Original Investigation

Innovative Self-Regulation Strategies to Reduce Weight Gain in Young Adults

The Study of Novel Approaches to Weight Gain Prevention (SNAP) Randomized Clinical Trial

Rena R. Wing, PhD; Deborah F. Tate, PhD; Mark A. Espeland, PhD; Cora E. Lewis, MD; Jessica Gokee LaRose, PhD; Amy A. Gorin, PhD; Judy Bahnson; Letitia H. Perdue, MS; Karen E. Hatley, MPH; Erica Ferguson, MSW; Katelyn R. Garcia, MS; Wei Lang, PhD; for the Study of Novel Approaches to Weight Gain Prevention (SNAP) Research Group

IMPORTANCE Weight gain occurs commonly in young adults and has adverse effects on health.

OBJECTIVE To compare 2 self-regulation interventions vs control in reducing weight gain in young adults over a mean follow-up of 3 years.

DESIGN, SETTING, AND PARTICIPANTS Randomized clinical trial in 2 academic settings of 599 participants aged 18 to 35 years with body mass index (BMI, calculated as weight in kilograms divided by height in meters squared) of 21.0 to 30.0, recruited via mailings and emails from August 2010 to February 2012. Data were analyzed from January 2015 to January 2016.

INTERVENTIONS Participants were randomized to control, self-regulation plus small changes, or self-regulation plus large changes. Both interventions focused on frequent self-weighing to cue behavior changes. "Small changes" taught participants to reduce intake and increase activity, both by approximately 100 calories per day. "Large changes" focused on losing 2.3 to 4.5 kg initially to buffer against expected weight gain.

MAIN OUTCOMES AND MEASURES Changes in weight from baseline over mean follow-up of 3 years. Secondary outcomes included proportion gaining at least 0.45 kg from baseline, proportion developing obesity (BMI, ≥30.0), and weight change baseline to 2 years.

RESULTS Among the 599 participants (22% men; 27% minority; mean [SD] age, 27.7 [4.4] years; mean [SD] BMI, 25.4 [2.6]), mean (SE) weight changes over a mean follow-up of 3 years were 0.26 (0.22), −0.56 (0.22), and −2.37 (0.22) kg in the control, small-changes, and large-changes groups, respectively ($P < .001$). Differences among all 3 groups were significant (large changes vs control, $P < .001$; small changes vs control, $P = .02$; large changes vs small changes, $P < .001$). On secondary outcomes, both interventions significantly reduced incidence of obesity relative to control (mean [SE], 8.6% [2.0%], 7.9% [2.0%], and 16.9% [2.7%] in the large-changes, small-changes, and control groups, respectively; $P = .02$ for large changes vs control and $P = .002$ for small changes vs control); a smaller percentage of participants in the large-changes group gained 0.45 kg or more (mean [SE], 23.6% [2.8%], 32.5% [3.8%], and 40.8% [4.4%], respectively; $P < .001$ vs control and $P = .02$ vs small changes) and weight change from baseline to 2 years was greater in control than in small or large changes (mean [SE], 0.54 [0.33], −0.77 [0.33], and −1.50 [0.34] kg, respectively; $P = .02$ vs small changes and $P < .001$ vs large changes).

CONCLUSIONS AND RELEVANCE Self-regulation with large or small changes both reduced weight gain in young adults over 3 years relative to control, but the large-changes intervention was more effective.

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Author Affiliations: Author affiliations are listed at the end of this article.

Group Information: The Study of Novel Approaches to Weight Gain Prevention (SNAP) Research Group members are listed at the end of this article.

Corresponding Author: Rena R. Wing, PhD, Warren Alpert Medical School of Brown University, Weight Control and Diabetes Research Center, Miriam Hospital, 196 Richmond St, Providence, RI 02903 (rwing@lifespan.org).

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 aged 18 to 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 observed participants for 2 to 3 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 2 novel interventions for weight gain prevention compared with a control condition on the magnitude of weight change across a mean 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 in the popular media and is supported by theoretical articles[16] and small studies[17-20] suggesting that both decreasing intake and increasing activity by approximately 100 kcal 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 2.3 to 6.8 kg, even though they were followed by some weight regain, was effective in reducing weight gain in menopausal women. The present study tested whether either or both of these approaches reduced weight gain in young adults.

Key Points

Question Would a self-regulation intervention involving periodic large or daily small behavior changes reduce weight gain in young adults over a mean follow-up of 3 years?

Findings In this randomized clinical trial, self-regulation with large or small changes both reduced weight gain in young adults over 3 years relative to control, but the large-changes intervention was more effective.

Meaning Dissemination of self-regulation behavior change approaches could help reduce obesity in young adults.

Methods

Study Design

The Study of Novel Approaches to Weight Gain Prevention (SNAP) is a 3-armed randomized 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 (study protocol available in Supplement 1).[22] The primary outcome was the mean weight gain over a mean follow-up of 3 years. Secondary outcomes were the proportion of participants gaining 0.45 kg or more (chosen to represent a stringent criterion of weight gain over baseline) and the incidence of obesity (body mass index [BMI, calculated as weight in kilograms divided by height in meters squared], ≥30.0) over the 3 years. We focused on outcomes over follow-up (rather than at 1 specific time point) to capture the cumulative effect of the interventions on body weight. We also examined weight change specifically at 2 years because 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, Rhode Island, and Chapel Hill, North Carolina) and a coordinating center (Winston-Salem, North Carolina) and was approved by each institutional review board. Participants completed written informed consent. A data safety monitoring board provided trial oversight.

Study Participants

SNAP targeted an enrollment of 600 participants (25% men and 25% racial/ethnic minorities), aged 18 to 35 years, with a BMI of 21.0 to 30.9. Both overweight and normal-weight individuals were included because 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 21.0 because 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 of 25.0 or greater is exceeded, the greater the mortality risk. A weight loss of 2.3 kg (as encouraged in 1 of the interventions) was considered safe in individuals with a BMI of 21.0 or more because their BMI would remain in the normal range. Other eligibility criteria, described previously,[22] focused on ability to participate in the program (eg, 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 emails (23%), using text that sought individuals who were concerned about gaining weight over time.[24]

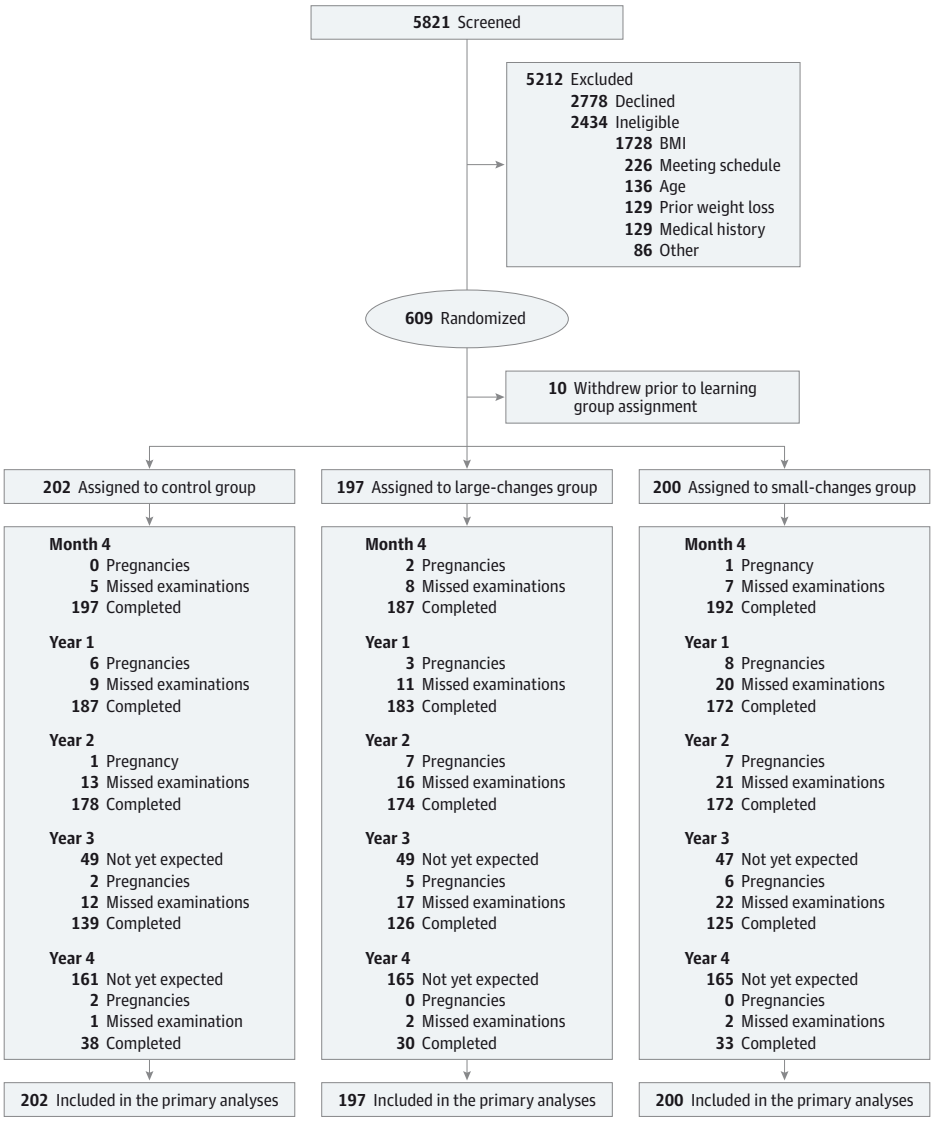
Randomization

Randomization assignment used variable block lengths, was stratified by clinical site, sex, and ethnicity (non-Hispanic white/other), and was implemented through a web-based data management system (**Figure 1**).

Study Interventions

The interventions have been described in detail.[22] The control group attended 1 face-to-face meeting where they were introduced to the issue of weight gain, the concept of self-

Figure 1. CONSORT Diagram



regulation, and an overview of both the small- and large-changes approaches to potentially prevent weight gain.

The small- and large-changes interventions both began with 10 face-to-face group meetings over 4 months. This treatment duration was selected to be sufficient to enable the 2.3- or 4.5-kg weight loss, but easily disseminated. Subsequently, the interventions were delivered primarily online. Each year, participants were invited to join 2 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 diabetes mellitus[29] and obesity[15] 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-changes 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, telephone, or face to face, but very few requested this assistance.

The specific recommendations related to diet and activity differed for the small-changes vs large-changes groups. Participants in small changes were taught to make daily small

changes (approximately 100 kcal/d) in both diet (eg, select lower-calorie coffee drinks, reduce portion sizes) and physical activity (eg, park farther from store when shopping, use stairs). Participants were given pedometers and instructed to add 2000 steps per day (equivalent to 1.7 km) above baseline. If participants in small changes experienced weight gains above baseline, they were encouraged to make additional daily small changes.

The large-changes intervention focused on losing weight (2.3 kg if normal weight; 4.5 kg if overweight) during the initial 4-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 prespecified data closeout on December 31, 2014. 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 clothing, without shoes; height was assessed with a wall-mounted stadiometer. Two measures were taken and averaged. Cellular network–connected scales ("smart" scales) were sent to those who had moved or could not attend a clinic visit. These nonprotocol smart scale weights constituted 4.7% of all weight data, with comparable numbers in the 3 groups, and were used only in sensitivity analyses.

Statistical Approach

The primary hypothesis of SNAP, that the mean weight change across a mean planned follow-up of 3 years would differ among the 3 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 using SAS. 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 prespecified 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 .05 across the 3 comparisons. Multiple imputation was used to assess the sensitivity of the primary inference to missing data.[32] Secondary aims were to examine group differences over time in the proportion of participants who gained 0.45 kg or more and the proportion who 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, 3 subgroup comparisons were prespecified: baseline BMI (<25.0 vs ≥25.0), age (<25 vs ≥25 years), and sex.

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

Results

Study Participants

A total of 599 adults were enrolled (292 in Providence, Rhode Island, and 307 in Chapel Hill, North Carolina) between August 2010 and February 2012 and randomly assigned to 1 of the 3 groups. Participants in the 3 groups were similar at baseline (**Table 1**). The study sample included 22% men and 27% from minority groups. Participants were a mean (SD) of 28.2 (4.4) years of age and 72% were older than 25 years; mean (SD) BMI was 25.4 (2.6), and approximately 50% were of 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 the large- and small-changes groups attended a mean of 87.4% and 86.0% of the 10 intervention sessions, respectively; 100% of the control group participants attended their 1 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-changes from small-changes sessions and for presentation of the appropriate behavioral content. Self-weighing, a cornerstone of self-regulation interventions, was increased in the 2 interventions. Whereas at baseline, 11% to 13% of each group reported daily self-weighing, at 4 months, daily self-weighing was reported by 75%, 72%, and 30% of large-changes, small-changes, and control participants, respectively ($P < .001$).

Use of the prescribed behavioral strategies also differed significantly ($P < .001$) by randomization group; for example, at 4 months, 64% of large-changes participants (and 10% and 11% in the small-changes and control groups) reported reducing calories by 500 to 1000 kcal/d at least "much of the time" and 75% of small-changes participants (and 28% and 24% in the large-changes and control groups) reported making small changes to diet every day. Weight losses during the first 4 months also differed significantly, with mean (SE) weight changes of −0.64 (0.22), −1.48 (0.23), and −3.60 (0.22) kg for the control, small-changes, and large-changes groups, respectively (all pairwise comparisons $P < .05$).

Weight Changes

Figure 2 presents the weight changes for the 3 groups at each assessment. The primary outcome, mean (SE) weight change averaged across all the follow-up assessment, was 0.26 (0.22), −0.56 (0.22), and −2.37 (0.22) kg in the control, small-

Table 1. Characteristics of the SNAP Participants at Enrollment by Intervention Assignment

Baseline Characteristic	Intervention Assignment[a] Control (n = 202)	Small Changes (n = 200)	Large Changes (n = 197)
Sex, No. (%)			
Male	44 (21.8)	43 (21.5)	43 (21.8)
Female	158 (78.2)	157 (78.5)	154 (78.2)
Age, y, No. (%)			
18-24	53 (26.2)	60 (30.0)	56 (28.4)
25-35	149 (73.8)	140 (70.0)	141 (71.6)
BMI, No. (%)			
<25.0	97 (48.0)	84 (42.0)	96 (48.7)
≥25.0	105 (52.0)	116 (58.0)	101 (51.3)
Weight, kg, mean (SD)	71.4 (10.2)	71.9 (11.0)	70.8 (11.0)
Race/ethnicity, No. (%)			
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, No. (%)			
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, No. (%)			
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)

Abbreviation: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared).

[a] None of these baseline characteristics differed significantly among the 3 groups.

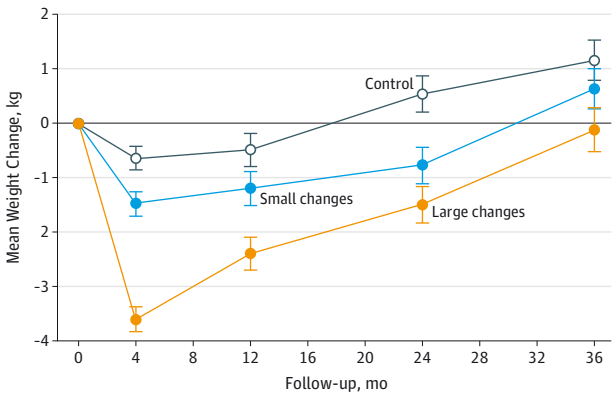
changes, and large-changes groups, respectively. All 3 pairwise comparisons were significant, with less weight gain (and even some weight loss) in the small-changes ($P = .02$) and large-changes ($P < .001$) groups relative to control and in the large-changes relative to the small-changes group ($P < .001$).

Sensitivity analyses (eFigures 1-3 in Supplement 2) including smart-scale weights, using percent weight change (rather than kilograms), or censoring the data at 2 years all confirmed that both the large-changes and small-changes groups differed significantly from control and the large-changes group differed from the small-changes group. Inference generated by multiple imputation of missing weight changes yielded comparable results.

Secondary Weight Outcomes

Results for the 2 dichotomous secondary outcomes are presented in **Figure 3**. The proportion of participants who gained 0.45 kg or more 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 of 0.45 kg or more were less common in the large-changes group (23.6%) than in either the small-changes or control groups (32.5% and 40.8%, respectively; $P = .02$ for small changes and $P < .001$ for control). The incidence of obesity was significantly greater in the control group (16.9%) than in either intervention group (7.9% in small changes and 8.6% in large changes, respectively; $P = .002$ for small changes and $P = .02$ for large changes). Weight changes between baseline and 2 years

Figure 2. Mean Weight Changes Over Time by Intervention Assignment



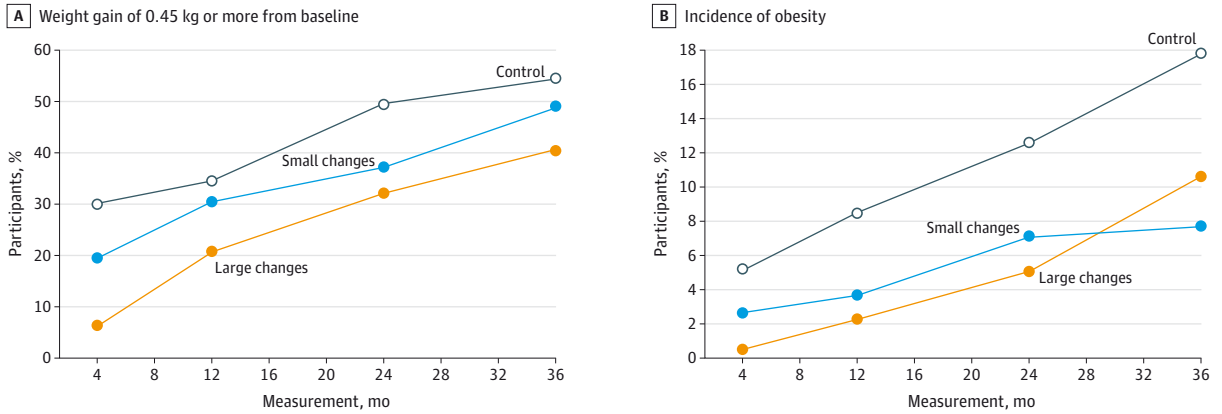
Weight was measured at 4, 12, 24, and 36 months. Error bars indicate standard error.

(Table 2) were greater in the control group than in either the small- or large-changes groups ($P = .02$ for comparison with small changes and $P < .001$ for comparison with large changes), which did not differ from each other. Safety alerts occurred very infrequently (eTable in Supplement 2).

Subgroup Effects

Prespecified interaction tests based on percent weight loss (to control for differences in baseline weights) revealed no

Figure 3. Proportion of Participants in the Control, Small-Changes, and Large-Changes Groups Who at 4, 12, 24, or 36 Months Had Gained 0.45 kg or More From Baseline or Developed Obesity



A, Participants who gained 0.45 kg or more from baseline. B, Participants who developed obesity (BMI [body mass index, calculated as weight in kilograms divided by height in meters squared], ≥30.0) (excludes 16 participants who had a BMI of 30.0-30.9 at baseline).

Table 2. Summary of Primary and Secondary Results: Mean (SE) From Generalized Linear Models

	Mean (SE)			Pairwise Comparisons[a]					
					Control vs Small Changes		Control vs Large Changes		Small Changes vs Large Changes	
Outcome	Control	Small Changes	Large Changes	Overall *P* Value	OR (95% CI)	*P* Value	OR (95% CI)	*P* Value	OR (95% CI)	*P* Value
Primary Outcome										
Change in weight over mean of 3 y follow-up, kg	0.26 (0.22)	−0.56 (0.22)	−2.37 (0.22)	<.001	0.82 (0.23-1.41)	.02	2.64 (2.05-3.22)	.001	1.81 (1.22-2.41)	<.001
Secondary Outcomes										
Participants gaining ≥0.45 kg over mean of 3 y follow-up, %	40.8 (4.4)	32.5 (3.8)	23.6 (2.8)	<.001	1.41 (1.02-1.98)	.09	2.28 (1.64-3.19)	<.001	1.62 (1.14-2.31)	.02
Participants developing obesity at least once during follow-up, %[b]	16.9 (2.7)	7.9 (2.0)	8.6 (2.0)	.008	2.36 (1.23-4.52)	.002	2.13 (1.12-4.10)	.02	0.92 (0.44-1.91)	.27
Change in weight from baseline to 2 y, kg	0.54 (0.33)	−0.77 (0.33)	−1.50 (0.34)	<.001	1.31 (0.39-2.24)	.02	2.04 (1.11-2.98)	<.001	0.74 (−0.20-1.66)	.33

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); OR, odds ratio.

[a] Bonferroni-adjusted comparisons between pairs of intervention groups.

[b] Excludes 16 participants (7, 5, 4 in control, small changes, large changes, respectively) with obesity at baseline (BMI between 30.0 and 30.9).

significant differences among intervention effects across subgroups based on sex, age, and baseline weight (eFigure 4 in Supplement 2). In addition, no differences among race/ethnicity subgroups were evident.

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 a mean follow-up of 3 years. In addition, the large-changes intervention was more effective than the small-changes intervention. These results were confirmed in several sensitivity analyses. The large-changes intervention also successfully decreased the proportion of participants who experienced weight gains of 0.45 kg or more 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.

To our knowledge, this is the first study to test 2 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,[33] we found that the small-changes approach had long-term efficacy in preventing weight gain relative to control. The large-changes approach 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 loss[34] and weight gain prevention trials[15] and by 2 years, large-changes participants had regained 2.1 kg (58% of their initial weight loss). In contrast, participants in the small-changes group lost less weight initially (a mean of 1.48 kg at 4 months) but had a more stable trajectory, gaining only 0.7 kg between month 4 and year 2. At 2 years, weight change in both the small-changes and large-changes groups differed significantly from the control group but not from each other. Because the difference between the large- and small-change approaches diminished over time, further follow-up is 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 reengage participants in the small-changes approach.

These interventions could easily be disseminated through community organizations and public health approaches using electronic communication or mobile devices. The format used in SNAP, with initial face-to-face group meetings followed by Internet-delivered maintenance approaches, may have improved outcomes because face-to-face approaches appear superior to Internet-delivered weight-loss interventions[35] and interventions involving exclusively electronic communication have not been effective in preventing weight gain.[36] Likewise, weight loss and maintenance programs that have included face-to-face or telephone counseling[15,37,38] appear more effective than Internet-only programs. Further research to determine how best to combine face-to-face and electronic approaches and which individuals respond better to the large- vs small-change approach is needed.

Observational studies of weight gain suggest that young adults typically gain approximately 0.6 to 0.8 kg per year,[4-7] whereas our control group gained a mean of 0.54 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 masked personnel, and the successful implementation and comparison of 2 different approaches to weight gain prevention. Other strengths include the fact that participants were observed over a mean 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 participating 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 2 interventions in other individuals more representative of the general population of young adults.

Conclusions

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 a large-changes approach may be particularly effective in reducing mean weight gain over 3 years of follow-up. Further follow-up is needed to determine whether effects are maintained over time and whether the large- or small-changes approach produces the best long-term outcomes. Because 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 the incidence of obesity in the present sample of young adults, dissemination of these approaches could help to combat the epidemic of obesity.

ARTICLE INFORMATION

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Author Affiliations: Alpert Medical School of Brown University, Miriam Hospital, Providence, Rhode Island (Wing, Ferguson); University of North Carolina–Chapel Hill, Chapel Hill (Tate, Hatley); Wake Forest School of Medicine, Winston Salem, North Carolina (Espeland, Bahnson, Perdue, Garcia, Lang); Department of Medicine, University of Alabama at Birmingham, Birmingham (Lewis); Department of Health Behavior and Policy, Virginia Commonwealth University School of Medicine, Richmond (LaRose); Department of Psychological Sciences, University of Connecticut, Storr (Gorin).

Author Contributions: Dr Espeland had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
Study concept and design: Wing, Tate, Espeland, Lewis, LaRose, Gorin, Lang.
Acquisition, analysis, or interpretation of data: Wing, Tate, Espeland, Lewis, Gorin, Bahnson, Perdue, Hatley, Ferguson, Garcia, Lang.
Drafting of the manuscript: Wing, Tate, Espeland, Hatley.
Critical revision of the manuscript for important intellectual content: Wing, Tate, Espeland, Lewis, LaRose, Gorin, Bahnson, Perdue, Ferguson, Garcia, Lang.
Statistical analysis: Espeland, Garcia, Lang.
Obtained funding: Wing, Tate, Espeland, LaRose, Gorin, Bahnson, Lang.
Administrative, technical, or material support: Tate, Lewis, Bahnson, Perdue, Hatley, Ferguson.
Study supervision: Wing, Tate, LaRose, Gorin.

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Group Information: The Study of Novel Approaches to Weight Gain Prevention (SNAP) Research Group members (listed alphabetically by site unless otherwise specified) were from the following clincal sites: Miriam Hospital/Brown Medical School: Rena R. Wing, PhD (principal investigator); Erica Ferguson, MSW, RD (program coordinator); Ana Almeida; Kirsten Annis, BA; Ryan Busha, MS; Isabella Cassell, BA; Eva Chen, BS; Pamela Coward, MEd, RD; Jose DaCruz; Caitlin Egan, MS; Michelle Fisher, RN; Stephanie Guerra, RD; Susan Himes, PhD; Brittany James, BA; Elissa Jelalian, PhD; Marie Kearns, MS; Angelica McHugh, MPH; Kevin O'Leary, MS; Kathy Palmer, BA; Deborah Ranslow-Robles; Amanda Samuels, BA; Kathryn Story, BA; Kelly Strohacker, PhD; Zeely Sylvia, BA; Jennifer Trautvetter, BS; Jessica Unick, PhD; Kristen Whitehead; Samantha Williams, MSc; Carolyn Wunsch, BS; and Annajane Yolken, BA. University of North Carolina at Chapel Hill: Deborah Tate, PhD (principal investigator); Karen E. Hatley, MPH (program coordinator); Candice Alick, MS; Shelia Barnes; Loneke Blackman, MS, RD; Rachel Bordogna, RD; Kimberly Cooper; Melissa Crane, PhD; Victoria Cryer, MS; Molly Diamond, MPH; Jennifer Frank, MPH; Noel Kulik, PhD; Hannah Lerner, MPH; Megan McMullin; Kristen Polzien,

PhD; Keneisha Quick, MS; Brooke Tompkins Nezami, MA; Brie Turner-McGrievey, PhD, MS, RD; Carmina Valle, PhD, MPH; Stephen Zablonski, BS; Erin Zeigler, BSN. Group members from the coordinating center at Wake Forest School of Medicine: Mark A. Espeland, PhD (principal investigator); Letitia H. Perdue, MS (program coordinator); Judy L. Bahnson, BA, CCRP (co-investigator); Wei Lang, PhD3; Cheryl Bentley; Patty Davis, BS; Katelyn Garcia, MS; Leah P. Griffin, MS; Lea Harvin, BS; Mary A. Hontz, BA; Mark King, BS; Kathy Lane, BS; Rebecca H. Neiberg, MS; Julia Roberston, BS. Consultant co-investigators were Cora E. Lewis, MD, MSPH, University of Alabama at Birmingham; Amy Gorin, PhD, University of Connecticut; Jessica G. LaRose, PhD, Virginia Commonwealth University School of Medicine. Group members from the central resource center at Central Laboratory, Northwest Lipid Metabolism and Diabetes Research Laboratories: Santica M. Marcovina, PhD, ScD (principal investigator); Jessica Hurting (program coordinator); Vinod Gaur, PhD. Group members from the federal sponsor, National Heart, Lung, and Blood Institute: S. Sonia Arteaga, PhD; Catherine Loria, PhD, MS, FAHA.

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