A Randomized Trial Testing the Efficacy of a Novel Approach to Weight Loss Among Men with Overweight and Obesity

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Objective: To test the efficacy of a weight loss intervention designed to appeal to men.

Methods: A randomized trial tested the efficacy of the Rethinking Eating and FITness (REFIT) weight loss program compared to a wait-list control. The 6-month intervention was delivered via two face-to-face sessions followed by Internet contacts. REFIT encouraged participants to create calorie deficits by making six 100-calorie changes to their eating daily while increasing physical activity, and the program encouraged customization through selection of specific diet strategies evaluated each week.

Results: Participants (N = 107, 44.2 years, 31.4 kg/m², 76.6% white) were randomized into the study, and 90.6% provided data at 6 months. REFIT participants lost −5.0 kg (95% CI: −6.1, −3.9) at 3 months, which was maintained through 6 months (−5.3 kg, 95% CI: −6.5, −4.2); this was greater than the control group (p < 0.001; 6 months: −0.6, 95% CI: −1.8, 0.5). More REFIT participants (49%) achieved a 5% weight loss than control participants (19%; OR 9.4; 95% CI: 3.2, 27.4). An average of 11.2 (±2.7) of 13 of the online intervention contacts were completed.

Conclusions: The novel REFIT intervention produced clinically significant weight losses. This approach holds promise as an alternative to traditional behavioral therapy for men.

Introduction

Recent estimates suggest that men and women have near-equal rates of combined overweight and obesity (1). Behavioral interventions for weight control have been developed that produce weight losses of approximately 5–10% of initial body weight and improve multiple health outcomes (2). However, several reviews have shown that men represent only approximately 27% of study samples (3-6). In order to help men reduce the negative consequences of obesity, it is important to better involve men in behavioral weight loss interventions.

A recent review suggests that men can lose weight when they participate in weight loss programs (7), indicating that men are not likely avoiding participation due to lack of success. Instead, it is hypothesized that a mismatch between men’s preferences for weight loss programs and the programs that are currently available is contributing to the low participation rates. Men have indicated that they view weight loss as a feminine activity (8-10) and perceive weight loss programs and the programs that are currently available is contributing to the low participation rates. Men have indicated that they view weight loss as a feminine activity (8-10) and perceive weight loss programs as targeted at women (10). Men report wanting individually focused programs that do not include strict meal plans and provide the ability to tailor the diet to their preferences. Additionally, they prefer programs that do not disrupt their daily routine and provide information in a clear and direct manner (8,9,11-13).

One approach that has been used to meet men’s preferences for weight loss programs has been to use lower intensity, self-directed programs. While this approach has been efficacious in some studies (14-17), other studies did not observe weight losses greater than the control group (18). Another approach that has been used has been to deliver programs via the Internet (e.g., Ref. 19) in order to minimize the potential for lifestyle disruptions caused by programs delivered via face-to-face sessions.

The purpose of this study was to test a multicomponent weight loss program designed to appeal to men, featuring novel (modest caloric restriction via 100-calorie reductions, self-tailored calorie-reduction strategy order, simplified self-monitoring) and established (physical activity progression, tailored feedback) treatment components. The primarily Internet-delivered Rethinking Eating and FITness (REFIT)
The program was tested in a randomized controlled trial compared to a wait-list control group over 6 months. The primary outcome was change in weight with secondary outcomes of change in waist circumference, body fat, caloric intake, and leisure-time physical activity.

Methods
Participants and recruitment
Participants were recruited via emails sent to the university community and local worksites, flyers distributed in surrounding communities, and word of mouth between July 2013 and March 2014. Men were required to be 18–65 years of age, have a body mass index (BMI) of 25–40 kg/m², have regular access to the Internet, and be able to exercise safely (20). Men were excluded if they reported high alcohol intake (21), major psychiatric conditions, weight loss >10 pounds over the previous 6 months, current treatment for cancer, or if they were unable/unwilling to attend group sessions. Participants who reported diagnoses of high blood pressure, diabetes, history of cancer, or any joint problems were required to obtain consent from their physician.

Procedure
Two hundred and seventy-seven individuals completed the online eligibility screener (Figure 1). Those who were initially eligible were contacted via telephone to complete the screening process and schedule an orientation session. At orientation, participants provided informed consent and scheduled their baseline assessment visit. Randomization occurred after baseline assessments and was revealed to participants during a face-to-face group session. Randomization was conducted using Excel’s random number generator in a 1:1 ratio.

Follow-up assessments were conducted at 3 and 6 months post-randomization. The first author, who was unblinded to participant randomization, conducted assessments. After completing each follow-up assessment, all participants received $20 and feedback reports including their anthropometric measurements and a summary of their diet. The University of North Carolina at Chapel Hill Institutional Review Board approved this study.

Intervention description
The REFIT intervention targeted constructs from social cognitive theory (22) and self-determination theory (23) and focused on promoting autonomy to enhance its appeal to men. Table 1 describes the constructs targeted by the intervention. Recommendations were provided for changing diet, physical activity, and self-monitoring behaviors and was delivered via two 1-h, face-to-face group sessions followed by interactive online intervention contacts weekly for 10 weeks and monthly online contact for 3 months. Intervention materials were developed and delivered by a doctorate-level public health trainee.

Diet recommendations and tailored lesson selection. The REFIT program utilized a novel approach to achieving a modest caloric deficit and allowed participants to self-tailor the order of calorie-reduction strategies and associated lessons. Participants were encouraged to create a modest calorie deficit by making a minimum of six 100-calorie changes from typical eating habits each day (approximately 4200 calories per week). Participants self-tailored the order of specific diet strategies to focus on each week and received a brief online lesson on how to implement the strategy. For example, reducing dietary fat was included as a strategy that encouraged replacing high-fat/high-calorie foods with low-fat foods with fewer calories. Reducing portion size was a strategy presented as a way to choose the foods participants preferred while reducing typical consumption. The lessons integrated behavioral techniques included in traditional weight loss programs [e.g., problem solving (24,25)]. Strategies and lessons later in the program focused on lifestyle changes that have demonstrated effects on weight loss [e.g., water to replace caloric beverages (26)] or weight loss maintenance [e.g., maintaining consistent eating patterns (27)].

Participants selected one strategy and associated lesson per week, which allowed them to independently evaluate the effect of the strategy on their weight loss. If the participant was successful (i.e., participant lost ≥ 1 lb), they had the option to continue using the successful strategy. Participants were presented with three strategies to choose from during their first selection and one new strategy was
presented each week; therefore participants had at least three strategies to select from during each online contact. Strategy introduction order was based on potential for impact on calorie balance where higher impact strategies were presented earlier. All lessons focused on diet because during weight loss programs, men have more difficulty implementing changes to their diet than to their physical activity (28).

**Physical activity.** The REFIT program provided progressive exercise plans with weekly exercise goals increasing to 225 min of moderate-to-vigorous physical activity per week (29). Behavioral strategies for increasing activity were included in the tailored feedback.

**Self-monitoring.** Participants were encouraged to monitor their diet through tracking the number of 100-calorie changes they made to their eating each day using a checklist paper tracking form recording only the number of changes they made each day. The form included areas to record their minutes of exercise and daily weight. Using detailed self-monitoring was a suggested strategy provided to participants who were consistently not meeting the weight loss goal. Daily self-weighing was presented as a form of self-regulation where participants could use the daily weights as objective feedback on their behaviors (30–32).

**Intervention procedure.** Prior to making changes, participants completed a 1-week self-evaluation, which occurred between two face-to-face group sessions. Participants used detailed self-monitoring (i.e., recording all calories and grams of fat eaten and all physical activity) and daily self-weighing to identify behaviors that they were interested in changing. Participants could choose to monitor using provided paper diaries or a mobile application or website. After the self-evaluation, participants were provided personalized estimates for calorie needs to lose approximately 1 and 2 pounds per week (1,200–3,308 calories) (33). The estimates were provided for reference only and participants were not instructed to continue tracking their daily calories.

After the two face-to-face sessions, intervention contact was delivered online through asynchronous interactive online contacts (Qualtrics survey). Participants reported their weight, physical activity, number of daily changes to diet, and days of self-weighing. Automated, tailored feedback was provided based on meeting or not meeting their physical activity goal, days of daily weighing (5 or more), their weight loss (≥1 pound), and the number of changes made to eating (≥42 changes per week). Participants selected their next strategy and created a SMART goal related to diet or exercise to accomplish over the next week. This process was completed in approximately 15–30 min. A reminder to complete the contact was sent midweek and a new strategy lesson was emailed if a participant did not complete the contact by week’s end. If a participant did not complete online contact for two consecutive weeks, they were contacted via telephone.

**Wait-list condition**
Participants randomized to the wait-list condition attended one group session to receive their randomization assignment. They received a feedback report, which included a summary of their baseline measures, but no treatment recommendations were provided. After the 6-month assessments, participants were offered one group session and 10 weeks of the online program.

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**TABLE 1 Intervention components and theory constructs**

| Theory construct | Intervention component |
|------------------|------------------------|
| Self-efficacy    | • Create opportunities for mastering one dietary change before adding another. |
|                  | • Encourage gradual exercise progression to 225 min/week starting at one of three initial levels of activity. |
|                  | • Guide participants through making personally relevant weekly SMART goals related to diet and physical activity. |
|                  | • Provide reinforcement of goal achievement and problem solving for overcoming barriers related to diet and physical activity during tailored feedback. |
| Autonomous motivation | • Provide participants with choice of calorie-reduction strategies and lessons describing options for implementing strategies. |
|                  | • Encourage participants to personalize exercise types and plans to enhance enjoyment of the activity. |
|                  | • Encourage participants to evaluate their motivation for weight loss and weight loss behaviors regularly. |
|                  | • Use nondirective language in lessons and tailored feedback. |
| Outcome expectancies | • Group sessions focus on connections between diet and physical activity and weight loss; emphasize health and psychological benefits with moderate (5–10%) weight loss. |
|                  | • Preintervention self-evaluation provides opportunity for participants to identify changes they want to make to their diet and physical activity habits. |
|                  | • Lessons and tailored feedback describe the expected outcome of changing each behavior and provide options for how that change can be achieved. |
| Self-regulation  | • Encourage consistent self-monitoring via a simple checklist self-monitoring form. |
|                  | • Record: |
|                  |   • 100-calorie changes to diet via checklist |
|                  |   • Minutes of physical activity |
|                  |   • Daily weight |
|                  | • Evaluate progress during weekly interactive online intervention contacts. |
Outcome measures

Demographic information. Demographic information including race, age, employment status, and marital status were obtained at baseline.

Anthropometrics. Weight was measured to the nearest 0.1 kg on a calibrated digital scale (Tanita BWB 800). Waist circumference was measured at the iliac crest using a flexible tape measure (Gulick II) to the nearest 0.1 cm. Height was measured to the nearest 0.1 cm using a wall-mounted stadiometer (baseline only). Measures were assessed twice for consistency. Body composition was assessed using air displacement plethysmography (Bod Pod, Cosmed).

Dietary intake. Dietary intake was measured using the National Cancer Institute’s Automated Self-Administered 24-h Recall (version 2011). Participants completed two recalls at each assessment (weekday and weekend). Recalls outside the probable range for a single-day intake for an adult man (650–5,700 calories) were removed (Baseline: \(n = 2\), 3M: \(n = 3\), 6M: \(n = 0\)).

Physical activity. Physical activity was measured using the Paffenbarger Activity Questionnaire (34). This questionnaire assesses walking for exercise and transportation, flights of stairs climbed, and leisure-time physical activity [classified using the metabolic equivalents from the Compendium of Physical Activities (35)].

Program utilization and evaluation. Completion of online contacts and selection of strategies were collected automatically through the online system. At each assessment, participants were asked how frequently they weighed themselves on a seven point scale (31,36).

During the 6-month assessment, REFIT group participants were asked how frequently they used strategies recommended including: made 100-calorie changes to their diet, used the study tracking sheet, tracked their intake using an application/website, or recorded their exercise. These were reported on a five-point scale ranging from 1 “never or hardly ever” to 5 “always or almost always.” They rated their satisfaction with the program and how likely they were to recommend the program to other men on a four-point scale. Finally, they rated their confidence that they would be able to continue using the approach recommended by the program on an eight-point scale (37).

Statistical analyses

An a priori power analysis estimated that 104 participants were needed to detect a 2.0 kg difference between treatment groups (15,16,18), assuming a 15% attrition rate (80% power and \(p = 0.025\), adjusting for multiple comparisons at 3 and 6 months).

Data were analyzed using SAS 9.3. Differences between groups at baseline and between study completers and noncompleters were tested using t-test and chi-square analyses. Changes in primary and secondary outcomes were tested in intent-to-treat analyses (\(N = 107\)) using linear mixed model analyses with multiple imputations to account for missing data. PROC MI was used to develop five data sets with data imputed for missing values using the Markov chain Monte Carlo procedure. Mean centered values for marital status and full-time employment were included as covariates in all models. Predictors of weight loss were assessed using Spearman's correlations.

Results

Baseline demographic characteristics are presented in Table 2. There were no differences between treatment groups (\(p > 0.05\)). The majority of participants returned for the 3-month (94.4%) and 6-month (90.7%) assessments, with no difference in completion rates by treatment group (\(p = 0.98\)). While not significant, participants who did not return for the follow-up assessment at 3 months were less likely to be married than those who returned (50.0% vs. 81.2%, \(p = 0.07\)). At 6-month assessments, dropouts were less likely to be employed full time (70.0% vs. 90.1%, \(p = 0.05\)). Dropouts did not otherwise differ from those who participated in the assessments (\(p \geq 0.13\)).

Weight loss and secondary outcomes

Table 3 shows the changes between baseline and 3 or 6 months for anthropomorphic values, intake, and exercise. Weight loss was significantly greater in the REFIT group as compared to the wait-list group at both 3 and 6 months (\(p < 0.001\); Figure 2). There were greater reductions in the REFIT group in waist circumference and percent body fat at both time points (\(p < 0.001\)). More REFIT participants achieved a 5% weight loss (49.1%) than the wait-list group (9.3%, odds ratio 9.4; 95% CI: 3.2, 27.4).

There were significant increases in physical activity reported by the REFIT group compared to the wait-list group at both follow-up time points (\(p \leq 0.001\)). There was a significant reduction in caloric intake reported by both groups at 3 months (group by time difference: \(p = 0.28\)). At 6 months, the difference between groups had increased; however, this between group difference did not reach significance (\(p = 0.08\)). Changes in diet between baseline and 3 and

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**TABLE 2** Baseline sample characteristics: mean ± SD or \(N\) (%)

| Outcome measure | REFIT | Wait-list | \(p\)-value (between groups) |
|-----------------|-------|-----------|-----------------------------|
| \(N\)           | 53    | 54        |                             |
| Age             | 44.7 ± 11.3 | 43.7 ± 11.6 | 0.63                       |
| Race/ethnicity  |       |           |                             |
| White, non-Hispanic | 44 (83%) | 38 (70%) | 0.19                       |
| Black           | 5 (9%) | 12 (22%)  |                             |
| Other           | 4 (8%) | 4 (7%)    |                             |
| Marital status  |       |           |                             |
| Married, living with partner | 43 (81%) | 42 (78%) | 0.67                       |
| Not married     | 10 (19%) | 12 (22%) |                             |
| Education       |       |           |                             |
| High school, vocational training, or partial college | 8 (15%) | 10 (19%) | 0.64                       |
| College graduate or more | 45 (85%) | 44 (81%) |                             |
| Employed full time | 48 (91%) | 47 (87%) | 0.56                       |
| Weight (kg)     | 99.6 ± 14.3 | 99.9 ± 14.8 | 0.91                       |
| BMI (kg/m²)     | 31.4 ± 3.9  | 31.5 ± 4.0  | 0.96                       |
| Waist circumference (cm) | 109.0 ± 10.2 | 108.5 ± 10.4 | 0.80                       |
| Percent body fat | 34.5 ± 6.1  | 34.1 ± 6.3  | 0.74                       |

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6 months were associated with weight loss in the REFIT group (Spearman’s $r = 0.40$, $p = 0.01$, $r = 0.33$, $p = 0.02$; respectively), whereas change in intake was only associated with weight change at 6 months in the wait-list group (3 m: $r = 0.01$, $p = 0.94$; 6 m: $r = 0.33$, $p = 0.02$). Change in physical activity was only associated with weight loss at 6 months in the REFIT group (3 m: $r = -0.24$, $p = 0.09$; 6 m: $r = -0.36$, $p = 0.01$; wait-list 3 m: $r = 0.10$, $p = 0.48$; 6 m: $r = -0.17$, $p = 0.23$).

**Program utilization**

All participants randomized to the REFIT group completed the two face-to-face sessions and completed 11.2 ± 2.7 of the 13 online intervention contacts. Participants reported making 28 ± 16 of the 42 recommended 100-calorie reductions per week during the first 12 weeks of the intervention and reported 224 ± 143 min of physical activity during intervention week 12. Table 4 shows the completion rates of each of the contacts and participants’ strategy selections. Across all weeks, participants selected the new strategy 50.8% of the time while they self-tailored strategy order by selecting a previously introduced strategy during 30.9% of contacts and reviewing a successful strategy 18.4% of the time. Participants selected an average of 13 (± 3) strategies during the program.

During the 6-month assessment, REFIT participants ($n = 47$) were asked how frequently they used the recommended strategies. Sixty-two percent reported that they made 100-calorie changes to their diet “much of the time” or “always or almost always.” Few participants (23.4%) reported tracking these changes using the checklist form while 44.7% reported routinely self-monitoring their diet using a mobile application or website. A greater percentage of participants reported self-weighing daily during the 6-month assessment (62.5%) than at baseline (16.7%; $p < 0.001$).

The number of online contacts completed was associated with weight loss at 6 months (Spearman’s $r = -0.37$, $p = 0.01$). Similarly, self-reported frequency of making 100-calorie changes to diet ($r = -0.54$, $p < 0.001$), using the study-created tracking sheet ($r = -0.35$, $p = 0.02$) or a mobile application to track diet ($r = -0.37$, $p = 0.01$), and self-weighing ($r = -0.36$, $p = 0.01$) were associated with weight loss. Total strategies selected and total strategies reviewed were not associated with weight loss ($r = -0.13$, $p = 0.36$; $r = -0.05$, $p = 0.71$, respectively). Predictors of achieving a 5% weight loss successful were similar to those of overall weight loss except that both modes of self-monitoring were nonsignificantly related to weight loss success (tracking sheet $p = 0.06$; application $p = 0.05$).

**Program satisfaction**

REFIT participants positively evaluated the intervention: 91.5% reported that they were satisfied or very satisfied with the program.
and 95.7% reported they would recommend the program to a friend. On a scale of 1 “not confident” to 8 “very confident,” participants reported feeling confident that they would be able to maintain the changes they made to their eating habits (6.2 ± 1.9) and physical activity (6.3 ± 1.7).

Discussion
This study tested the efficacy of a multicomponent, mainly Internet-delivered weight loss intervention for men with overweight and obesity. This program produced weight losses of approximately 5 kg (5%) at 3 months, which was maintained during the reduced-contact period through the 6-month assessment as compared to a nonsignificant 0.6 kg (0.6%) weight loss in the wait-list comparison group. Nearly 50% of REFIT participants lost 5% of their initial body weight, an amount associated with significant health improvements. In addition to weight losses, there were improvements in waist circumference, percent body fat, and physical activity among REFIT recipients. Moreover, the REFIT program was well utilized and was positively reviewed by recipients.

This study contributes to the limited literature on creating behavioral weight loss programs targeting men. It builds on prior studies where participants were encouraged to change their eating and exercise through following recommendations related to a limited number of diet and physical activity behaviors (14-18). The focus on a smaller number of behaviors was designed to streamline communication and minimize the time participants spent interacting with the intervention, thus making it appealing to men. Prior studies have differed on the emphasis placed on reducing intake ranging from reducing caloric density of the diet (18) to using traditional monitoring to stay below a calorie goal (14-17). Given that men in REFIT and in the studies utilizing traditional calorie-reduction strategies achieved clinically meaningful weight losses, continuing to emphasize calorie reduction during weight loss programs with men appears important.

The REFIT program encouraged making changes related to one strategy each week, which was selected because it was hypothesized to be more appealing to men than traditional approaches. Similar approaches have been developed for general populations (38-40). In these earlier studies, participants selected a single eating and physical activity goal and worked toward meeting this goal until it was achieved. By contrast, the REFIT program encouraged participants to work toward a study-developed goal (i.e., six 100-calorie changes) but allowed the participants to personalize their approach toward reaching this goal via selection of strategies to focus on each week. This unique approach to choice within a weight loss program may be appealing to men and other populations underrepresented in weight loss programs.

Interestingly, and unexpectedly, more participants in the REFIT study reported using a mobile application or website to self-monitor diet than the simplified paper self-monitoring checklist created for this study. Despite this, use of either type of self-monitoring was associated with greater weight loss and there were trends for increased likelihood of achieving a 5% weight loss. Providing options for modes and/or types of self-monitoring may be an important public health strategy.

### Table 4: Online intervention contact completion rates and participant strategy selections

| Program week | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 |
|--------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Complete intervention online contact (n) | – | 48 | 48 | 48 | 48 | 48 | 51 | 45 | 48 | 47 | 42 | 40 | 39 | 42 | – | – | – | – | – |
| Complete intervention online contact (%) | – | 90.6 | 90.6 | 90.6 | 90.6 | 90.6 | 96.2 | 84.9 | 90.6 | 88.7 | 79.2 | 73.6 | 75.5 | 79.2 | – | – | – | – | – |
| Percent eligible to review strategy based on successful weight loss (≥1 lb/week) | 81.3 | 81.3 | 87.5 | 72.9 | 85.4 | 72.5 | 68.9 | 75.0 | 68.1 | 66.7 | 77.5 | 76.9 | 57.1 | 56.1 | 56.1 | 56.1 | 56.1 | 56.1 | 56.1 |
| Review strategy after weight loss | N/a | 27.1 | 12.5 | 18.8 | 29.2 | 21.6 | 11.1 | 29.2 | 21.6 | 11.1 | 29.2 | 21.6 | 11.1 | 29.2 | 21.6 | 11.1 | 29.2 | 21.6 | 11.1 |
| Select previously introduced strategy (self-tailored order) | N/a | 33.3 | 62.5 | 27.1 | 47.9 | 29.2 | 27.5 | 35.6 | 31.3 | 40.4 | 4.8 | 25.0 | 10.3 | 26.2 | 10.3 | 26.2 | 10.3 | 26.2 | 10.3 |
| Select newly introduced strategy (program order) | 100% | 39.6 | 25.0 | 54.2 | 33.3 | 41.7 | 51.0 | 53.3 | 39.6 | 42.6 | 83.3 | 57.5 | 79.5 | 59.5 |

Note: Strategy options in order of introduction: fat reduction, reducing calories from beverages, reduce portion sizes (week 2), calories from snacks, calories from meats, using meal replacements, fast food, reducing added sugar, restaurant eating, calorie density, eating during sedentary behavior, meal patterns, water as beverage replacement, eating in social situations, relapse prevention, and maintaining motivation.
of self-monitoring may be helpful in improving adherence to this recommended behavior.

Larger between-group differences were observed on self-reported changes in physical activity than changes in diet in this study. However, weight change and behavior change were more strongly associated within the intervention group than within the wait-list group. This suggests that the intervention group may have more accurately recalled their diet and physical activity behaviors or that the days reported were more representative of their usual behaviors than the recalls provided by wait-list participants. Given the challenge of accurately assessing diet and physical activity, it will be important to continue to explore how both aspects of energy balance contribute to the weight losses observed in lower intensity weight loss programs.

While this study contributes to the limited literature on men’s weight loss programs, there are limitations to consider. First, the relatively homogenous study sample is not representative of all men with overweight and obesity; thus, study results may not generalize to other groups. Second, this program was implemented and assessed by the same unblinded researcher (MMC). This may have influenced participants and increased their compliance to program recommendations and participation in follow-up assessments. Finally, this study utilized a wait-list control group; therefore, there is no way to test which intervention components were effective.

This study evaluated the effect of a novel weight loss program designed to meet men’s weight loss needs in a manner that was appealing to them in a randomized trial with high retention and program utilization rates. Future studies are needed to test the approach employed in this program using a more generalizable sample of men in order to understand if the results can be replicated. Additionally, there is a need to test the effects of this approach over a longer time period. Because there was no evidence of weight regain after the weekly sessions ended, the weight loss approach encouraged in this program may be more sustainable than the calorie-counting approach used in more traditional programs.

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