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

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

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**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.

**TRIAL REGISTRATION**
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Self-Regulation Strategies Reduce 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). 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. 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. 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. 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, 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.

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 I).

Study Interventions
The interventions have been described in detail. The control group attended 1 face-to-face meeting where they were introduced to the issue of weight gain, the concept of self-
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 24-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 and has been applied to diabetes mellitus and obesity and was used in a pilot study for this trial. 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 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

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Figure 1. CONSPORT Diagram

5821 Screened

- 5212 Excluded
  - 2778 Declined
  - 2434 Ineligible
  - 1728 BMI
  - 226 Meeting schedule
  - 136 Age
  - 129 Prior weight loss
  - 129 Medical history
  - 86 Other

609 Randomized

10 Withdrawd prior to learning group assignment

202 Assigned to control group
- Month 4
  - 0 Pregnancies
  - 5 Missed examinations
  - 197 Completed
- Year 1
  - 6 Pregnancies
  - 9 Missed examinations
  - 187 Completed
- Year 2
  - 1 Pregnancy
  - 13 Missed examinations
  - 178 Completed
- Year 3
  - 49 Not yet expected
  - 12 Missed examinations
  - 139 Completed
- Year 4
  - 161 Not yet expected
  - 2 Pregnancies
  - 3 Missed examination
  - 38 Completed

197 Assigned to large-changes group
- Month 4
  - 2 Pregnacies
  - 8 Missed examinations
  - 187 Completed
- Year 1
  - 3 Pregnancies
  - 11 Missed examinations
  - 183 Completed
- Year 2
  - 7 Pregnancies
  - 16 Missed examinations
  - 174 Completed
- Year 3
  - 49 Not yet expected
  - 17 Missed examinations
  - 126 Completed
- Year 4
  - 165 Not yet expected
  - 2 Missed examinations
  - 30 Completed

200 Assigned to small-changes group
- Month 4
  - 1 Pregnacies
  - 7 Missed examinations
  - 192 Completed
- Year 1
  - 8 Pregnacies
  - 20 Missed examinations
  - 172 Completed
- Year 2
  - 7 Pregnacies
  - 21 Missed examinations
  - 172 Completed
- Year 3
  - 47 Not yet expected
  - 22 Missed examinations
  - 125 Completed
- Year 4
  - 165 Not yet expected
  - 2 Pregnancies
  - 33 Completed

202 Included in the primary analyses

197 Included in the primary analyses

200 Included in the primary analyses
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 study 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. Cellulard network–connected scales (“smart” scales) were sent to participants in the 3 groups sessions, were 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 (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 assessments, was 0.26 (0.22), −0.56 (0.22), and −2.37 (0.22) kg in the control, small-
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 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

<table>
<thead>
<tr>
<th>Table 1. Characteristics of the SNAP Participants at Enrollment by Intervention Assignment</th>
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<tbody>
<tr>
<td>Baseline Characteristic</td>
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<tr>
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<tr>
<td>Male</td>
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<tr>
<td>Female</td>
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<tr>
<td>Age, y, No. (%)</td>
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<tr>
<td>18-24</td>
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<tr>
<td>25-35</td>
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<tr>
<td>BMI, No. (%)</td>
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<tr>
<td>&lt;25.0</td>
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<tr>
<td>≥25.0</td>
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<tr>
<td>Weight, kg, mean (SD)</td>
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<tr>
<td>Other</td>
</tr>
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</table>

Abbreviation: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared).
* None of these baseline characteristics differed significantly among the 3 groups.
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 and weight gain prevention trials 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 and interventions involving exclusively electronic communication have not been effective in preventing weight gain. Likewise, weight loss and maintenance programs that have included face-to-face or telephone counseling 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, 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- vs 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.
Changes in body mass index by age, mass index at different adult ages, weight change, and demographic predictors of 5-year weight cardiovascular disease by baseline weight status in participants who made this study possible.

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REFERENCES


