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Innovative Self-Regulation Strategies Reduce Weight Gain in Young Adults: The Study of Novel Approaches to Weight Gain Prevention (SNAP) Randomized Controlled Trial

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Abstract

Importance—Weight gain occurs commonly in young adults and has adverse effects on health. Reducing weight gain in young adults would have significant public health impact.

Objective—To compare two self-regulation interventions versus control in reducing weight gain in young adults over an average follow-up of 3 years.

Design—Randomized controlled trial

Setting—Two academic settings

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Financial Disclosures:

Dr. Tate reports being a member of the Scientific Advisory Board for Weight Watcher's International.

Role of Sponsor: The sponsor approved study design and interpretation of the data and coordinated this trial with others in the EARLY Consortium.

Additional Contributions: We wish to thank the SNAP Data and Safety Monitoring Board and the participants who made this study possible.

Participants—599 participants (22% men; 27% minority), age 18–35 (27.7 (4.4)), BMI 21–30 kg/m² (25.4 (2.6)), recruited via mailings and e-mails between August 2010 and February 2012.

Interventions—Participants were randomly assigned to: Control, Self-Regulation plus Small Changes or Self-Regulation plus Large Changes. The interventions focused on frequent self-weighing and using this information to know when behavior changes were needed. “Small Changes” taught participants to reduce intake and increase activity, both by approximately 100 calories per day. “Large Changes” focused on losing 5–10 pounds initially to buffer against expected weight gain. Interventions were delivered via 10 in-person group sessions during months 1–4 and then primarily online. Assessments occurred at randomization, 4 months, and then annually for 2–4 years (depending on time of recruitment).

Main outcome—Changes in weight from baseline over average follow-up of 3 years. Secondary outcomes: proportion gaining 1 pound from baseline, proportion developing obesity (BMI 30 kg/m²), weight change baseline to 2 years (last assessment reached by all cohorts)

Results—Mean (SE) weight changes over an average follow-up of 3 years were +0.26 kg (0.22), –0.56 kg (0.22), and –2.37 kg (0.22) in Control, Small Changes and Large Changes, respectively (p=0.001). Differences among all three groups were significant (Large Changes vs Control, p<.001; Small Changes vs Control, p<.02 and Large Changes vs Small Changes, p<.001). Both interventions significantly reduced incidence of obesity (p<.05) relative to Control (8.6%, 7.9% and 16.9% in Large, Small and Control, respectively); Large Changes reduced the proportion that gained 1 pound (p<.05).

Conclusions and Relevance—Self-regulation with Large or Small Changes both reduced weight gain in young adults over three years relative to Control, but Large Changes was most effective. These interventions could easily be implemented on a large scale and may impact public health.

Trial registration—ClinicalTrials.gov, NCT01183689

Introduction

Weight gain occurs commonly throughout adulthood and is associated with many adverse health outcomes.^{1–4} Young adults are the age group that is gaining weight the fastest;^{5–7} moreover, weight gain in those age 18 – 35 years has stronger negative associations with critical outcomes such as cancer risk and mortality than weight gain at later ages.^{8,9} Developing effective approaches to reduce weight gain in young adults is thus an important public health priority.

Previous efforts to prevent weight gain during adulthood, particularly in young adults, have had limited success.^{1,10} Although positive effects are often observed initially, few studies have followed participants for two to three years^{11–13} and long-term differences between intervention and control are rarely significant. Moreover, many of these programs have been implemented in college courses, limiting generalizability.¹⁴

The present study examined two novel interventions for weight gain prevention compared to a control condition on the magnitude of weight change across an average planned follow-up of 3 years. Both interventions were based on a self-regulation model shown previously to be

effective in preventing weight regain;¹⁵ both emphasized frequent self-weighing and changes in eating and activity to prevent weight gain. One approach focused on making daily small changes in eating and activity to prevent weight gain. This “small changes” approach has received a great deal of attention through programs such as America on the Move (<http://www.anschutzwellness.com/community-wellness-programs/america-the-move>) and is supported by theoretical papers¹⁶ and small studies^{17–20} suggesting that both decreasing intake and increasing activity by approximately 100 calories per day should be sufficient to prevent weight gain. The other approach emphasized larger initial changes in behavior to produce weight loss as a buffer against anticipated weight gains. Evidence favoring the “large changes” approach comes from the Women’s Healthy Lifestyle Project,²¹ which showed that producing initial weight losses of 5–15 pounds, even though they were followed by some weight regain, was effective in reducing weight gain in menopausal women. The current study tested whether either or both of these approaches reduced weight gain in young adults.

Methods

Study Design

The Study of Novel Approaches to Weight Gain Prevention (SNAP) is a 3-armed randomized controlled clinical trial, with equal allocation, comparing self-regulation with small daily behavior changes (Small Changes), self-regulation with large periodic behavior changes (Large Changes), and a minimal treatment control condition (protocol available in Supplement).²² The primary outcome is the mean weight gain over an average follow-up of 3 years. Secondary outcomes were the proportion of participants gaining 1 pound (chosen to represent a stringent criterion of weight gain over baseline) and the incidence of obesity (BMI ≥ 30 kg/m²) over the 3 years. We focused on outcomes over follow-up (rather than at one specific time point) to capture the cumulative effect of the interventions on body weight. We also examined weight change specifically at 2 years, since this is the last time point reached by all participants in SNAP and the outcome in several other current trials on weight gain prevention in young adults.²³ The study was funded by the National Heart Lung and Blood Institute and involved 2 clinical sites (Providence, RI and Chapel Hill, NC) and a coordinating center (Winston-Salem, NC) and was approved by each Institutional Review Board. A Data Safety Monitoring Board provided trial oversight.

Study Participants

SNAP targeted an enrollment of 600 participants (25% men and 25% racial / ethnic minorities), age 18–35, with a BMI of 21–30.9 kg/m². Both overweight and normal weight individuals were included since young adults in both weight groups (especially those who are overweight) are at greater risk of weight gain than older individuals.⁵ We included individuals with a BMI of 21 kg/m² since epidemiological studies have shown that higher BMI in young adults, even within the normal range, is associated with elevated mortality risk.⁹ In addition, the earlier the age that the threshold of BMI ≥ 25 kg/m² is exceeded, the greater the mortality risk. A weight loss of 5 pounds (as encouraged in one of the interventions), was considered safe in individuals with a BMI of 21 kg/m² because their BMI would remain in the normal range. Other eligibility criteria, described previously,²²

focused on ability to participate in the program (e.g. internet access, English speaking), safety (no history of eating disorders, ability to walk for activity) and completion of screening and baseline assessment visits. Participants were recruited primarily by mass mailings (38%) and e-mails (23%), using text that sought individuals who were concerned about gaining weight over time.²⁴

Randomization

Randomization assignment used variable block lengths, was stratified by clinical site, gender and ethnicity (non-Hispanic white/other), and was implemented through a web-based data management system.

Study Interventions

The interventions have been described in detail.²² The Control group attended one face-to-face meeting where they were introduced to the issue of weight gain, the concept of self-regulation, and an overview of both Small and Large Change approaches to potentially prevent weight gain.

Small and Large Changes interventions both began with 10 face-to-face group meetings over 4 months. This treatment length was selected to be sufficient to enable the 5 or 10 pound weight loss, but easily disseminated. Subsequently, the interventions were delivered primarily online. Each year, participants were invited to join two 4-week online refresher campaigns reinforcing the behaviors taught during the initial program. All participants received identical quarterly newsletters and personalized feedback reports on their assessment data, including the Control group.

The interventions were both framed in a self-regulation model that forms the basis for several self-control theories^{25–28} and has been applied to diabetes²⁹ and obesity¹⁵ and was used in a pilot study for this trial.³⁰ Self-regulation is based on a negative feedback loop, in which there is a goal, error detector and controlling responses. In SNAP, the goal was to not exceed baseline weight, the error detector was the scale and daily self-weighing, and the controlling responses involved changes in diet and exercise consistent with the Small or Large Change approach. To encourage self-regulation, participants were instructed to weigh themselves daily and submit their weight via the study website, text message or email. They received monthly email feedback on their weight, which was based on a color-coded system^{15,22} and either reinforced their success, encouraged problem-solving, or recommended additional strategies to help reverse weight gain. Participants who gained above baseline were invited to contact a study interventionist for problem solving assistance via email, phone or face-to-face, but very few requested this assistance.

The specific recommendations related to diet and activity differed for Small Changes vs Large Changes. Participants in Small Changes were taught to make daily small changes (approximately 100 kcal/day) in both diet (e.g. select lower calorie coffee drinks, reduce portion sizes) and physical activity (e.g. park farther from store, use stairs). Participants were given pedometers and instructed to add 2000 steps per day (equivalent to 1 mile) above baseline. If participants in Small Changes experienced weight gains above baseline, they were encouraged to make additional daily small changes.

Large Changes focused on losing weight (5 lbs if normal weight; 10 lbs if overweight) during the initial four-month program to create a buffer against subsequent weight gain. To achieve this, participants were prescribed a calorie goal based on a 500 to 1000 kcal deficit from baseline to use during the initial 8 weeks. They were also encouraged to gradually increase moderate intensity physical activity to a goal of 250 minutes/week, the level recommended for weight loss maintenance,³¹ and to maintain this over time. If weight exceeded baseline, they were to return to their calorie goal and confirm that they were achieving the activity goal.

Study Assessment

All participants were scheduled to complete assessments at baseline, month 4, year 1 and year 2. Depending on when participants were randomized, some were also scheduled to reach year 3 (N=437) and year 4 (N=106) before pre-specified data close-out on 12/31/14. All assessments were completed by masked staff members, who were centrally trained and certified. Participants received a \$50 honorarium for each follow-up assessment.

Weight was measured on a calibrated scale in light clothes, without shoes; height was assessed with a wall-mounted stadiometer. Two measures were taken and averaged. Cellular connected scales (“Smart” scales) were sent to those who had moved or could not attend a clinic visit. These non-protocol smart scale weights constituted 4.7% of all weight data with comparable numbers in the three groups, and were used only in sensitivity analyses.

Statistical approach

The primary hypothesis of SNAP, that the mean weight change across an average planned follow-up of 3 years would differ among the three arms, was assessed by fitting a mixed effects linear model to the changes in measured weight from baseline to 4, 12, 24, 36, and 48 months.³² This is similar to defining the area-under-the curve, and captures the overall exposure to weight. Participants were grouped according to randomization assignment with clinic site as the only pre-specified covariate. Estimated mean differences for each pairwise comparison from linear contrasts were assessed with Wald statistics, Bonferroni adjustment was used to control total Type I error to be 0.05 across the three comparisons. Multiple imputation was used to assess the sensitivity of the primary inference to missing data.³³ Secondary aims were to examine group differences over time in the proportion of participants who gained 1 pound and the proportion that developed obesity, using generalized estimating equations, and mean weight change from baseline to 2 years, with a linear contrast. All measured weights were included in analyses, except those during or within 6 months after pregnancies. To assess heterogeneity in intervention responses, three subgroup comparisons were pre-specified: baseline BMI (<25 kg/m² versus ≥25 kg/m²), age (<25 years versus ≥25 years), and gender.

The targeted sample of N=600 was projected to provide 90% power to detect an average difference between groups of 1.36 kg weight change over time while accommodating loss to follow-up of 7.5% month 4, additional 7.5% at year 1, and 5% per year thereafter.

Results

Study Participants

A total of 599 adults were enrolled (292 in Providence RI and 307 in Chapel Hill, NC) between August 2010 and February 2012 and randomly assigned to one of the three groups. Participants in the three groups were similar at baseline (Table 1). The study sample included 22% males and 27% from minority groups. Participants were [Mean (SD)] 28.2 (4.4) years of age and over 70% were above age 25; average BMI was 25.4 (2.6) kg/m² and approximately 50% were normal weight. The majority (63%) were employed full-time. Figure 1 presents the CONSORT diagram showing retention at each of the follow-up assessments. Retention did not differ among groups.

Intervention Delivery

Participants in Large and Small Changes attended an average of 87.4% and 86.0% of the 10 intervention sessions; 100% of the control group participants attended their one session. Intervention fidelity, determined by masked raters evaluating a randomly selected sample of 20% of recorded group sessions, was excellent, with 100% accuracy for distinguishing Large from Small Change sessions and for presentation of the appropriate behavioral content. Self-weighing, a cornerstone of self-regulation interventions, was increased in the two interventions. Whereas at baseline, 11–13% of each group reported daily self-weighing, at four months, daily self-weighing was reported by 75%, 72%, and 30% of Large Changes, Small Changes, and Control participants respectively ($p < 0.001$).

Use of the prescribed behavioral strategies also differed significantly ($p < 0.05$) by randomization group; for example at 4 months, 64% of Large Changes participants (and 10% and 11% in Small Changes and Control) reported reducing calories by 500–1000 kcal/day at least “much of the time” and 75% of Small Changes (and 28% and 24% in Large and Control) reported making small changes to diet every day. Weight losses during the first 4 months also differed significantly, with weight losses (mean [SE]) of -0.64 (0.22), -1.48 (0.23) and -3.60 (0.22) kg for Control, Small Changes and Large Changes respectively (all pairwise comparisons $p < 0.05$).

Weight Changes

Figure 2 presents the weight changes for the three groups at each assessment. The primary outcome -- mean (SE) weight change averaged across all the follow-up assessments —was 0.26 (0.22), -0.56 (0.22), and -2.37 (0.22) kg in Control, Small Changes and Large Changes, respectively. All three pair-wise comparisons were significant, with less weight gain (and even some weight loss) in Small Changes ($p = 0.018$) and Large Changes ($p < 0.001$) relative to Control and in Large Changes relative to Small Changes ($p < 0.001$).

Sensitivity analyses (Supplement Figure 1a–1c) including Smart-scale weights, using percent weight change (rather than kg) or censoring the data at 2 years all confirmed that both Large and Small Changes differed significantly from Control and Large Changes differed from Small Changes. Inference generated by multiple imputation of missing weight changes yielded comparable results.

Secondary Weight Outcomes

Results for the two dichotomous secondary outcomes are presented in Figure 3. The proportion of participants who gained ≥ 1 lb over baseline and the proportion that developed obesity increased steadily over time, with the greatest increases seen in the Control group. Across the 3 years of follow-up (Table 2), weight gains ≥ 1 lb were less common in Large Changes (23.6%) than in either Small Changes or Control (32.5% and 40.8% respectively). The incidence of obesity was significantly greater in the Control group (16.9%) than in either intervention group (7.9% in Small and 8.6% in Large Changes, respectively, $p < 0.05$). Weight changes between baseline and 2 years (Table 2)) were greater in the Control group than in either Small or Large Changes ($p < 0.05$), which did not differ from each other. Safety alerts occurred very infrequently (Supplement Table 1).

Subgroup Effects

Pre-specified interaction tests based on percent weight loss (to control for differences in baseline weights) revealed no significant differences among intervention effects across subgroups based on gender, age, and baseline weight. (Supplement Figure 2). In addition, no differences among race/ethnicity subgroups were evident ($p > 0.10$).

Discussion

Previous studies have failed to identify interventions with long-term effects on weight gain in young adults, who are at high risk for weight gain.^{10,12,13} In our study, we found that self-regulation interventions involving small or large changes were both effective in reducing the mean weight gain (and producing small weight loss) relative to control over an average follow-up of 3 years. In addition, Large Changes was more effective than Small Changes. These results were confirmed in several sensitivity analyses. The Large Changes intervention also successfully decreased the proportion of participants who experienced weight gains ≥ 1 pound over the follow-up, and both interventions reduced the incidence of obesity during follow-up by almost 50% relative to Control, representing a clinically significant reduction in risk of developing obesity.

This is the first study to test two different behavior change approaches to weight gain prevention and the first large study of the small changes approach.¹⁶ Although the theoretical basis of small changes has recently been questioned,³⁴ we found that the Small Changes approach had long-term efficacy in preventing weight gain relative to Control. Large Changes was more effective over the follow-up because of the significant weight losses produced at 4 months. This weight loss was followed by gradual regain, as seen in other weight loss³⁵ and weight gain prevention trials¹⁵ and by 2 years, Large Change participants had regained 2.1 kg (58% of their initial weight loss). In contrast, Small Changes lost less initially (1.48 kg at 4 months), but had a more stable trajectory, gaining only 0.7 kg between months 4 and year 2. At two years, weight change in both Small and Large Changes differed significantly from the Control group, but not from each other. Because the difference between Large and Small Change approaches diminished over time, further follow-up is clearly needed. In addition, it would be important to determine whether success at weight gain prevention would be maximized by periodically repeating the initial 4

month program to reinstate the buffer and/or re-engage participants in the small changes approach.

These interventions could easily be disseminated through community organizations and eHealth or mHealth approaches. The format used in SNAP, with initial face-to-face group meetings followed by Internet delivered maintenance approaches, may have improved outcomes as face-to-face approaches appear superior to Internet delivered weight loss interventions³⁶ and purely eHealth interventions have not been effective in preventing weight gain.³⁷ Likewise, weight loss and maintenance programs, which have included face-to-face or telephone counseling,^{15,38,39} appear more effective than internet only programs. Further research to determine how best to combine face-to-face and eHealth approaches and which individuals respond better to the Large versus Small Change approach is needed.

Observational studies of weight gain suggest that young adults gain about .6 – .8 kg per year,⁴⁻⁷ whereas our control group gained .54 kg at 2 years. The smaller weight gains in our control group may reflect the fact that SNAP was a weight gain prevention trial (vs an observational study) and the Control group received some, albeit modest, intervention.

Strengths of this trial include the large sample size, recruitment beyond college campuses, objectively measured outcome by blinded personnel, and the successful implementation and comparison of two different approaches to weight gain prevention. Other strengths include the fact that participants were followed over an average of 3 years and retention rates remained high. The main limitation of this efficacy trial is the generalizability of the results; participants in the trial were disproportionately female, non-Hispanic white, and college graduates. All participants were interested in being in a weight gain prevention trial and the screening process likely led to the selection of a highly motivated sample. Future studies should examine the effectiveness of these two interventions in other individuals more representative of the general population of young adults. The findings from this trial suggest that self-regulation approaches that include frequent self-weighing have clinically significant beneficial effects on reducing weight gain and risk of obesity in young adults and indicate that Large Changes may be particularly effective in reducing average weight gain over three years of follow-up. Further follow-up is clearly needed to determine whether effects are maintained over time and whether Large or Small Changes produce the best long-term outcomes. Since both small and large change interventions reduced weight gain relative to control, it may be important to consider individual preferences in selecting which approach to recommend. Given the success of both approaches in reducing incidence of obesity in the current sample of high-risk young adults, dissemination of these approaches could help to combat the epidemic of obesity.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

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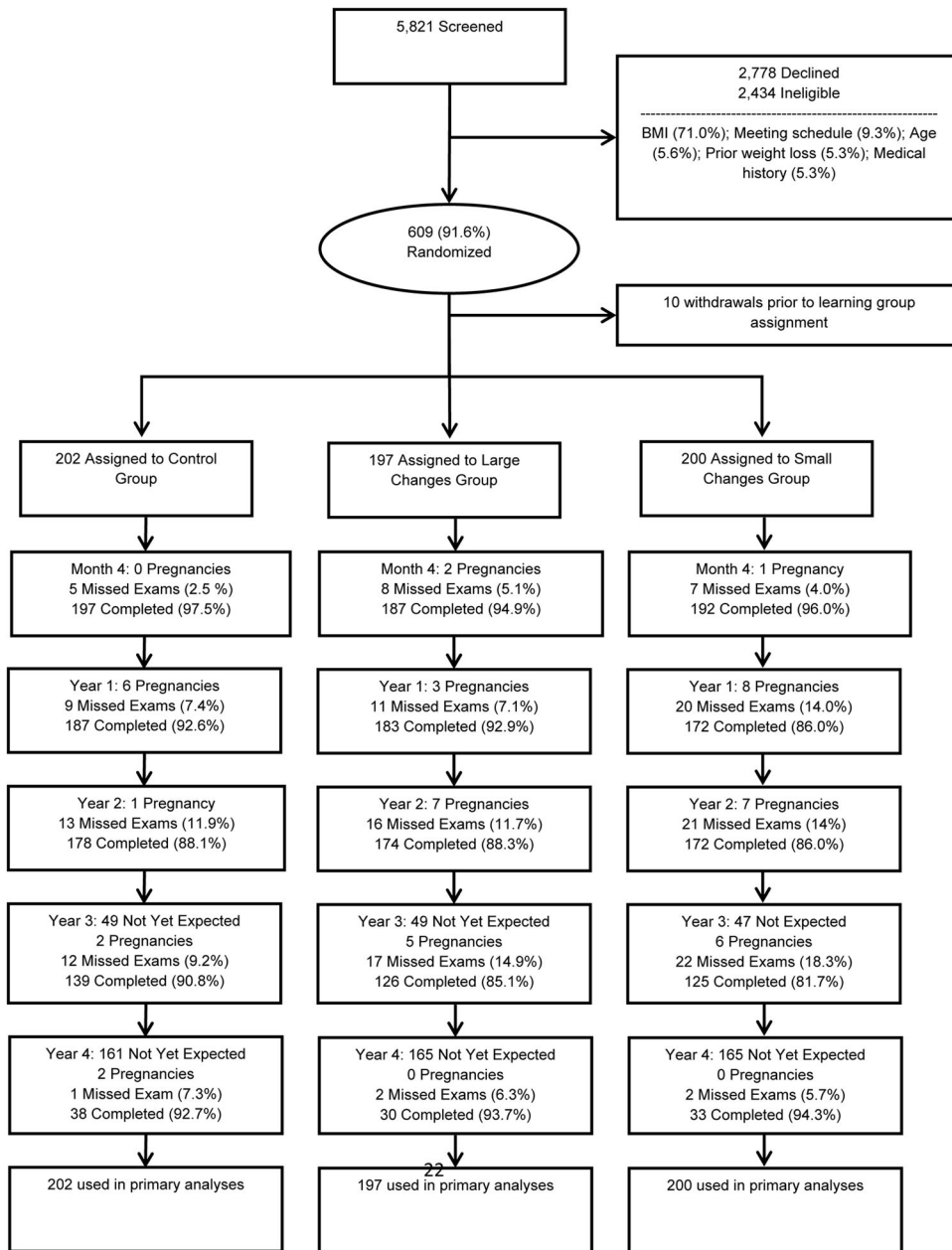


Figure 1.
Consort Diagram

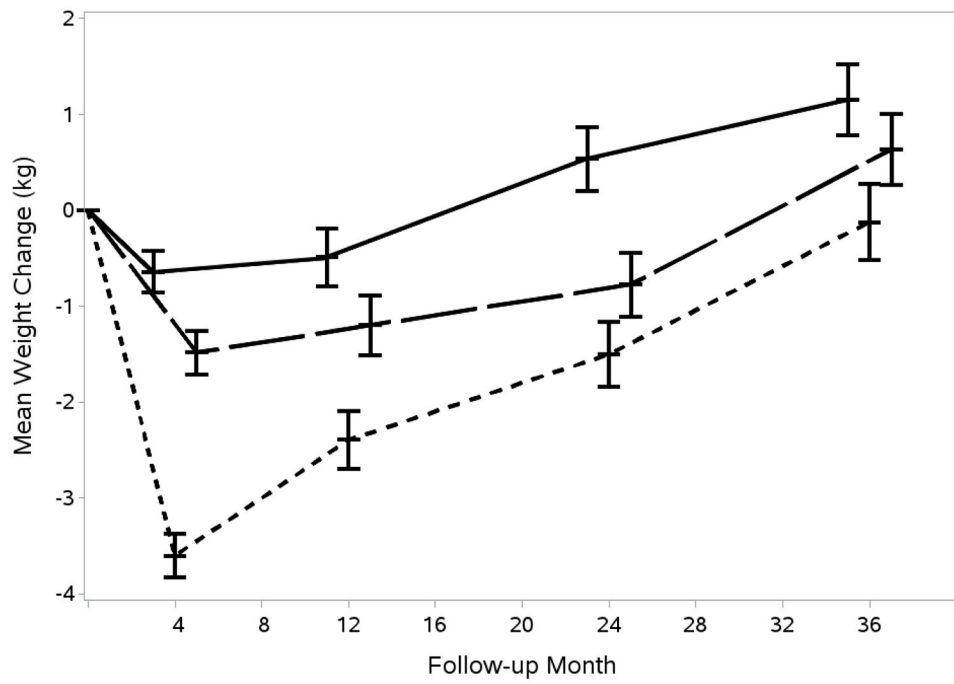


Figure 2. Mean (± 1 standard error) weight changes over time by intervention assignment.

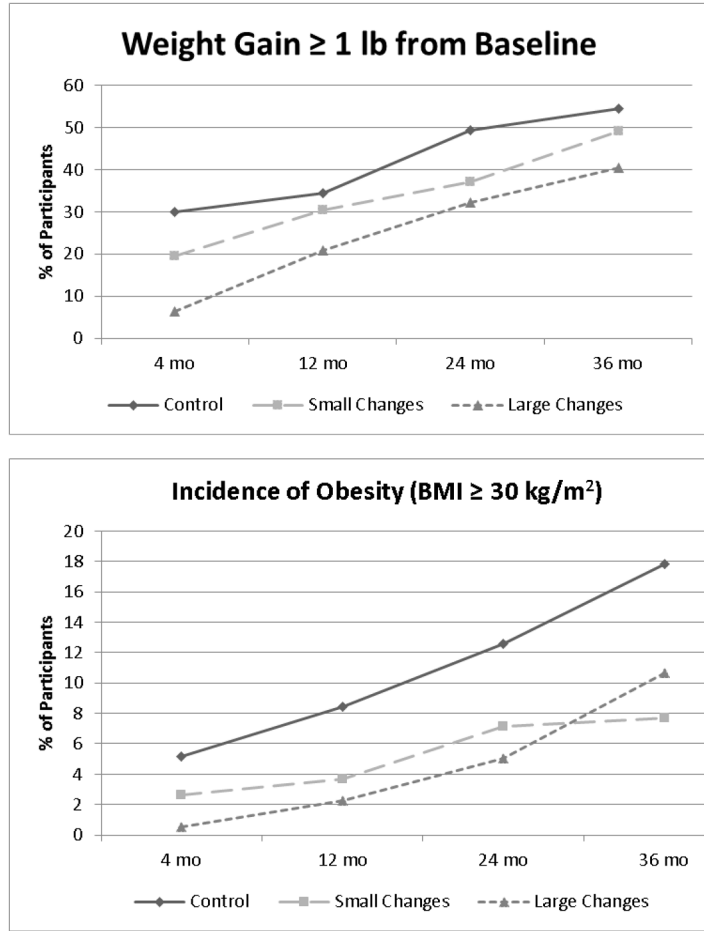


Figure 3. Proportion of participants in the Control, Small Changes and Large Changes groups who at 4, 12, 24, or 36 months had gained 1 lb from baseline (Figure 3a) or developed obesity (BMI ≥ 30 kg/m²) (Figure 3b). (Figure 3b excludes 16 participants who had a BMI of 30 – 30.9 at baseline)

Table 1

Characteristics of the SNAP participants at enrollment by intervention assignment: Mean (Standard Deviation) or Frequency (Percent).

Baseline Characteristics	Intervention Assignment*		
	Control N=202	Small Changes N=200	Large Changes N=197
Gender			
Female	158 (78.2%)	157 (78.5%)	154 (78.2%)
Male	44 (21.8%)	43 (21.5%)	43 (21.8%)
Age, years			
18–24.9	53 (26.2%)	60 (30.0%)	56 (28.4%)
25–35	149 (73.8%)	140 (70.0%)	141 (71.6%)
BMI, kg/m ²			
<25	97 (48.0%)	84 (42.0%)	96 (48.7%)
≥25	105 (52.0%)	116 (58.0%)	101 (51.3%)
Weight, kg	71.4 (10.2)	71.9 (11.0)	70.8 (11.0)
Race/ethnicity			
African-American	19 (9.4%)	25 (12.5%)	22 (11.2%)
Non-Hispanic White	148 (73.3%)	146 (73.0%)	144 (73.1%)
Asian/Pacific Islander	7 (3.5%)	11 (5.5%)	7 (3.5%)
Hispanic	15 (7.4%)	10 (5.0%)	21 (10.6%)
Multiple/Refusal	13 (6.4%)	8 (4.0%)	3 (1.5%)
Education			
Not college graduate	39 (19.3%)	46 (23.0%)	35 (17.8%)
College graduate	163 (80.7%)	154 (77.0%)	162 (82.2%)
Employment Status			
Employed full time	127 (62.9%)	125 (62.5%)	125 (63.5%)
Student full time	59 (24.3%)	61 (30.5%)	55 (27.9%)
Other	26 (12.8%)	14 (7.0%)	17 (8.6%)

* None of these baseline characteristics differed significantly among the three groups

Table 2

Summary of primary and secondary results: mean (standard errors) from generalized linear models.

	Control	Small	Large	Overall	Pairwise comparisons*		
					C vs S	C vs L	S vs L
<u>Primary Outcome</u>							
Change in weight (kg) over average of 3 years follow-up	0.26 (0.22)	-0.56 (0.22)	-2.37 (0.22)	<0.001	Mean=0.82 95% CI [0.23, 1.41] P=0.018	Mean=2.64 [2.05, 3.22] <0.001	Mean=1.81 [1.22, 2.41] <0.001
<u>Secondary Outcomes</u>							
% gaining 1 lb over average of 3 years follow-up	40.8 (4.4)	32.5 (3.8)	23.6 (2.8)	<0.001	OR=1.41 95% CI [1.02, 1.98] P = 0.09	OR=2.28 [1.64, 3.19] <0.001	OR=1.62 [1.14, 2.31] 0.025
% developing obesity at least once during follow-up ^a	16.9 (2.7)	7.9 (2.0)	8.6 (2.0)	0.008	OR=2.36 95% CI [1.23, 4.52] P = 0.002	OR=2.13 [1.12, 4.10] 0.02	OR=0.92 [0.44, 1.91] 0.27
Change in weight (kg) from baseline to 2 years	0.54 (0.33)	-0.77 (0.33)	-1.50 (0.34)	<0.001	1.31 95% CI [0.39, 2.24] P = 0.016	2.04 [1.11, 2.98] <0.001	0.74 [-0.20, 1.66] 0.33

^a Excludes 16 participants (7, 5, 4 in Control, Small Changes, Large Changes respectively) with obesity at baseline (BMI between 30 and 30.9)

* Bonferroni-adjusted comparisons between pairs of intervention groups