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Effect of a Stepped-Care Intervention Approach on Weight Loss in Adults: The Step-Up Study Randomized Trial

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Abstract

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 paradigms.

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

Design—Randomized trial with participants enrolled between May 2008 and February 2010. Data collection was completed by September 2011.

Setting—2 universities affiliated with academic medical centers.

Participants—Participants were 363 overweight and obese adults (BMI: 25 to <40 kg/m^2; age: 18–55 years; 33% non-white, 83% female) who were randomized to SBWI or STEP interventions.

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Interventions—All participants were placed on a low calorie diet, prescribed increases in physical activity and had group counseling sessions ranging from weekly to monthly during an 18-month time period. SBWI participants were assigned to a fixed program. Among STEP participants, counseling frequency, type, and weight loss strategies could be modified every 3 months 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 include resting heart rate and blood pressure, waist girth, body composition, fitness, physical activity, dietary intake, and costs.

Results—Of the 363 participants randomized, 260 participants (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, 95.2) to 85.6 kg (95% CI: 83.4, 88.0) ($p<0.01$) in SBWI and from 92.7 kg (95% CI: 90.8, 94.6) to 86.4 kg (95% CI: 84.5, 88.4) in STEP ($p<0.01$). Percent weight change from baseline to 18 months was −8.1% (95% CI: −9.4, −6.9) in SBWI ($p<0.01$) and −6.9% (95% CI: −8.0, −5.8) in STEP ($p<0.01$). Although the between group difference in 18 month weight loss was not statistically different (1.3 kg (95% CI: −2.8, 0.2) ($p=0.09$)) there was a significant Group X Time interaction effect ($p=0.04$). The cost per participant was $1,357 (CI: 1,272–1,442) for SBWI vs. $785 (CI: 739–830) for STEP ($p<0.01$). Both groups had significant and comparable improvements in resting heart rate, blood pressure, and fitness.

Conclusions—Among overweight and obese adults, the use of a standard behavioral weight loss intervention resulted in a greater mean weight loss than a stepped-care intervention over 18 months. As compared to a standard behavioral weight loss intervention, Stepped care resulted in clinically meaningful weight loss that cost less to implement than a standard behavioral weight loss intervention.

Keywords

obesity; weight loss; exercise; diet; behavior

INTRODUCTION

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 8–10% 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. This 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 since treatment intensity is escalated if weight loss goals are not met as time passes during the treatment period. Prior studies of stepped care for obesity treatment were short duration,[11–13] included

limited step progression,[11–13] and did not have control groups of standard behavioral weight loss intervention.[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 obesity intervention with stepped-care (STEP) would result in greater weight loss compared to a standard behavioral weight loss intervention (STEP).

METHODS

Design

This randomized clinical trial included two clinical sites (University of Pittsburgh and University of North Carolina at Chapel Hill). Eligible participants were randomized to SBWI or STEP. Randomization was stratified within each clinical site based on gender and ethnicity (white or non-white). Gender and ethnicity were self-reported on a questionnaire that was administered prior to randomization using the categories included in Table 1. Randomization occurred using a computer generated assignment with variable block size ranging from 4 to 8. For block sizes of 4, 6, or 8, randomization was evenly split between STEP and SBWI. However, because the design of the study required that more participants be randomized to STEP versus SBWI, block sizes of 5 or 7 resulted in more subjects randomized to STEP compared to SBWI. The random allocation sequence was generated by the statistician (Dr. Lang). Randomization was assigned once the investigators confirmed that a participant was eligible following completion of baseline assessments.

Participants

Recruitment included television and newspaper advertisements. Verbal consent was provided by the participant to complete a telephone screening to determine initial eligibility, with this information confirmed during an in-person visit after written informed consent was obtained. Eligibility included body mass index (BMI) within 25.0 to <40.0 kg/m^2 and age between 18 to 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 within the past 6 months, regular participation in physical activity equivalent to ≥20 min/d on ≥3 days/wk over the prior 6 months. Ineligibility included recent pregnancy (within 6 months) and current or planned pregnancy within the subsequent 18 months. Individuals appearing 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. Participants completed a medical history and a physical activity readiness questionnaire,[14] and provided clearance from their physician prior to further participation. Procedures were approved by the Institutional Review Boards at the University of Pittsburgh and University of North Carolina at Chapel Hill. Participants were enrolled between May 2008 and February 2010, with data collection completed by September 2011.

Outcome Assessments

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 girth, 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 for this study because this study did not include a no-treatment control condition. 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 light-weight clothing. Height was measured to the nearest 0.1 cm. BMI was computed as kg/m^2.

Lean body mass (LBM) was assessed using bioelectrical impedance [15], which was used to compute percent 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 two measures in which systolic pressure (SBP) differed by ≤10 mmHg and diastolic pressure (DBP) differed by ≤6 mmHg. Resting heart rate was measured via palpation.

Fitness was assessed using a submaximal graded treadmill test terminated at ≥85% of age-predicted maximal heart rate, computed as 220 minus the participant's age. Participants with ECG abnormalities or possessing contraindications to exercise were referred to their 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 one week (SenseWear Pro Armband, BodyMedia, Inc). Data from this device was used to identify minutes from bouts that were ≥10 minutes in duration performed at ≥3 metabolic equivalents (METs). A food frequency questionnaire was used to estimate energy intake (kcal/d) 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 non-labor costs. Labor costs consist of the market value for staff time associated with preparing and delivering the intervention sessions. Non-labor costs from the payer perspective include an imputed cost for the rental space required to hold the intervention sessions and costs for all intervention materials. This includes 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 progress to Step 5 or beyond. Participant costs include an imputed (opportunity) cost for the time they spent in intervention sessions and related travel time and costs. Additional details of the methodology, assumptions and costs for each intervention are provided in eTable 1 along with accompanying online text.

Interventions

SBWI and STEP 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 1,200 kcal/d for participants ≤90 kg, 1,500 kcal/d for participants >90 kg, or 1,800 kcal/d for participants ≥113 kg. Prescribed kcal/d was adjusted downward for participants if the mean weight loss was less than 0.9 kg per week, the participant had a BMI ≥25 kg/m^2, and the participant expressed a desire to continue to lose weight. Prescribed kcal/d was adjusted upward in 100 kcal/d increments each week when further weight loss was not indicated (BMI <25 kg/m^2) 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. SBWI returned diaries at intervention sessions, whereas STEP returned diaries at in person sessions but otherwise returned diaries via postal mail.

Prescribed physical activity progressed to 300 min/wk 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 for this study.

SBWI included group-based intervention sessions throughout the 18-month intervention. Sessions were weekly for months 1–6, twice per month during months 7–12, and once per month during months 13–18. 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 behavior change such as barrier identification, problem solving, mastery experiences for self-efficacy, and others.

The STEP intervention was identical in content to SBWI but 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 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 shown in Figure 2.

Step 1—Participants were offered a monthly group intervention session. On weeks that a session was not scheduled, lessons that were identical to what was provided to SBWI 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 receive one individual in-person intervention contact per month.

Step 5—Continued with Step 4 and were provided meal replacement shakes and bars to replace one meal and one snack per day.

Step 6—Continued with Step 5 but replaced one of the telephone contacts with a second individual session per month.

Statistical Analysis

An a-priori power calculation was computed based on expected differences in body weight at 18 months between the randomized groups. Randomization of 133 participants per group would provide 90% power at a two-sided alpha level of 0.05 to detect approximately a 2.8 kg weight loss difference between the STEP and SBWP groups, equivalent to a 40% effect size. 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 to the Metformin intervention in the Diabetes Prevention Program, and this additional weight loss was associated with a 39% reduction in onset of type 2 diabetes in overweight and obese adults.[19] Moreover, the hypothesized 2.8 kg difference 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 (see Table 2), 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 include intention-to-treat analyses for the 363 participants randomized to the intervention. Missing data were estimated from multiple imputation using SAS (version 9.2) procedures PROC MI and PROC MIANALYZE. For each outcome, ten datasets were imputed and results were then combined.

Analyses were performed with the type I error rate fixed at 0.05 (two-tailed). Normality of the variables was checked using the Kolmogorov-Smirnov test. Baseline characteristics were checked for imbalance between STEP and SBWP groups. Categorical variables were tested using the Chi-square, with other variables tested using either a Student’s T-test or Wilcoxon Rank Sum test.

Separate mixed effects models using the first-order autoregressive AR(1) 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 randomization stratification factors: clinical site, gender, and 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, weight changes from baseline, included a covariate adjustment for baseline weight. Inferences were focused on the treatment effect, time effect, and treatment by 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 percent weight loss were compared between STEP and SBWP groups using the Chi-square test. Logistic regression models were fitted to 5%, 7%, 10% weight loss adjusting for clinical site, gender, race, 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). Randomization occurred for 363 participants (SBWI = 165, STEP = 198), with 260 participants (71.6%) providing a measure of weight at the 18 month assessment (Figure 1). Following randomization, 21 participants were removed from the study following randomization, with reasons shown in Figure 1. 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 randomized to intervention.

Weight Change

When adjusted for baseline body weight, there was a significant Group X Time interaction ($p=0.03$) 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 SBWI versus STEP. Weight loss at 6 months was −9.6kg (95% CI: −10.7, −8.6) [−10.4% (95% CI: −11.5, −9.2)] ($p<0.01$) in SBWI and −7.6kg (95% CI: −8.6, −6.7) [−8.2% (95% CI: −9.2, −7.2)]) ($p<0.01$) in STEP. The comparison between SBWI and STEP at 6 months is statistically significant for change in weight ($p<0.01$) and percent change in weight ($p<0.01$). Weight loss at 18 months was −7.6kg (95% CI: −8.7, −6.5) [−8.1% (95% CI: −9.4, −6.9)] ($p<0.01$) and −6.2kg (95% CI: −7.3, −5.2) [−6.9% (95% CI: −8.0, −5.8)] ($p<0.01$) in SBWI and STEP, respectively. However, SBWI and STEP were not significantly different when compared for weight loss ($p=0.09$) or percent weight loss ($p=0.20$) at 18 months. The effect size for the difference in absolute weight at 18 months between the groups is 6.3%, and the effect size for the weight loss at 18 months between the groups is 18%. Moreover, the 95% confidence interval for the body weight at 18 months was (83.43, 87.69) for SBWI and (84.47, 88.41) for STEP, with the confidence intervals overlapping. The patterns of change in BMI, waist circumference, and percent body fat are presented in Table 2.

Participants were grouped on percent weight loss. There was no difference between SBWI and STEP for the distribution of participants in these categories (Table 3). At 18 months 33.3% in SBWI and 26.3% in STEP achieved a weight loss of ≥10% of initial weight.

For STEP, 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 2). 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% weight loss at this point, with 32.8% remaining at Step 1 following the 9 month assessments, which indicated achievement of ≥10% weight loss.

Additional Outcomes

Resting heart rate decreased significantly ($p<0.01$) from baseline to 18 months in both SBWI [73.8 beats per minute (95% CI: 72.2, 75.3) to 69.6 beats per minute (68.0, 71.2)] and STEP [73.1 beats per minute (95% CI: 71.7, 74.5) to 69.1 beats per minute (67.4, 70.8)], with no difference between groups (Table 2). A similar pattern was observed for change in SBP and DBP (Table 2). Fitness, defined as the time to achieve 85% of age-predicted maximal heart rate, increased significantly in both SBWI [10.1 minutes (95% CI: 9.5, 10.6) to 12.8 minutes (12.2, 13.4)] and STEP [10.1 minutes (95% CI: 9.7, 10.6) to 12.8 minutes (12.3, 13.3)] ($p<0.01$), with no significant difference between groups (Table 2). Data for change in dietary intake and physical activity are also presented in Table 2.

Costs

From the payer perspective, the mean cost per participant was $358 (95% CI: $340 – $376) for STEP and $494 ($465 – $524) for SBWI ($p<0.01$). Costs from the participant perspective were also lower in STEP: $427 (95% CI: $397 – $457) vs. $863 (95% CI: $805 – $921) per participant for SBWI ($p<0.01$). From the societal perspective, the sum of payer and participant, the average cost for STEP is $785 (95% CI: $739 – $830). This is significantly less expensive than the average cost for SBWI, estimated to be $1,357 (95% CI: $1,272 – $1,442) ($p<0.01$). Details of the cost analysis are presented in eTable 1 and the accompanying online text.

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 participant's time, which was assumed to be $23.31 per hour in the base case. Using these estimates, the societal costs for SBWI and STEP respectively are $1,170 (CI: 1,098–1,241) and $688 (CI: 650–726) ($p<0.01$) in the first sensitivity analysis and $778 (CI: 732–823) and $493 (CI: 468–517) ($p<0.01$) in the second. In each case, STEP remains significantly less expensive from the societal (and payer) perspectives.

Using the base case cost estimates we find that from the societal perspective, relative to status quo, the incremental cost effectiveness ratio (ICER) for STEP is $127 per kg of weight lost. The ICER for SBWI, relative to the less expensive STEP, is $409 per kg of

weight lost. From the payer perspective, the ICERs are reduced to $58 per kg of weight lost for STEP and $97 per kg of weight lost for SBWI.

DISCUSSION

Behavioral weight loss interventions reduce weight by approximately 8 to 10 percent of initial weight within the initial 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] SBWI reduced weight by 9.6 kg at 6 months and 7.6 kg at 18 months, which is comparable to other studies.[22, 25] STEP resulted in significant weight loss of 7.6 kg and 6.2 kg at 6 and 18 months, respectively. While the overall weight loss over the 18 month intervention period was significantly greater in SBWI compared to STEP (see Table 2), the difference in weight loss of −1.3 kg (95% CI: −2.8, 0.2)] at 18 months in SBWI compared to STEP was not significantly different.

Although the SBWI intervention resulted in greater weight loss compared to STEP, this additional weight loss came at a higher cost to both payers and participants. Whether or not 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 (QALYs) and forecasting the extent to which the weight losses would be sustained is beyond the scope of this analysis, comparisons with the literature suggests these results are likely to compare favorably with other pharmacologic and behavioral weight loss interventions. For example, over an 18 month period, the average cost of Alli, the most popular over the counter weight loss drug is roughly $744 (assuming $1.36 per capsule * 547 days). From a payer's perspective, this cost is greater than the costs 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 self-help and those not achieving the goal stepped-up to receive weekly group intervention sessions for a period of 12 weeks. The stepped care group achieved 1.8% and the self-help group achieved 8.1% weight loss at 6 months post-treatment. 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 to the standard group intervention, but no significant difference between interventions after 1 year.[11] Another study showed that the addition of group sessions when 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 to weight loss at 3 months in response to a minimal intensity intervention.[13] Moreover, 22.2% of participants remained at Step 1 (Table 3), suggesting that some overweight or obese adults will respond to a low intensity intervention. STEP was equally effective at producing weight loss of ≥5%, ≥7%, and ≥10% when compared to SBWI (Table 3). Thus, STEP may be a viable alternative to traditional SBWI interventions.

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 to SBWI. An alternative that should be considered is a design that a-priori tests for weight loss equivalency between SBWI and STEP. An additional limitation of this study is that it is 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 for who either the SBWI or the STEP intervention can be most effective awaits further investigation.

CONCLUSIONS

Among overweight and obese adults, the use of a standard behavioral weight loss intervention resulted in a greater mean weight loss than a stepped-care intervention over 18 months. Stepped care 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.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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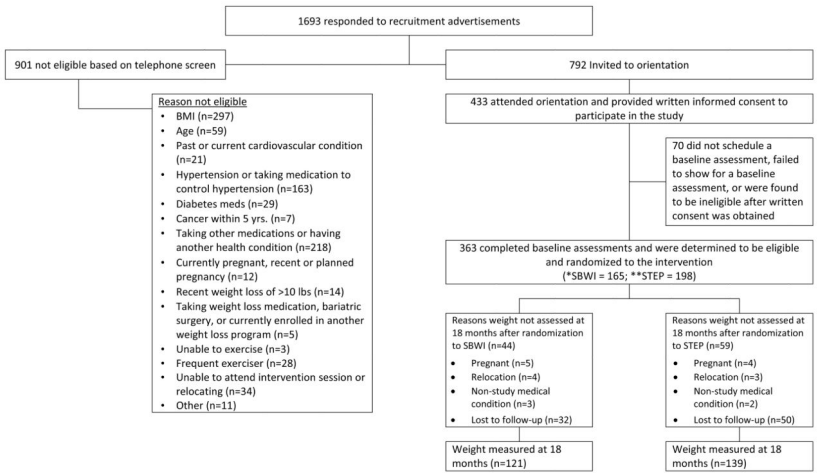

Figure 1.
Consort Diagram

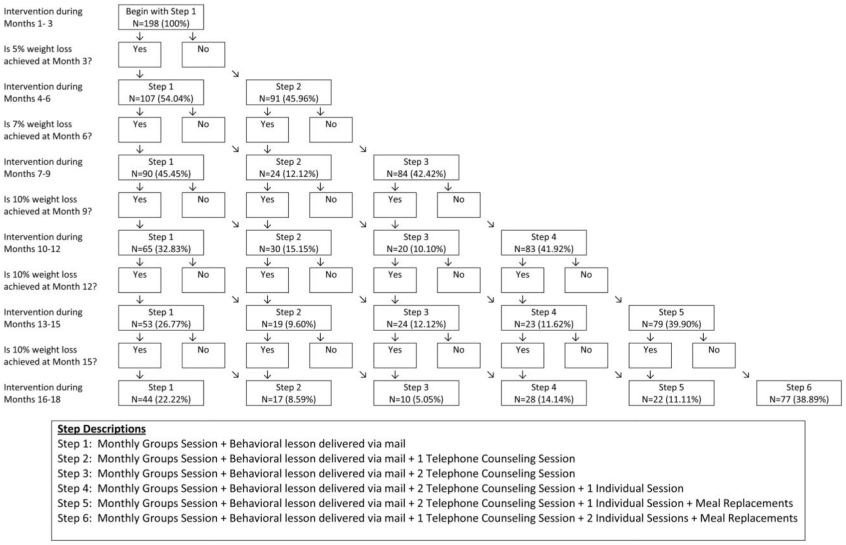

Figure 2.
Transition across weight loss steps in Stepped-Care (STEP) Intervention (N=198)

Table 1

Demographic Characteristics of Randomized Subjects (N=363).

	Total	SBWI	STEP	P-value[#] for treatment
Number of Subjects				
Intention-to-Treat Analysis	N=363 (100%)	N=165 (100%)	N=198 (100%)	
Completers	N=260 (71.6%)	N=121 (73.3%)	N=139 (70.2%)	
Lost to Follow-Up	N=103 (28.4%)	N=44 (26.7%)	N=59 (29.8%)	
Gender(Females)				
Intention-to-Treat Analysis	N=300	N=136	N=164	0.92
Completers	N=206	N=96	N=110	0.97
Lost to Follow-Up	N=94	N=40	N=54	0.92
Age(years)				
Intention-to-Treat Analysis	42.20±9.03	42.39±9.22	42.04±8.89	0.71
Completers	42.81±8.95	43.28±8.82	42.40±9.07	0.43
Lost to Follow-Up	40.65±9.10	39.95±9.94	41.17±8.47	0.51
Body Mass Index(kg/m^2)				
Intention-to-Treat Analysis	32.95±3.63	32.98±3.61	32.93±3.65	0.89
Completers	32.75±3.53	32.72±3.52	32.77±3.55	0.92
Lost to Follow-Up	33.47±3.83	33.69±3.78	33.30±3.88	0.61
Ethnicity[+]				
Asian	N=2(N=2)	N=2(N=2)	N=0(N=0)	0.34
Black or African-American	N=103(N=69)	N=47(N=29)	N=56(N=40)	
Hispanic, Latino, Portuguese, Cape Verdean	N=7(N=5)	N=1(N=1)	N=6(N=4)	
White	N=243(N=181)	N=110(N=86)	N=133(N=95)	
Other	N=8(N=3)	N=5(N=3)	N=3(N=0)	
Education Level[+]				
High School(10–12 years)	N=24(N=15)	N=14(N=9)	N=10(N=6)	0.92
Vocational Training(beyond High School)	N=18(N=11)	N=8(N=5)	N=10(N=6)	
Some College(less than 4 years)	N=105(N=75)	N=55(N=42)	N=50(N=33)	
College/University Degree	N=122(N=90)	N=47(N=35)	N=75(N=55)	
Graduate or Professional Education	N=92(N=68)	N=40(N=30)	N=52(N=38)	

[+] Indicates that numbers not in parenthesis are based on the intent-to-treat analysis and numbers in parenthesis are based on subjects completing 18 months.

[#] P-values for between treatment group comparisons were obtained using the Chi-square test for categorical variables and the Student's T-test for continuous variables.

Table 2

Change in weight and other outcomes by intervention condition [least square mean (95% confidence interval)] (N=363, SBWI=165, STEP=198).

Variable	Group	Baseline	Change from Baseline to 3 Months	Change from Baseline to 6 Months	Change from Baseline to 9 Months	Change from Baseline to 12 Months	Change from Baseline to 15 Months	Change from Baseline to 18 Months	P-Values		
									Group	Time	Group X Time
Weight Change from Baseline (kg)	SBWI	93.1 (91.0,95.2)	−6.9 (−7.9, −5.9)	−9.6 (−10.7, −8.6)	−9.1 (−10.2, −8.0)	−9.1 (−10.2, −8.1)	−7.7 (−8.8, −6.6)	−7.6 (−8.7, −6.5)	0.02	<0.01	0.03
	STEP	92.7 (90.8,94.6)	−5.5 (−6.5, −4.6)	−7.6 (−8.6, −6.7)	−7.7 (−8.7, −6.7)	−7.5 (−8.5, −6.5)	−6.2 (−7.2, −5.1)	−6.2 (−7.3, −5.2)			
	Difference*		−1.36 (−2.8,0.0) (p= 0.06)	−2.0 (−3.4, −0.6) (p= 0.01)	−1.4 (−2.9,0.1) (p= 0.06)	−1.6 (−3.1, −0.2) (p= 0.03)	−1.6 (−3.1, −0.1) (p= 0.04)	−1.3 (−2.8,0.2) (p= 0.09)			
Percent Weight Change from Baseline (%)	SBWI		−7.4 (−8.47, −6.25)	−10.4 (−11.5, −9.20)	−9.8 (−11.0, −8.57)	−9.9 (−11.1, −8.6)	−8.4 (−9.7, −7.1)	−8.1 (−9.4, −6.9)	0.02	<0.01	0.04
	STEP		−5.90 (−6.9, −4.9)	−8.2 (−9.2, −7.2)	−8.3 (−9.3, −7.3)	−8.3 (−9.3, −7.2)	−6.8 (−7.8, −5.7)	−6.9 (−8.0, −5.8)			
	Difference*		−1.5 (−3.0,0.0) (p= 0.06)	−2.1 (−3.7, −0.6) (p= 0.01)	−1.5 (−3.2,0.1) (p= 0.07)	−1.6 (−3.3,0.1) (p= 0.06)	−1.6 (−3.3,0.2) (p= 0.08)	−1.2 (−3.0,0.6) (p= 0.20)			
Body Mass Index (kg/m^2)	SBWI	33.0 (32.4,33.6)	−2.4 (−2.8, −2.1)	−3.4 (−3.8, −3.0)	−3.2 (−3.6, −2.9)	−3.2 (−3.6, −2.9)	−2.73 (−3.13, −2.34)	−2.67 (−3.06, −2.28)	0.02	<.01	0.04
	STEP	33.0 (32.4,33.5)	−1.9 (−2.3, −1.6)	−2.7 (−3.0, −2.4)	−2.7 (−3.1, −2.4)	−2.7 (−3.0, −2.3)	−2.18 (−2.53, −1.82)	−2.21 (−2.58, −1.84)			
	Difference*		−0.5 (−1.0,0.0) (p= 0.06)	−0.7 (−1.2, −0.2) (p= 0.01)	−0.5 (−1.0,0.0) (p= 0.06)	−0.6 (−1.1, −0.0) (p= 0.04)	−0.56 (−1.08, −0.03) (p= 0.0384)	−0.47 (−1.00,0.06) (p= 0.0861)			
Waist (cm)	SBWI	106.5 (104.9,108.2)		−10.6 (−12.0, −9.21)		−10.4 (−11.9, −9.0)		−10.0 (−11.4, −8.5)	0.10	0.14	0.11
	STEP	107.1 (105.6,108.6)		−8.7 (−9.8, −7.5)		−9.6 (−10.8, −8.3)		−9.2 (−10.4, −8.0)			
	Difference*			−1.9 (−3.8, −0.2) (p= 0.03)		−0.9 (−2.7,1.0) (p= 0.37)		−0.8 (−2.6,1.1) (p= 0.44)			
Percent Body Fat (%)	SBWI	34.0 (32.9,35.0)		−6.3 (−7.1, −5.6)		−6.1 (−6.9, −5.3)		−5.6 (−6.4, −4.8)	0.09	0.01	0.51
	STEP	34.1 (33.2,35.1)		−5.4 (−6.1, −4.7)		−5.3 (−6.1, −4.5)		−5.0 (−5.7, −4.3)			
	Difference*			−0.9 (−2.02,0.09) (p= 0.07)		−0.8 (−1.9,0.3) (p= 0.17)		−0.6 (−1.7,0.5) (p= 0.25)			
Resting Heart Rate (beats per minute)	SBWI	73.8 (72.2,75.3)		−5.1 (−6.6, −3.7)		−3.9 (−5.5, −2.3)		−3.6 (−5.1, −2.2)	0.64	0.01	0.69
	STEP	73.1 (71.7,74.5)		−5.1 (−6.4, −3.9)		−4.0 (−5.6, −2.5)		−4.5 (−5.5, −3.0)			
	Difference*			−0.01 (−2.0,1.9) (p= 0.99)		0.2 (−1.7,2.0) (p= 0.85)		0.6 (−1.2,2.5) (p= 0.51)			
Resting Systolic Blood Pressure (mmHg)	SBWI	117.5 (115.7,119.2)		−8.6 (−10.1, −7.1)		−6.5 (−8.3, −4.8)		−7.3 (−8.8, −5.7)	0.52	<0.01	0.40
	STEP	118.4 (116.8,120.0)		−7.6 (−8.9, −6.3)		−6.1 (−7.7, −4.4)		−7.5 (−8.9, −6.2)			
	Difference*			−1.0 (−3.1,1.1) (p= 0.35)		−0.5 (−2.4,1.5) (p= 0.64)		0.3 (−1.7,2.3) (p= 0.78)			

Variable	Group	Baseline	Change from Baseline to 3 Months	Change from Baseline to 6 Months	Change from Baseline to 9 Months	Change from Baseline to 12 Months	Change from Baseline to 15 Months	Change from Baseline to 18 Months	P-Values		
									Group	Time	Group X Time
Resting Diastolic Blood Pressure (mmHg)	SBWI	77.9 (76.7,79.1)		−4.8 (−5.8, −3.8)		−3.1 (−4.3, −1.9)		−4.2 (−5.3, −3.2)	0.58	<.01	0.31
	STEP	77.5 (76.5,78.6)		−4.2 (−5.1, −3.3)		−3.3 (−4.4, −2.2)		−3.9 (−4.8, −3.0)			
	Difference*			−0.6 (−2.0,0.8) (p= 0.39)		0.2 (−1.1,1.6) (p= 0.76)		−0.3 (−1.7,1.0) (p= 0.63)			
Fitness (minutes)	SBWI	10.1 (9.5,10.6)		3.3 (2.9,3.8)		3.1 (2.7,3.6)		2.7 (2.2,3.2)	0.33	<0.01	0.33
	STEP	10.1 (9.7,10.6)		3.0 (2.6,3.4)		2.9 (2.5,3.3)		2.7 (2.3,3.1)			
	Difference*			0.3 (−0.2,1.0) (p= 0.25)		0.2 (−0.4,0.9) (p= 0.43)		0.0 (−0.6,0.7) (p= 0.92)			
Paffenbarger Physical Activity (kcal/wk)	SBWI	717.1 (516.3,917.9)	1204 (987,1422)	1273 (1041,1506)	876 (617,1135)	830 (589,1072)	962 (719,1204)	700 (474,926)	0.42	<.01	0.66
	STEP	654.8 (471.8,837.7)	1101 (903,1298)	1262 (1049,1475)	1014 (807,1220)	938 (717,1159)	1050 (807,1292)	841 (627,1054)			
	Difference*		103 (−189,396) (p= 0.49)	11 (−290,312) (p= 0.94)	−138 (−488,213) (p= 0.44)	−108 (−431,215) (p= 0.51)	−88 (−405,230) (p= 0.59)	−141 (−449,168) (p= 0.37)			
Armband Physical Activity (min/wk)	SBWI	92.9 (64.2,121.6)		145.0 (113.8,176.3)		80.7 (49.8,111.6)		84.1 (52.4,115.8)	0.37	<.01	0.83
	STEP	86.9 (60.3,113.4)		136.7 (106.6,166.9)		67.7 (39.3,96.2)		68.7 (39.2,98.2)			
	Difference*			8.3 (−32.7,49.3) (p= 0.69)		13.0 (−27.6,53.6) (p= 0.53)		15.4 (−27.0,57.7) (p= 0.48)			
Dietary Intake(kcal/d)	SBWI	2140 (2028,2252)		−601 (−675, −526)		−545 (−633, −456)		−511 (−602, −420)	0.39	0.08	0.25
	STEP	1965 (1865,2064)		−546 (−619, −473)		−508 (−582, −434)		−537 (−611, −463)			
	Difference*			−54.7 (−162,52) (p= 0.32)		−37 (−152,78) (p= 0.53)		26 (−96,148) (p= 0.68)			
Percent Dietary Fat Intake (%)	SBWI	37.5 (36.6,38.4)		−6.2 (−7.0, −5.3)		−4.7 (−5.7, −3.7)		−3.9 (−5.0, −2.9)	0.43	<.01	0.60
	STEP	37.8 (37.0,38.6)		−5.8 (−6.7, −5.0)		−4.4 (−5.2, −3.6)		−4.0 (−4.8, −3.1)			
	Difference*			−0.3 (−1.6,0.9) (p= 0.58)		−0.3 (−1.6,1.0) (p= 0.65)		0.1 (−1.4,1.4) (p= 0.98)			
Percent Carbohydrate Intake (%)	SBWI	47.2 (46.0,48.3)		5.1 (4.1,6.2)		4.4 (3.2,5.6)		3.6 (2.3,4.8)	0.22	<0.01	0.50
	STEP	46.3 (45.2,47.3)		4.5 (3.5,5.6)		3.5 (2.5,4.6)		3.2 (2.2,4.3)			
	Difference*			0.6 (−0.9,2.1) (p= 0.45)		0.9 (−0.7,2.5) (p= 0.28)		0.4 (−1.4,2.1) (p= 0.69)			
Percent Protein Intake (%)	SBWI	15.5 (15.1,16.0)		1.3 (0.9,1.7)		0.9 (0.4,1.4)		0.8 (0.3,1.3)	0.27	<0.01	0.69
	STEP	15.8 (15.4,16.2)		1.5 (1.1,2.0)		1.1 (0.7,1.5)		1.0 (0.5,1.4)			

Variable	Group	Baseline	Change from Baseline to 3 Months	Change from Baseline to 6 Months	Change from Baseline to 9 Months	Change from Baseline to 12 Months	Change from Baseline to 15 Months	Change from Baseline to 18 Months	P-Values		
									Group	Time	Group X Time
	Difference*			−0.2 (−0.9,0.4) (p= 0.47)		−0.2 (−0.9,0.5) (p= 0.52)		−0.2 (−0.9,0.6) (p= 0.66)			

*Represents the difference in the change values from baseline between SBWI and STEP. These models are adjusted for baseline value.

Table 3

Distribution of subjects achieving different weight loss criteria by randomized group assignment. (SBWI: N=165; STEP: N=198)

			Group Based on Percent Weight Loss Using Measured Weight					
Assessment Period	**Group**		**Missing Data**	**<5%**	**5% to <7%**	**7% to <10%**	**≥10%**	**p-value***
3-months	SBWI	Number of Subjects (% of Subjects)	14 (8.48%)	47 (28.48%)	27 (16.36%)	33 (20.00%)	44 (26.67%)	0.22
	STEP	Number of Subjects (% of Subjects)	14 (7.07%)	79 (39.90%)	27 (13.64%)	38 (19.19%)	40 (20.20%)	
6-months	SBWI	Number of Subjects (% of Subjects)	26 (15.76%)	29 (17.58%)	16 (9.70%)	20 (12.12%)	74 (44.85%)	0.12
	STEP	Number of Subjects (% of Subjects)	24 (12.12%)	51 (25.76%)	25 (12.63%)	30 (15.15%)	68 (34.34%)	
9-months	SBWI	Number of Subjects (% of Subjects)	39 (23.64%)	41 (24.85%)	7 (4.24%)	10 (6.06%)	68 (41.21%)	0.31
	STEP	Number of Subjects (% of Subjects)	43 (21.72%)	48 (24.24%)	13 (6.57%)	23 (11.62%)	71 (35.86%)	
12-months	SBWI	Number of Subjects (% of Subjects)	36 (21.82%)	39 (23.64%)	10 (6.06%)	13 (7.88%)	67 (40.61%)	0.29
	STEP	Number of Subjects (% of Subjects)	52 (26.26%)	42 (21.21%)	20 (10.10%)	20 (10.10%)	64 (32.32%)	
15-months	SBWI	Number of Subjects (% of Subjects)	42 (25.45%)	46 (27.88%)	7 (4.24%)	15 (9.09%)	55 (33.33%)	0.86
	STEP	Number of Subjects (% of Subjects)	58 (29.29%)	54 (27.27%)	8 (4.04%)	21 (10.61%)	57 (28.79%)	
18-months	SBWI	Number of Subjects (% of Subjects)	44 (26.67%)	46 (27.88%)	12 (7.27%)	8 (4.85%)	55 (33.33%)	0.11
	STEP	Number of Subjects (% of Subjects)	59 (29.80%)	50 (25.25%)	13 (6.57%)	24 (12.12%)	52 (26.26%)	

			Group Based on Percent Weight Loss Using Imputed Weight for Missing Data					
Assessment Period	**Group**		**Missing Data**	**<5%**	**5% to <7%**	**7% to <10%**	**≥10%**	**p-value***
3-months	SBWI	Number of Subjects (% of Subjects)	-----	50 (30.30%)	32 (19.39%)	40 (24.24%)	43 (26.06%)	0.17
	STEP	Number of Subjects (% of Subjects)	-----	82 (41.41%)	35 (17.68%)	41 (20.71%)	40 (20.20%)	
6-months	SBWI	Number of Subjects (% of Subjects)	-----	36 (21.82%)	18 (10.91%)	29 (17.58%)	82 (49.70%)	0.04
	STEP	Number of Subjects (% of Subjects)	-----	63 (31.82%)	28 (14.14%)	37 (18.69%)	70 (35.35%)	
9-months	SBWI	Number of Subjects (% of Subjects)	-----	55 (33.33%)	13 (7.88%)	18 (10.91%)	79 (47.88%)	0.22
	STEP	Number of Subjects (% of Subjects)	-----	73 (36.87%)	18 (9.09%)	32 (16.16%)	75 (37.88%)	
12-months	SBWI	Number of Subjects (% of Subjects)	-----	52 (31.52%)	17 (10.30%)	19 (11.52%)	77 (46.67%)	0.12
	STEP	Number of Subjects (% of Subjects)	-----	70 (35.35%)	30 (15.15%)	29 (14.65%)	69 (34.85%)	
15-months	SBWI	Number of Subjects (% of Subjects)	-----	69 (41.82%)	11 (6.67%)	21 (12.73%)	64 (38.79%)	0.32
	STEP	Number of Subjects (% of Subjects)	-----	92 (46.46%)	18 (9.09%)	29 (14.65%)	59 (29.80%)	
18-months	SBWI	Number of Subjects (% of Subjects)	-----	69 (41.82%)	18 (10.91%)	14 (8.48%)	64 (38.79%)	0.05

			Group Based on Percent Weight Loss Using Imputed Weight for Missing Data					
Assessment Period	**Group**		**Missing Data**	**<5%**	**5% to <7%**	**7% to <10%**	**≥10%**	**p-value***
	STEP	Number of Subjects (% of Subjects)	-----	87 (43.94%)	24 (12.12%)	32 (16.16%)	55 (27.78%)	

* The p-value was obtained using the Chi-Square test