolute weight at 18 months between the groups was 6.3%, and the effect size for the weight loss at 18 months between the groups was 18%. Moreover, the 95% CI for the reduction in body weight at 18 months was 83.43 to 87.69 for the SBWI group and 84.47 to 88.41 for the STEP group, with the 95% CIs overlapping. The patterns of

Table 2. Change in Weight, Body Mass Index, and Paffenbarger Physical Activity (PPA)[a]

	Least-Square Mean (95% CI)						
		Change From Baseline					
	Baseline	To 3 mo	To 6 mo	To 9 mo	To 12 mo	To 15 mo	To 18 mo
Weight change from baseline, kg[b]							
SBWI group	93.1 (91.0 to 95.2)	–6.9 (–7.9 to –5.9)	–9.6 (–10.7 to –8.6)	–9.1 (–10.2 to –8.0)	–9.1 (–10.2 to –8.1)	–7.7 (–8.8 to –6.6)	–7.6 (–8.7 to –6.5)
STEP group	92.7 (90.8 to 94.6)	–5.5 (–6.5 to –4.6)	–7.6 (–8.6 to –6.7)	–7.7 (–8.7 to –6.7)	–7.5 (–8.5 to –6.5)	–6.2 (–7.2 to –5.1)	–6.2 (–7.3 to –5.2)
Difference[c]		–1.36 (–2.8 to 0)	–2.0 (–3.4 to –0.6)	–1.4 (–2.9 to 0.1)	–1.6 (–3.1 to –0.2)	–1.6 (–3.1 to –0.1)	–1.3 (–2.8 to 0.2)
P Value		.06	.006	.06	.03	.04	.09
Weight change from baseline, %[b,d]							
SBWI group		–7.4 (–8.5 to –6.3)	–10.4 (–11.5 to –9.2)	–9.8 (–11.0 to –8.57)	–9.9 (–11.1 to –8.6)	–8.4 (–9.7 to –7.1)	–8.1 (–9.4 to –6.9)
STEP group		–5.90 (–6.9 to –4.9)	–8.2 (–9.2 to –7.2)	–8.3 (–9.3 to –7.3)	–8.3 (–9.3 to –7.2)	–6.8 (–7.8 to –5.7)	–6.9 (–8.0 to –5.8)
Difference[c]		–1.5 (–3.0 to 0)	–2.1 (–3.7 to –0.6)	–1.5 (–3.2 to 0.1)	–1.6 (–3.3 to 0.1)	–1.6 (–3.3 to 0.2)	–1.2 (–3.0 to 0.6)
P Value		.06	.006	.07	.06	.08	.20
BMI[d,e]							
SBWI group	33.0 (32.4 to 33.6)	–2.4 (–2.8 to –2.1)	–3.4 (–3.8 to –3.0)	–3.2 (–3.6 to –2.9)	–3.2 (–3.6 to –2.9)	–2.73 (–3.13 to –2.34)	–2.67 (–3.06 to –2.28)
STEP group	33.0 (32.4 to 33.5)	–1.9 (–2.3 to –1.6)	–2.7 (–3.0 to –2.4)	–2.7 (–3.1 to –2.4)	–2.7 (–3.0 to –2.3)	–2.18 (–2.53 to –1.82)	–2.21 (–2.58 to –1.84)
Difference[c]		–0.5 (–1.0 to 0)	–0.7 (–1.2 to –0.2)	–0.5 (–1.0 to 0)	–0.6 (–1.1 to 0)	–0.56 (–1.08 to –0.03)	–0.47 (–1.00 to 0.06)
P Value		.06	.007	.06	.04	.04	.09
PPA, kcal/wk[f]							
SBWI group	717.1 (516.3 to 917.9)	1204 (987 to 1422)	1273 (1041 to 1506)	876 (617 to 1135)	830 (589 to 1072)	962 (719 to 1204)	700 (474 to 926)
STEP group	654.8 (471.8 to 837.7)	1101 (903 to 1298)	1262 (1049 to 1475)	1014 (807 to 1220)	938 (717 to 1159)	1050 (807 to 1292)	841 (627 to 1054)
Difference[c]		103 (–189 to 396)	11 (–290 to 312)	–138 (–488 to 213)	–108 (–431 to 215)	–88 (–405 to 230)	–141 (–449 to 168)
P Value		.49	.94	.44	.51	.59	.37

Abbreviations: BMI, body mass index; SBWI, standard behavioral weight loss intervention; STEP, stepped-care weight loss intervention.
[a]There were 165 patients in the SBWI group and 198 patients in the STEP group.
[b]The *P* values were .02 for difference in change values from baseline between the SBWI and STEP groups, less than .001 for time, and .03 for the group × time interaction.
[c]Indicates the change values from baseline between the SBWI and STEP groups. The models were adjusted for baseline value.
[d]The *P* values were .02 for difference in change values from baseline between the SBWI and STEP groups, less than .001 for time, and .04 for the group × time interaction.
[e]Calculated as weight in kilograms divided by height in meters squared.
[f]The *P* values were .42 for difference in change values from baseline between the SBWI and STEP groups, less than .001 for time, and .66 for the group × time interaction.

change in BMI, waist circumference, and percentage of body fat are presented in Table 2 and TABLE 3.

Participants were grouped by percentage of weight loss and there was no difference between the SBWI and the STEP groups for distribution in these categories (TABLE 4). At 18 months, 33.3% in the SBWI group and 26.3% in the STEP group achieved a weight loss of 10% or greater of initial weight.

For the STEP group, 22.2% of participants remained at step 1 throughout the 18 months, with 8.6% progressing to step 2 and 5.1% progressing to step 3 (Figure 1). Thus, 35.9% of participants progressed to steps 1, 2, or 3 to achieve a 10% weight loss at 18 months. At 6 months, 45.5% remained at step 1, which indicated achievement of 7% or greater weight loss, with 32.8% remaining at step 1 following the 9-month assessments, which indicated achievement of 10% or greater weight loss.

Resting heart rate decreased significantly from baseline to 18 months in the SBWI group (73.8 beats/min [95% CI, 72.2-75.3 beats/min] to 69.6 beats/min [95% CI, 68.0-71.2 beats/min]; $P<.001$) and in the STEP group (73.1 beats/min [95% CI, 71.7-74.5 beats/min] to 69.1 beats/min [95% CI, 67.4-70.8 beats/min]; $P<.001$), with no difference between groups (Table 3). A similar pattern was observed for change in resting SBP and DBP. Fitness, defined as the time to achieve 85% of age-predicted maximal heart rate, increased significantly in both the SBWI group (10.1 minutes [95% CI, 9.5-10.6 minutes] to 12.8 minutes [95% CI, 12.2-13.4 minutes]; $P<.001$) and the STEP group (10.1 minutes [95% CI, 9.7-10.6 minutes] to 12.8 minutes [95% CI, 12.3-13.3 minutes]; $P<.001$), with no significant difference between groups. Data for change in dietary intake and physical activity also are presented in Table 2 and Table 3.

From the payer perspective, the mean cost per participant was $358 (95% CI, $340-$376) for the STEP group and $494 (95% CI, $465-$524) for the SBWI group ($P<.001$). Costs from the participant perspective also were lower in the STEP group ($427; 95% CI, $397-$457) per participant compared with the SBWI group ($863 [95% CI, $805-$921]; $P<.001$). From the societal perspective (ie, the sum of payer and participant), the average cost for STEP was $785 (95% CI, $739-$830). This was significantly less expensive than the average cost for SBWI, which was estimated to be $1357 (95% CI, $1272-$1442; $P<.001$). Details of the cost analysis are presented in the eAppendix and eTable at http://www.jama.com.

The significantly lower costs for STEP can be attributed to the reduced reliance on face-to-face meetings. As a result, in sensitivity analyses we explored whether STEP would remain a less expensive intervention if we assumed (1) health educators and rental space could be obtained at half price, or (2) health educators and rental space could be obtained at half price and we halved the value of each participant's time, which was assumed to be $23.31 per hour in the base case. Using these estimates, the societal cost was $1170 (95% CI, $1098-$1241) for SBWI and $688 (95% CI, $650-726) for STEP in the first sensitivity analysis ($P<.001$) and $778 (95% CI, $732-$823) and $493 (95% CI, $468-$517), respectively, in the second sensitivity analysis ($P<.001$). In each case, STEP remained significantly less expensive from the societal (and payer) perspectives.

Using the base-case cost estimates, we found that from the societal perspective, relative to status quo, the incremental cost-effectiveness ratio for STEP was $127 per 1 kg of weight lost. The incremental cost-effectiveness ratio for SBWI, relative to the less expensive STEP, was $409 per 1 kg of weight lost. From the payer perspective, the incremental cost-effectiveness ratios were reduced to $58 per 1 kg of weight lost for STEP and $97 per 1 kg of weight lost for SBWI.

COMMENT

Behavioral weight loss interventions reduce weight by approximately 8% to 10% within the first 6 months of treatment.[2] While some weight regain is typical, these interventions can result in maintenance of significant weight loss beyond the initial 6 months of the intervention.[19,21-24] There was a reduction in weight of 9.6 kg at 6 months in the SBWI group and 7.6 kg at 18 months, which is comparable with other studies.[22,25] There was significant weight loss in the STEP group of 7.6 kg at 6 months and 6.2 kg at 18 months. Although the overall weight loss over the 18-month intervention period was significantly greater in the SBWI group compared with the STEP group (Table 2), the difference in weight loss of –1.3 kg (95% CI, –2.8 to 0.2 kg) at 18 months in the SBWI group compared with the STEP group was not significantly different.

Although SBWI resulted in greater weight loss compared with STEP, this additional weight loss came at a higher cost to both payers and participants. Whether a given decision maker would be willing to pay the additional costs likely depends on many factors, including funding, labor, time, and space availability. Although a full cost-effectiveness analysis that would require converting the weight loss estimates to quality-adjusted life-years saved and forecasting the extent to which the weight losses would be sustained is beyond the scope of this analysis, comparisons with the literature suggest these results are likely to compare favorably with other pharmacological and behavioral weight loss interventions. For example, over an 18-month period, the average cost of orlistat (the most popular over-the-counter weight loss drug) is roughly $744 (assuming $1.36 per capsule for 547 days). From a payer's perspective, this cost is greater than the cost for either STEP or SBWI.

Few randomized clinical trials have been conducted to evaluate the effectiveness of a stepped-care intervention approach for weight loss. Carels et al[12] examined a non–randomized self-help intervention for a period of 6 weeks. Participants who achieved a 2.5% weight loss continued with

Table 3. Change in Waist Circumference, Body Fat Percentage, Resting Heart Rate and Blood Pressure, Fitness and Armband Physical Activity (APA) Durations, and Dietary, Dietary Fat, Carbohydrate, and Protein Intakes[a]

	Least-Square Mean (95% CI)				*P* Value		
		Change From Baseline					
	Baseline	To 6 mo	To 12 mo	To 18 mo	Group	Time	Group × Time
Waist circumference, cm							
SBWI group	106.5 (104.9 to 108.2)	−10.6 (−12.0 to −9.21)	−10.4 (−11.9 to −9.0)	−10.0 (−11.4 to −8.5)	.10	.14	.11
STEP group	107.1 (105.6 to 108.6)	−8.7 (−9.8 to −7.5)	−9.6 (−10.8 to −8.3)	−9.2 (−10.4 to −8.0)			
Difference[b]		−1.9 (−3.8 to −0.2)	−0.9 (−2.7 to 1.0)	−0.8 (−2.6 to 1.1)			
P Value		.03	.37	.44			
Body fat, %							
SBWI group	34.0 (32.9 to 35.0)	−6.3 (−7.1 to −5.6)	−6.1 (−6.9 to −5.3)	−5.6 (−6.4 to −4.8)	.09	.008	.51
STEP group	34.1 (33.2 to 35.1)	−5.4 (−6.1 to −4.7)	−5.3 (−6.1 to −4.5)	−5.0 (−5.7 to −4.3)			
Difference[b]		−0.9 (−2.02 to 0.09)	−0.8 (−1.9 to 0.3)	−0.6 (−1.7 to 0.5)			
P Value		.07	.17	.25			
Resting heart rate, beats/min							
SBWI group	73.8 (72.2 to 75.3)	−5.1 (−6.6 to −3.7)	−3.9 (−5.5 to −2.3)	−3.6 (−5.1 to −2.2)	.64	.01	.69
STEP group	73.1 (71.7 to 74.5)	−5.1 (−6.4 to −3.9)	−4.0 (−5.6 to −2.5)	−4.5 (−5.5 to −3.0)			
Difference[b]		−0.01 (−2.0 to 1.9)	0.2 (−1.7 to 2.0)	0.6 (−1.2 to 2.5)			
P Value		.99	.85	.51			
Resting SBP, mm Hg							
SBWI group	117.5 (115.7 to 119.2)	−8.6 (−10.1 to −7.1)	−6.5 (−8.3 to −4.8)	−7.3 (−8.8 to −5.7)	.52	<.001	.40
STEP group	118.4 (116.8 to 120.0)	−7.6 (−8.9 to −6.3)	−6.1 (−7.7 to −4.4)	−7.5 (−8.9 to −6.2)			
Difference[b]		−1.0 (−3.1 to 1.1)	−0.5 (−2.4 to 1.5)	0.3 (−1.7 to 2.3)			
P Value		.35	.64	.78			
Resting DBP, mm Hg							
SBWI group	77.9 (76.7 to 79.1)	−4.8 (−5.8 to −3.8)	−3.1 (−4.3 to −1.9)	−4.2 (−5.3 to −3.2)	.58	<.001	.31
STEP group	77.5 (76.5 to 78.6)	−4.2 (−5.1 to −3.3)	−3.3 (−4.4 to −2.2)	−3.9 (−4.8 to −3.0)			
Difference[b]		−0.6 (−2.0 to 0.8)	−0.2 (−1.1 to 1.6)	−0.3 (−1.7 to 1.0)			
P Value		.39	.76	.63			
Fitness duration, min[c]							
SBWI group	10.1 (9.5 to 10.6)	3.3 (2.9 to 3.8)	3.1 (2.7 to 3.6)	2.7 (2.2 to 3.2)	.33	<.001	.33
STEP group	10.1 (9.7 to 10.6)	3.0 (2.6 to 3.4)	2.9 (2.5 to 3.3)	2.7 (2.3 to 3.1)			
Difference[b]		0.3 (−0.2 to 1.0)	0.2 (−0.4 to 0.9)	0 (−0.6 to 0.7)			
P Value		.25	.43	.92			
APA duration, min/wk							
SBWI group	716.1 (521.6 to 910.6)	145.0 (113.8 to 176.3)	80.7 (49.8 to 111.6)	84.1 (52.4 to 115.8)	.37	<.001	.83
STEP group	655.4 (478.3 to 832.5)	136.7 (106.6 to 166.9)	67.7 (39.3 to 96.2)	68.7 (39.2 to 98.2)			
Difference[b]		8.3 (−32.7 to 49.3)	13.0 (−27.6 to 53.6)	15.4 (−27.0 to 57.7)			
P Value		.69	.53	.48			
Dietary intake, kcal/d							
SBWI group	2140 (2028 to 2252)	−601 (−675 to −526)	−545 (−633 to −456)	−511 (−602 to −420)	.39	.08	.25
STEP group	1965 (1865 to 2064)	−546 (−619 to −473)	−508 (−582 to −434)	−537 (−611 to −463)			
Difference[b]		−54.7 (−162 to 52)	−37 (−152 to 78)	26 (−96 to 148)			
P Value		.32	.53	.68			
Dietary fat intake, %							
SBWI group	37.5 (36.6 to 38.4)	−6.2 (−7.0 to −5.3)	−4.7 (−5.7 to −3.7)	−3.9 (−5.0 to −2.9)	.43	<.001	.60
STEP group	37.8 (37.0 to 38.6)	−5.8 (−6.7 to −5.0)	−4.4 (−5.2 to −3.6)	−4.0 (−4.8 to −3.1)			
Difference[b]		−0.3 (−1.6 to 0.9)	−0.3 (−1.6 to 1.0)	0.1 (−1.4 to 1.4)			
P Value		.58	.65	.98			
Carbohydrate intake, %							
SBWI group	47.2 (46.0 to 48.3)	5.1 (4.1 to 6.2)	4.4 (3.2 to 5.6)	3.6 (2.3 to 4.8)	.22	.001	.50
STEP group	46.3 (45.2 to 47.3)	4.5 (3.5 to 5.6)	3.5 (2.5 to 4.6)	3.2 (2.2 to 4.3)			
Difference[b]		0.6 (−0.9 to 2.1)	0.9 (−0.7 to 2.5)	0.4 (−1.4 to 2.1)			
P Value		.45	.28	.69			
Protein intake, %							
SBWI group	15.5 (15.1 to 16.0)	1.3 (0.9 to 1.7)	0.9 (0.4 to 1.4)	0.8 (0.3 to 1.3)	.27	.003	.69
STEP group	15.8 (15.4 to 16.2)	1.5 (1.1 to 2.0)	1.1 (0.7 to 1.5)	1.0 (0.5 to 1.4)			
Difference[b]		−0.2 (−0.9 to 0.4)	−0.2 (−0.9 to 0.5)	−0.2 (−0.9 to 0.6)			
P Value		.47	.52				

Abbreviations: DBP, diastolic blood pressure; SBP, systolic blood pressure; SBWI, standard behavioral weight loss intervention; STEP, stepped-care weight loss intervention.
[a]There were 165 patients in the SBWI group and 198 patients in the STEP group.
[b]Indicates the change values from baseline between the SBWI and STEP groups. The models were adjusted for baseline value.
[c]Defined as the time to achieve 85% of age-predicted maximal heart rate.

self-help and those not achieving the goal were stepped up to receive weekly group intervention sessions for a period of 12 weeks. The stepped care group achieved 1.8% weight loss and the self-help group achieved 8.1% weight loss at 6 months posttreatment. A study that examined the addition of individual problem solving counseling to a standard group intervention when a participant did not reach a predetermined weight loss goal showed improved initial weight loss compared with the standard group intervention, but no significant difference between interventions after 1 year.[11] Another study showed that the addition of group sessions with either a self-help or therapist-assisted intervention was unsuccessful at improving weight loss.[13] In the current study, 53.5% of participants achieved the 5% weight loss goal at 3 months, which is comparable with weight loss at 3 months in response to a minimal intensity intervention.[13] Moreover, 22.2% of participants remained at step 1, suggesting that some overweight or obese adults will respond to a low-intensity intervention. STEP was equally effective at producing weight loss of 5% or greater, 7% or greater, and 10% or greater compared with SBWI (Table 4). Thus, STEP may be a viable alternative to traditional SBWI.

There are limitations to this study that should be considered when interpreting the findings presented. First, this study was designed to test whether STEP would result in greater weight loss compared with SBWI. An alternative that should be considered is a design

Table 4. Distribution of Patients by Percentage of Weight Loss[a]

Assessment Period	No. (%) of Patients by Percentage of Weight Loss Category					*P* Value[b]
	Missing Data	<5%	5%-<7%	7%-<10%	≥10%	
3 mo						
SBWI group	14 (8.48)	47 (28.48)	27 (16.36)	33 (20.00)	44 (26.67)	.22
STEP group	14 (7.07)	79 (39.90)	27 (13.64)	38 (19.19)	40 (20.20)	
6 mo						
SBWI group	26 (15.76)	29 (17.58)	16 (9.70)	20 (12.12)	74 (44.85)	.12
STEP group	24 (12.12)	51 (25.76)	25 (12.63)	30 (15.15)	68 (34.34)	
9 mo						
SBWI group	39 (23.64)	41 (24.85)	7 (4.24)	10 (6.06)	68 (41.21)	.31
STEP group	43 (21.72)	48 (24.24)	13 (6.57)	23 (11.62)	71 (35.86)	
12 mo						
SBWI group	36 (21.82)	39 (23.64)	10 (6.06)	13 (7.88)	67 (40.61)	.29
STEP group	52 (26.26)	42 (21.21)	20 (10.10)	20 (10.10)	64 (32.32)	
15 mo						
SBWI group	42 (25.45)	46 (27.88)	7 (4.24)	15 (9.09)	55 (33.33)	.86
STEP group	58 (29.29)	54 (27.27)	8 (4.04)	21 (10.61)	57 (28.79)	
18 mo						
SBWI group	44 (26.67)	46 (27.88)	12 (7.27)	8 (4.85)	55 (33.33)	.11
STEP group	59 (29.80)	50 (25.25)	13 (6.57)	24 (12.12)	52 (26.26)	
	No. (%) of Patients by Percentage of Weight Loss Category Using Imputed Weight for Missing Data					
3 mo						
SBWI group		50 (30.30)	32 (19.39)	40 (24.24)	43 (26.06)	.17
STEP group		82 (41.41)	35 (17.68)	41 (20.71)	40 (20.20)	
6 mo						
SBWI group		36 (21.82)	18 (10.91)	29 (17.58)	82 (49.70)	.04
STEP group		63 (31.82)	28 (14.14)	37 (18.69)	70 (35.35)	
9 mo						
SBWI group		55 (33.33)	13 (7.88)	18 (10.91)	79 (47.88)	.22
STEP group		73 (36.87)	18 (9.09)	32 (16.16)	75 (37.88)	
12 mo						
SBWI group		52 (31.52)	17 (10.30)	19 (11.52)	77 (46.67)	.12
STEP group		70 (35.35)	30 (15.15)	29 (14.65)	69 (34.85)	
15 mo						
SBWI group		69 (41.82)	11 (6.67)	21 (12.73)	64 (38.79)	.32
STEP group		92 (46.46)	18 (9.09)	29 (14.65)	59 (29.80)	
18 mo						
SBWI group		69 (41.82)	18 (10.91)	14 (8.48)	64 (38.79)	.05
STEP group		87 (43.94)	24 (12.12)	32 (16.16)	55 (27.78)	

Abbreviations: SBWI, standard behavioral weight loss intervention; STEP, stepped-care weight loss intervention.
[a] There were 165 patients in the SBWI group and 198 patients in the STEP group.
[b] Obtained using the χ^2 test.

that a priori tests for weight loss equivalency between SBWI and STEP. An additional limitation of this study is that it was unable to be determined from the results presented whether an alternative intensity or frequency of intervention steps within the STEP condition would be more or less effective for weight loss than what was observed in this study. Moreover, identifying characteristics of those for whom either the SBWI or the STEP intervention can be most effective awaits further investigation.

CONCLUSIONS

Among overweight and obese adults, the use of SBWI resulted in a greater mean weight loss than STEP over 18 months. STEP resulted in clinically meaningful weight loss that cost less to implement than SWBI. Whether this weight loss results in improved health-related outcomes warrants further investigation.

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