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Keep It Off: A phone-based intervention for long-term weight-loss maintenance

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Abstract

Long-term weight-loss maintenance is notoriously difficult to achieve and promote. As the novelty of weight loss treatment fades, enthusiasm for diet and exercise tends to wane in the maintenance phase. Given the recognition of obesity as a chronic disorder requiring continued engagement in weight-control behaviors, there is a need to identify cost-effective and supportive therapies that can sustain motivation. In this paper, we describe the study design and baseline characteristics of participants enrolled in a trial to evaluate a program (Keep It Off) developed specifically for weight-loss maintenance using therapeutic phone contact with recent weight losers throughout the period in which they are at highest risk for weight regain. In the Keep It Off randomized clinical trial we are evaluating this phone-based intervention that focuses on key weight-loss maintenance behaviors followed by continued self-monitoring, reporting of weight, feedback, and outreach in members of a Minnesota managed-care organization. The goal of the intervention is to flatten the typical relapse curve. Moreover, data from this trial will inform our understanding of weight-loss maintenance, including predictors and behaviors that increase the likelihood of success over the long term.

Keywords

Weight loss; exercise; diet; reducing; obesity; overweight; weight gain

Introduction

Although many behavioral weight-loss treatments are efficacious in the short-term, long-term maintenance remains a critical challenge.^{1–2} Behavioral strategies to improve long-term outcomes have included increasing treatment duration^{1–4} and incorporating key lessons learned about successful weight-loss maintenance (e.g., high levels of physical activity, self-weighing) from the National Weight Control Registry.^{5–9} Virtually all past intervention

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studies have started by inducing weight loss among overweight or obese individuals, whereas our study begins after the initial, intentional weight loss.

The period of initial weight loss is typically the most intensive treatment phase. The maintenance phase occurs after the novelty of treatment may have faded, when participants tend to participate in treatment sessions sporadically^{10–11} and begin to question whether continued weight-loss efforts are worth the energy.¹² Given the recognition of obesity as a chronic disorder requiring continuity of care and engagement in weight-control behaviors, there is a need for cost-effective therapies to support motivation for weight loss maintenance efforts over the long term.

An alternative and innovative approach is to develop programs focused exclusively on maintenance of weight loss, without regard to initial weight-loss methods. The intervention content for such a program would be tailored for weight maintenance and offer critical support by providing therapeutic contact to participants through the period in which they are at highest risk for weight regain. We are aware of only one other published study that has used a similar approach to recruitment and treatment.¹³

Treatment delivery modality is also a key consideration. Phone-based counseling has been found to be a convenient and viable alternative to more intensive therapies for affecting a variety of health behaviors.^{14–17} Advantages of phone contact over other treatment modalities including print mail and web-based formats, include provision of immediate feedback, a reduction in message ambiguity, the use of natural language, and a personal focus.^{18–19} Phone-based interventions have been shown to be moderately effective in weight-loss maintenance^{14, 20} and suggest that it may be an appropriate population-based treatment modality to support weight-loss maintenance in adults. To date, phone counseling has been evaluated only as a component of a program that started with weight-loss initiation.^{14, 20}

New methods are needed for maintaining long-term weight loss to address the practical challenges identified in previous research and build on current theoretical understanding of the processes associated with successful weight-loss maintenance.²¹ We reasoned that recruiting individuals who have recently intentionally lost weight may be an effective strategy. Moreover, treatment content and delivery for this maintenance-specific program was informed by several theoretical models including Rothman's Decision Criteria Maintenance Model²¹ and the Relapse Prevention Model.^{22–23} Key elements of these maintenance-focused models, including helping participants appreciate the benefits of their achieved weight loss and develop an active plan for self-monitoring progress and responding to weight gain before it becomes more difficult to reverse, were incorporated into an intervention package that also helped participants achieve and maintain the key behaviors associated with successful weight loss maintenance.^{2, 9, 24–28}

This paper describes the study design and baseline characteristics of the Keep It Off study, a randomized clinical trial in which we are evaluating a phone-based intervention for long-term weight-loss maintenance. The intervention integrates a core set of phone sessions focusing on key weight-loss maintenance behaviors and skills followed by continued self-monitoring and reporting of weight, bimonthly tailored feedback, monthly and bimonthly check-in calls and, for those who experience a small weight regain, additional outreach calls to problem-solve regarding weight-gain-reversal strategies.

Study design

This study was designed to evaluate an innovative intervention to improve weight-loss maintenance in members of the Minnesota-based HealthPartners managed-care organization

who had recently lost weight. Four hundred nineteen adult men and women who had intentionally lost at least 10% of their body weight during the previous year were randomized to either the Self-Directed Maintenance Intervention Comparison Condition (Self-Directed) or the Guided Maintenance Intervention (Guided). Primary study outcomes are weight change and weight loss maintenance at 24 month follow-up. We hypothesize that Guided participants will have regained less weight at 24 month follow-up compared to those in the Self-Directed condition, and be more likely to have maintained their baseline weight loss. Secondary study aims include assessments of: a) subgroup analysis of intervention effectiveness (e.g., BMI status, weight loss method, gender); b) mediating factors (e.g., self-efficacy for and barriers to engaging in weight maintenance behaviors, physical activity, dietary intake, and social support); c) process measures (e.g., adherence and intervention “dose”) as predictors of weight outcomes; and d) intervention costs to evaluate intervention scalability.

Recruitment and enrollment

The recruitment goal was to obtain baseline data from 400 adults who had intentionally lost at least 10% of their body weight during the past year and met the following criteria: 1) 19 to 70 years old; 2) enrolled in the managed-care organization health plan for at least 1 year prior to screening; 3) BMI ≥ 20.5 kg/m²; and 4) ability to communicate with the research staff by telephone. Exclusion criteria included 1) history of anorexia nervosa; 2) bariatric surgery; 3) modified Charlson²⁹ score ≥ 3 (using prior-year diagnoses), non-skin cancer, or congestive heart failure; 4) participation in a phone-based weight-loss program; and 5) current participation in another weight-management research study. Adopting procedures from the National Weight Control Registry (NWCR)⁶, potential participants were asked to provide weight-loss documentation (e.g., “before-and-after” photographs, names of individuals able to verify weight loss) to ensure the veracity of their self-reported weight loss. NWCR data show a strong association between documented and self-reported weight change ($r=.87$).⁶

Recruitment took place from May 2007 to September 2008 using multiple strategies and channels. Specific recruitment messages across these methods focused on “keeping weight off can be as difficult as losing it in the first place” and “have you recently lost weight and are interested in keeping it off?” Strategies included: 1) direct emails to employees known to have HealthPartners insurance; 2) advertisements in online and print newsletters through worksites where a large number employees were known to have HealthPartners insurance; 3) HealthPartners member- and patient-based advertisement on the HealthPartners website, print newsletters, and the company on-hold messaging system; 4) targeted mailings based on participation in a HealthPartners online physical activity program and weights recorded in the HealthPartners electronic medical record; and 5) community-based recruitment such as local newspaper and radio advertisements.

Interested people could call or email the study team. During phone screening calls, a Keep It Off recruitment staff member described the study in detail. If the caller was interested, the staff member asked questions to assess eligibility, documenting the responses in the study database. If interested and eligible, the potential participant was scheduled for an in-person baseline visit, during which they reviewed and signed consent forms, were weighed and measured, and completed baseline questionnaires.

Methods

Participants

Figure 1 depicts a modified Consolidated Standards Of Reporting Trials (CONSORT) diagram that documents the number of potential participants assessed for eligibility, the number of participants and reasons for exclusion, and the number of participants who completed the baseline measurement visit and were randomly assigned to a study arm. A total of 875 potential participants were assessed for eligibility. Of that number, 256 were ineligible, 128 did not complete the phone screening, and 72 decided not to participate due to lack of interest or time. The most common reason for ineligibility was not meeting the minimum weight-loss criteria ($n=117$).

Measures

Data collection points include baseline, 6, 12, 18, and 24 month follow-up. The baseline, 12, and 24 month measurements are conducted in-person and the 6- and 18 month measurements are conducted via telephone. Participants were not paid for completing the baseline visit, but received gift cards to a national retail outlet for completing the subsequent assessments. Participants received a \$40 gift card for completing the one year in-person measurement visit, a \$50 gift card for completing the two year in-person measurement visit, and a \$20 gift card for completing each of the six- and 18-month phone surveys.

Weight and height—At baseline, 12- and 24-month follow-up, weight and height were measured in person with participants in light clothing without shoes (Seca 770 Medical Scale; Seca 214 Portable Height Rod). At 6- and 18-month follow-up, weight was self-reported. BMI was computed from weight and height (kg/m^2).

Weight-loss experience and history—During the phone screening, weight loss prior to joining the study was computed by subtracting self-reported body weight from self-reported highest body weight during the past year. Weight loss was also computed at baseline by subtracting measured baseline body weight from self-reported highest body weight. Participants were also asked how they achieved the 10% weight loss that made them eligible for the study, including specific weight-loss methods (e.g., increased physical activity, reduced-calorie diet, low-carbohydrate diet, commercial weight-loss program) and whether they lost the weight on their own or as part of a formal weight-loss program. Participants were also asked to indicate why they decided to lose weight. Responses to these open-ended questions were reviewed by the study team, who coded responses into the following categories: prevent health problem, current health problem, improve appearance, improve physical functioning, improve self-esteem, frustrated with self, feel better, event (e.g., wedding), doctor suggestion.

History of intentional weight-loss episodes was assessed at baseline. Participants reported the number of times since age 15 that they had lost each of the following number of pounds: 5 to 9, 10 to 19, 20 to 49, 50 to 79, 80 to 99, and ≥ 100 . Response options were 0, 1 or 2 times, 3 or 4 times, 5 or 6 times, and ≥ 7 times. A continuous intentional weight-loss episode measure was created by assigning the midpoint value of the range for the frequency category and summing across the amounts. This approach has been shown previously to be reliable and valid.³⁰

Weight satisfaction—Participants were asked to numerically define four different weight-loss outcomes.^{31–33} These weights and their criteria included the following: dream weight (“the weight you would choose if you could weigh whatever you wanted”), happy weight (“This weight is not as ideal as the first one. It is a weight, however, that you would

be happy to achieve”), acceptable weight (“a weight that you would not be particularly happy with but one that you could accept”), and disappointed weight (“a weight that you could not view as successful in any way. You would be disappointed if this were your final weight after the program”). Patients assigned a numerical equivalent (in pounds) to each of these categories. At baseline, the discrepancy between participant baseline body weight and each of the previously mentioned weight categories was computed.

Physical activity—Physical activity was assessed using the Paffenbarger Physical Activity Questionnaire.³³ This instrument asks individuals to indicate the number of city blocks walked, flights of stairs climbed, and light (5 kcal/min), medium (7.5 kcal/min), and heavy (10 kcal/min) leisure time activities in the past week. The caloric expenditure from each of these activities is then summed to estimate total kcal of energy expenditure. The Paffenbarger questionnaire has been shown to have satisfactory reliability³⁴ and predictive validity.³⁵ It also has been shown to be sensitive to physical activity change in intervention studies.^{7, 11}

Television viewing—Participants were asked how many hours they watch TV on the average weekday and weekend day. Response options included: 0, <1, 1, 2, 3, 4, and 5+. These response options were dichotomized so that “0” represented less than 3 hours of TV watching per day and “1” represented 3 or more hours per day.

Physical activity self-concept—Participants also reported the extent to which being physically active was incorporated into the self-concept using an adaptation of the Athletic Identity Measurement Scale.³⁶ Six (e.g., “physical activity is an important part of my life,” “other people see me as a physically active person”) of the original 10 items were rated on a five-point scale (1=not at all true, 5=very true) and averaged into a single score at each time point.

Physical activity social support—The 10-item Social Support for Exercise Behavior Questionnaire³⁷ was used to assess participants’ perceived weight-related social support from family and friends. Participants were asked to rate how often their family and friends were supportive of being physical active. Separate scores for perceived support from family and friends were computed. This measure has been shown to have adequate test-retest reliability and validity in adults.¹²⁶

Exercise equipment in the home—Participants completed an inventory of 38 exercise equipment items available in the home³⁸

Dietary intake—Dietary intake was assessed using the National Cancer Institute’s Web-based Diet History Questionnaire (DHQ). Although no formal, large validation study of the Web-based DHQ has been conducted, several studies document acceptable reliability and validity of the paper-and-pencil version.³⁹⁴⁰ DHQ-derived total energy intake (kcal) and percent energy from fat are reported here.

Breakfast eating—Frequency of breakfast eating was assessed with the question “During the past week, how many times did you eat breakfast?” Response options included: “0,” “1 or 2,” “3 or 4,” “5 or 6,” and “7+” and were re-coded so that “0” represented <7 and “1” represented 7+.

Household food availability—A modified version of the Household Food Inventory Checklist⁴¹ was used to assess home availability of different food groups. Participants were asked to indicate if a given food was in their house, regardless of quantity. Responses were

categorized into number of fruits, vegetables, salty snacks (e.g., total, full-fat, reduced-fat options), sweetened beverages, (soft drinks through sweetened drinks), and sweets.

Self-monitoring behaviors—Response options to the question “How often do you weigh yourself?”⁴² included: “never,” “once a year or less,” “every couple of months,” “every month,” “every week,” “every day,” and “more than once a day.” Responses were dichotomized ($\geq$ daily self-weighing vs. $<$ daily self-weighing). Participants were also asked to report how often they 1) write down the calorie content of the foods they eat; 2) write down the amount and type of exercise they do; 3) use meal-replacement products to manage their weight; 4) plan their meals to manage their weight; and 5) plan their exercise to manage their weight. Response options were dichotomized (“never,” “rarely,” “sometimes,” “often,” and “very often”) so that “0” represented “never, rarely, or sometimes” and “1” represented “often or very often”.

Probable binge eaters—Partial *Diagnostic and Statistical Manual of Mental Disorders IV* criteria for binge eating disorder were self-reported (i.e., eating within a 2-hour period what most people would regard as an unusually large amount of food, perceived lack of control during these episodes, and frequency of episodes). Participants who reported bingeing 2 or 3 days a week or more were classified as “probable binge eaters.”⁴³

Body shape satisfaction—A 16-item version of the Body Shape Questionnaire shown to have acceptable reliability and validity⁴⁴ was used to measure body shape satisfaction. Participants rated the frequency with which they experience body shape concerns on items such as “Have you been so worried about your shape that you have been feeling you ought to diet?” Items are rated on a six-point Likert scale; the average item score is presented with higher scores indicating greater body shape satisfaction.

Social influence—To assess social factors that may influence the weight-loss and maintenance process, participants were asked to rate the following statements on a seven-point scale (strongly disagree to strongly agree): 1) “I often see or talk to someone to whom I feel accountable for my weight”; 2) “I often see or talk to someone to whom I feel accountable about being physically active”; 3) “I often see or talk to someone to whom I feel accountable for eating healthy”; 4) “People made positive comments when I started losing weight”; and 5) “People have recently made positive comments about my weight”; and 6) “People have recently made positive comments about my appearance.” These items were developed by the research team for this study.

Depression—We used the 11-item short form of the Center for Epidemiological Studies Depression symptoms scale.⁴⁵

Keep It Off interventions

The Keep It Off phone coaches who conducted the intervention calls were masters’ and/or bachelor’s level individuals with expertise in nutrition, physical activity, and weight loss, and behavior change methods.

Self-directed

The self-directed arm of the study included a two-session phone course to teach participants about strategies to keep off weight, with calls taking place in the month following randomization. Participants randomly assigned to this arm received a Keep It Off course book, which includes 10 chapters on weight-loss maintenance. Chapter topics include weight-loss history, physical activity, menu planning, stimulus control, problem solving, relapse prevention, and body image and weight goals. Participants also received a Keep It

Off logbook in which to record their eating, physical activity, and weight for 1 month. During the two one-on-one calls with a Keep It Off coach which were approximately 20 minutes long, participants reviewed the instructions for self-monitoring and the information in the course book. Self-Directed participants did not submit their self-monitoring log to their coach, however, participants could talk to their phone coach during the second and final call about what they learned from recording their food and activity in the log. After the calls, participants had no more contact with their phone coach.

Guided

As stated previously, treatment content and delivery for the Guided intervention was informed by several theoretical models including Rothman's Decision Criteria Maintenance Model²¹ and the Relapse Prevention Model.^{22–23} Rothman argues that behavioral initiation and behavioral maintenance processes are driven by different decision criteria. Decisions regarding initiation focus on the favorability of future outcomes that will result from behavior change, an "approach-based" perspective. Alternatively, a decision to maintain a pattern of behavior is thought to be based on a person's satisfaction with the outcomes produced by their current behavior, and not wanting to lose that satisfaction, an "avoidance-based" perspective. In other words, during weight loss initiation, individuals may be more focused on anticipated gains in valued outcomes, while in the maintenance phase, the focus may be more on avoiding anticipated losses in valued outcomes that would be associated with regaining weight. This model suggests that a key element of weight maintenance programs may be enhancing satisfaction with perceived benefits of having lost weight, including helping participants appreciate the benefits of weight losses that may have fallen short of their "dream weight."⁴⁶ The Relapse Prevention Model (RPM) has also been used to help maintain healthy behaviors among recent adopters.^{47–48} A key component of RPM is its distinction between "lapses" and "relapse", with lapses defined as a "single event, a reemergence of a previous habit, which may or may not lead to the state of relapse,"⁴⁹ whereas "relapse" refers to a full return to an unhealthy state. An individual's response to a "lapse" is thought to determine the likelihood of relapse. The "abstinence violation effect" is the reaction to a behavioral slip, guilt, and perceived loss to control; when this occurs an individual is more likely to experience a full relapse. Alternatively, when framed as a "lapse", people can respond to a slip in behavior proactively, thus avoiding complete relapse. Defining a "lapse" in the context of weight gain prevention is not as clear cut as defining a lapse in the case of substance abuse; lapses can include dietary and activity slips as well as weight gain. Thus, although RPM is not a perfect fit with weight maintenance, it provides a useful framework and offers specific suggestions for weight maintenance intervention strategies.^{14, 50} Such strategies may include helping individuals manage lapses in behavior, identifying high-risk situations for relapse, enhancing skill for coping with these situations and increasing self-efficacy for avoiding relapse.

The first phase of the Guided intervention included 10 one-on-one phone coaching sessions focused on developing key behaviors and skills necessary for weight loss maintenance through regularly scheduled bi-weekly phone coaching calls, including helping participants appreciate the benefits of their achieved weight loss (Table 2). The 10 core phone coaching sessions were approximately 20 minutes long, with the subsequent monthly and bimonthly calls approximately 10–15 minutes each. Guided participants received the same Keep It Off course book described previously; however, they worked through it in the 10 biweekly phone coaching calls with a Keep It Off coach. Guided participants also received Keep It Off logbooks and reported their weight weekly for the duration of the study. Participants were not given specific calorie and fat goals, but were encouraged to self-monitor dietary intake, calories, fat grams, and body weight in order to establish their optimal calorie range

for weight maintenance. Participants were encouraged to work towards the goal of engaging in 60 to 90 minutes of moderate-to-vigorous physical activity, most days a week.

The second phase of the intervention included eight monthly calls and six bimonthly calls, weekly reporting of weight, and bimonthly weight graphs and tailored letters beginning at month 8 (Table 2). Guided participants could report their weight during scheduled phone calls, by email, or on the study website. During the latter phase when phone coaching calls become less frequent, the intervention builds on the Relapse Prevention model. During this phase, participants submit weekly weights to their phone coach and receive bimonthly tailored feedback reports based on whether they are maintaining, losing or gaining weight. Accompanying each mailing was a small incentive (e.g., Keep It Off pen, sticky notes, refrigerator magnet) for continuing participation. The incentives were mailed to participants at regular intervals regardless of progress along with a brief letter tailored to their current status. The primary letter types included: 1) a “weight maintenance” letter for participants who were reporting their weight and maintaining their weight loss; 2) a “weight gain” letter for participants who were reporting their weight, but had gained weight; 3) a “no weight” letter for participants who were not reporting their weight. All letters provided positive feedback for their continued participation in the Keep It Off study and their efforts to maintain weight loss, regardless of current success.

In addition to receiving the regularly scheduled calls for weight maintenance support, participants who experience small weight gains receive additional outreach calls to problem solve regarding weight gain reversal strategies. Specifically, if participants showed a weight gain trend and did not have a call scheduled in the next 2 weeks, phone coaches emailed or called them to provide extra support to help reverse the weight gain. The challenge was to intervene at a point when it would have been relatively easy to reverse weight gain without responding to inconsequential weight gain. The amount of weight gain that needed to occur before study staff initiated contact was 2 pounds. Because we did not want to “flag” a weight gain that was likely to be temporary, we developed two algorithms that focused on weight across a 4 week period. The first call algorithm was used for people with valid data for 4 consecutive weeks of self-reported weights. Using all four of these values, participants were identified as needing a trigger call if a) the average of weights 3 and 4 was at least two pounds greater than the average of weights 1 and 2, or if b) weight 4 was at least two points greater than weight 1 and there was a steady increase from weight 1 to weight 4. The second call algorithm was used for people with at least one missing data value over 4 consecutive weeks of self-reported weights. Using available values able, a participant would get identified as needing a Keep It Off phone coach to look at their data (and possibly recommend a trigger call) if the last observed value in the last 4 weeks is at least 2 pounds greater than the first observed value in the last 4 weeks. Before reaching out to a Guided participant for a “weight gain trigger” call, the data were reviewed by the intervention team. If there was an upcoming scheduled call with a participant, the Keep It Off phone coach would wait until that appointment to discuss the recent weight gain.

The goal of these intervention calls was to engage in a problem-solving encounter with the participant to determine which intervention module would be most helpful in reversing the weight gain. Participant reports of diet and activity were used to target which components of their weight-maintenance plan appeared to be contributing to weight gain. An action plan was developed, and up to two follow-up phone calls were scheduled to help the participant stabilize their weight.

Objectives

The goal of the Keep It Off study was to evaluate the primary program outcomes, which were:

Weight—Weight in kilograms at 24-month follow-up relative to baseline weight. We hypothesized that guided participants would regain less weight, on average, at 24-month follow-up than self-directed participants.

Weight maintenance—Binary classification based on body weight at 24-month follow-up relative to baseline weight. We hypothesized that a higher percentage of guided participants would maintain a weight that was less than or equal to 105% of baseline weight at 24-month follow-up than self-directed participants.

Secondary study aims included assessments of: a) subgroup analysis of intervention effectiveness (e.g., BMI, weight-loss method, gender); b) mediating factors (e.g., self-efficacy for and barriers to engaging in weight-maintenance behaviors, physical activity, dietary intake, and social support); c) process measures (e.g., adherence, intervention “dose”) as predictors of weight outcomes; and d) intervention costs to evaluate guided program scalability. Intervention cost data include program development, materials/supplies and program implementation. Implementation cost will be derived from time spent in interactions between the participants and the phone coaches, using the phone coach salaries (including fringe benefits). Phone coach time will include actual time conducting phone coaching calls, time for documentation and scheduling, and time spent in weekly intervention supervision meetings. Development cost will be based on staff time and material for intervention development.

Power analysis—A priori power analyses were carried out to determine the minimum detectable difference between groups in weight regain and weight-loss maintenance at 24 months at .90 power ($\alpha_2 = .05$) with a sample size of $n=200$ per group and 80% retention. The minimum detectable effects were estimated at .90 power to ensure joint significance of both outcome variables at power $\geq .80$. A pilot study of weight-loss maintenance provided empirically based assumptions for these analyses. The pilot participants reported an average weight loss of about 13 kg ($SD=2.2$) on study entry; the variation in weight change was $SD=2.47$ at 6 months. Assuming $SD_{\text{regain}}=2.50$, the minimum detectable difference in weight change at 24 months was estimated to be .91 kg (Cohen’s $d = .36$).

Assuming that 35% of the self-directed participants would maintain weight loss at 24 months, we estimated that a statistically significant difference could be observed if at least 53% of the guided participants maintained their weight loss. We determined that the study would be adequately powered to detect a meaningful difference between groups at 24 months and that a sample size of $n=400$ would be sufficient to accurately estimate parameters in secondary analyses investigating subgroup treatment effects and mediation of treatment effects.

Randomization

After completion of the baseline measures, the study coordinator randomized participants to study condition. A letter was then sent to each participant to inform them of their randomization assignment, which was determined in order of enrollment according to a predefined schedule. The study statistician created the schedule prior to study enrollment, and the study programmer embedded it in the “back end” of the study database such that it would be unobservable to the study coordinator. On the basis of a random number table, the schedule randomized participants evenly into two groups (guided $n=209$, self-directed $n=210$) in blocks of 20 to maintain study arm balance throughout recruitment.

Statistical methods

Mixed-model regression (time within participant, unstructured covariance structure, restricted maximum likelihood estimation) will be used to test the hypothesis that, relative to self-directed participants, Keep It Off guided participants will regain less weight and be more likely to maintain weight loss at the end of the study, with secondary consideration of differences at 6, 12, and 18 months. Multiple measures of weight regain (follow-up minus baseline) and weight-loss maintenance (binary indicator) will be separately predicted from the time at which weight was measured, which varies within participants, randomized treatment group (Guided, Self-Directed), which varies across participants, and the cross-level time by treatment group interaction. Static (e.g., weight loss prior to study entry, sex) and time-varying (e.g., method of weight measurement) covariates may be included as appropriate. This intent to treat approach will ensure that all available weight observations from all randomized participants will be used to estimate model parameters.

The primary hypothesis will be supported if, for both the weight regain and weight maintenance outcome variables, 1) the Guided*24month parameter is statistically significant, and 2) the simple effects comparison of Guided relative to Self-Directed participants at 24 months shows better outcomes among participants in the Guided relative to Self-Directed group. Comparable parameters assessing between groups differences at 6, 12 and 18 months will be assessed but of secondary interest to the primary hypothesis.

Results

Table 1 shows descriptive characteristics of the study sample at baseline, overall and by treatment group. The typical participant was female, highly educated, married or living together as married, white, and currently employed for wages. On average, participants lost 16% of their body weight prior to study entry and were still overweight. Participants reported a variety of reasons for initiating weight loss, most commonly health reasons. Participants also reported a variety of weight-loss methods, including the use of both dietary strategies and physical activity. About half reported obtaining professional help for their weight loss, either through a commercial weight-loss program or a physician or registered dietitian.

With respect to activity patterns, Keep It Off participants reported high levels of physical activity at baseline, the equivalent of about an hour a day of brisk walking. Less than one-quarter of participants reported watching more than 3 hours a day of television on weekdays, although weekend television watching was more frequently reported. Participants reported high levels of physical activity-related self-concept and similar levels of support for physical activity from friends and families. On average, participants reported having 11 pieces of exercise equipment in their homes.

Dietary intake pattern data showed that participants, on average, consumed about 1,600 kcals/day, with just under one-third of their caloric intake from dietary fat. Most participants reported consuming breakfast daily; however, over two-thirds reported eating a snack or meal while watching television. Moreover, about half reported eating at a fast-food restaurant at least once a week, and over two-thirds reported eating at a sit-down restaurant at least once a week. Participants reported a high number of fruits and vegetables available in the household; participants also reported the presence of snacks, sweets, and sweetened beverages in the home.

Planning meals and exercise and daily self-weighing were among the most common behavioral weight-control strategies reported by participants, with self-monitoring of caloric intake and exercise and use of meal replacements reported less often. Participants reported

receiving frequent positive comments about their weight, but were less likely to report feeling accountable to someone with respect to their weight. Although scores on the body image measure suggested a moderate level of body shape dissatisfaction, scores on the depression measure suggested low levels of depression. The majority of participants did not indicate struggling with binge eating, however, about 10% reported a low frequency of binge eating, and another 10% reported a binge-eating frequency that could potentially classify them as having binge-eating disorder.

Discussion

This paper describes the design of the Keep It Off (KIO) trial and the baseline characteristics of the KIO Guided and Self-Directed intervention groups. This randomized controlled trial will evaluate the efficacy of a phone and mail-based intervention designed to promote weight loss maintenance among adults who have lost at least 10% of their body weight during the past year. With the exception of the Stop Regain trial¹³, most randomized weight-management trials have enrolled people at the point of weight loss initiation with attention paid to maintenance after the novelty of the program may have waned. Recruitment to a maintenance-focused intervention provides an opportunity to engage people during the period in which they may otherwise be vulnerable to weight regain. Both the content and delivery of the Keep It Off intervention were tailored to address maintenance.

Telephone-based counseling has an increasing evidence base^{15–17} and may be particularly suitable for a maintenance-focused intervention given that it is flexible and relatively low intensity. The Keep It Off intervention is also based on a theoretical model specifically developed to address issues related to physical activity maintenance, which integrates principles of Bandura's Social Cognitive Theory^{51–53} and relapse-prevention theory.^{22–23, 50} Intervention strategies were weighted heavily toward self-management, including cognitive (e.g., goal setting, identification of barriers, problem solving), behavioral (e.g., self-monitoring through use of pedometers and log books, use of environmental cues), and environmental (e.g., phone coach support, development, leverage of social support) strategies.

Data suggest that Keep It Off participants share characteristics of participants in the NWCR, including high levels of physical activity, moderate levels of dietary intake, frequent breakfast eating, and frequent self-weighing.^{6, 8–9, 24, 54–58} Although all study participants were required to meet the 10% weight-loss threshold, the amount of weight lost and weight status at the time of study entry varied considerably. Consistent with previous research^{31–32}, despite the significant and clinically meaningful amount of weight lost prior to study entry, many participants are still overweight and satisfaction with achieved weight loss varied across participants. Subgroup analyses will examine whether the interventions are differentially effective based on weight loss history, amount of weight lost prior to study entry, and baseline weight status.

Strengths of the Keep It Off trial are its unique focus on maintenance and implementation of theory-based intervention. Moreover, the use of phone- and mail-based delivery mechanisms, due to their relatively low cost, may have a high potential for dissemination if they are shown to be efficacious over the long term. In addition, the wide range of measures, including dietary, physical activity, and psychosocial variables, provide informative data regarding the characteristics of people who are successful at losing weight, at least in the short-term. This comprehensive set of measures will also provide useful data regarding both moderators and mediators of successful long-term weight loss maintenance.

Limitations of the study include measurement of dietary intake using a food frequency as oppose to in-depth diet recalls, reliance on self-report of physical activity (with only a sub-sample having accelerometer data), and the limited ethnic diversity of the study sample. Despite these limitations, Keep It Off offers an innovative approach to the vexing problem of weight regain. By focusing explicitly on weight-loss maintenance, our interventions hold considerable promise for modifying the typical relapse curve. Moreover, Keep It Off provided data to inform our understanding of and predictors of weight-loss maintenance.

Abbreviations

CONSORT	Consolidated Standards Of Reporting Trials
DHQ	Diet History Questionnaire
NWCR	National Weight Control Registry

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Figure 1.
Modified CONSORT diagram for the Keep It Off Trial

Table 1

Baseline descriptive characteristics at baseline, overall and by treatment arm

	Total	Guided	Self-directed	<i>p</i>
N	419	209	210	
Demographic characteristics				
Female	81.6%	80.9%	82.4%	.69
Age in years	47.0 (10.8)	47.1 (10.9)	46.9 (10.7)	.87
Educational status				
College or graduate degree	64.4%	67.0%	61.9%	.28
Marital status				
Married/unmarried couple	67.9%	66.0%	69.9%	.64
Divorced/widowed/separated	17.9%	19.6%	16.3%	
Never married	14.1%	14.3%	13.9%	
Employment status				
Employed for wages	87.1%	86.6%	87.6%	.76
Race/ethnicity				
Non-Hispanic white	86.9%	87.1%	86.7%	.90
Weight-related characteristics				
Body mass index, kg/m ²	28.4 (5.0)	28.6 (4.5)	28.2 (5.6)	.45
% weight loss prior to study entry	16.2 (5.3)	16.6 (5.6)	15.7 (5.5)	.07
Reasons for losing weight				
Prevent health problem	40.2%	42.9%	37.5%	.26
Current health problem	51.8%	51.7%	51.9%	.96
Improve appearance	11.1%	9.8%	12.5%	.38
Improve physical functioning	14.3%	18.5%	10.1%	.01
Improve self-esteem	5.1%	5.4%	4.8%	.80
Frustrated with self	21.3%	18.5%	24.0%	.17
Feel better	11.9%	10.2%	13.5%	.31
Event (e.g., wedding)	14.0%	15.1%	13.0%	.53
Doctor suggestion	2.7%	2.9%	2.4%	.74
Weight loss method				
Exercise	67.3%	65.1%	69.5%	.33
Low-calorie diet	36.0%	34.0%	38.1%	.38
Low-fat diet	17.4%	15.8%	19.1%	.38
High protein/low-carb diet	2.4%	3.4%	1.4%	.20
Weight-loss program	48.9%	51.2%	46.7%	.35
Meal replacement	1.0%	0.5%	1.4%	.32
Self-weighing	0.5%	1.0%	0.0%	.16
“Own plan”	13.4%	13.4%	13.3%	.98
Baseline relative to...				

	Total	Guided	Self-directed	p
“dream weight”	31.2 (24.3)	30.6 (22.1)	31.8 (26.5)	.60
“happy weight”	22.5 (20.7)	22.1 (18.6)	22.8 (22.6)	.72
“acceptable weight”	15.6 (17.5)	15.2 (16.1)	15.9 (18.8)	.71
“disappointed weight”	5.8 (14.4)	5.9 (14.0)	5.8 (14.8)	.92
Estimated lifetime weight loss	157.3 (141.9)	153.3 (122.8)	161.3 (158.8)	.56
Weight-related behaviors				
Physical activity				
Paffenbarger				
kcal/week total	2,010.2 (1697.8)	1,931.7 (1623.1)	2,088.4(1769.5)	.35
TV ≥3 hours/weekday	21.9%	22.5%	21.4%	.81
TV ≥3 hours/weekend day	37.5%	36.4%	38.6%	.61
Physical activity self-concept M (SD)	4.8 (1.3)	4.7 (1.3)	4.9 (1.2)	.10
Physical activity social support, family	2.7 (0.7)	2.7 (0.7)	2.8 (0.7)	.69
Physical activity social support, friend	2.7 (0.7)	2.7 (0.7)	2.7 (0.7)	.74
Exercise equipment	11.0 (5.0)	10.9 (5.0)	11.1 (5.1)	.61
Dietary intake				
DHQ-total energy intake, kcal	1,615.6 (746.9)	1,603.0 (804.4)	1,628.2 (686.6)	.73
% energy from total fat	31.6 (6.8)	31.7 (6.9)	31.6 (6.7)	.80
Breakfast eaten daily	62.1%	59.8%	64.3%	.35
Snack while watching TV 1+/week	77.5%	78.9%	76.1%	.50
Meal while watching TV 1+/week	67.8%	69.2%	66.4%	.53
Eat at fast-food restaurant 1+/week	48.4%	50.7%	46.2%	.35
Eat at Sit-down restaurant 1+/week	70.3%	71.8%	68.9%	.52
Household food availability				
Fruits	6.2 (2.5)	5.9 (2.4)	6.2 (2.6)	.26
Vegetables	11.1 (3.6)	11.0 (3.6)	11.2 (3.6)	.76
Salty snacks, full-fat	2.8 (1.4)	2.9 (1.5)	2.8 (1.4)	.66
Salty snacks, reduced-fat	1.9 (1.5)	1.8 (1.4)	2.1 (1.5)	.01
Sweetened beverages	1.0 (1.1)	1.0 (1.1)	1.1 (1.1)	.70
Sweets	3.3 (2.5)	3.2 (2.5)	3.4 (2.5)	.44
Self-monitoring behaviors				
Daily self-weighing	47.5%	42.6%	52.4%	.04
Write down calorie content often	11.9%	11.5%	12.4%	.78
Write down exercise often	23.2%	22.0%	24.3%	.58
Use meal replacements often	7.6%	8.1%	7.1%	.70
Plan meals often	66.4%	64.6%	68.1%	.45
Plan exercise often	62.3%	59.8%	64.8%	.30
Psychosocial factors				
Accountability for weight	3.5 (1.8)	3.7 (1.8)	3.4 (1.9)	.14

	Total	Guided	Self-directed	<i>p</i>
Positive comments about weight	5.7 (1.4)	5.8 (1.3)	5.7 (1.4)	.21
Body image	4.6 (0.9)	4.6 (0.9)	4.6 (0.9)	.70
Binge eating				
Not a binge eater	79.4%	80.3%	78.6%	.61
Low-frequency binge eating	9.6%	8.2%	10.9%	
Probable binge eating disorder	11.0%	11.5%	10.5%	
Center for Epidemiological Studies Depression scale	5.2 (3.8)	5.3 (3.9)	5.1 (3.8)	.56

DHQ, Diet History Questionnaire.

Table 2

Overview of all Keep It Off guided intervention components by coursebook chapter topic

Core biweekly phone coaching calls	
1. Introduction	<ul style="list-style-type: none"> • Discuss seven strategies for successful weight-loss maintenance • Assess current status and goal for each strategy • Provide instruction for completion of food and activity logbook
2. Your Weight Story, Then and Now	<ul style="list-style-type: none"> • Review weight and dieting history • Discuss current weight-loss episode and benefits • Talk about long-term weight, exercise, and eating goals
3. Physical Activity: The Key to Successful Weight Loss Maintenance	<ul style="list-style-type: none"> • Discuss benefits of physical activity • Review physical activity history and current level • Talk about physical activity goals and strategies
4. Menu Planning for Successful Weight Management	<ul style="list-style-type: none"> • Explore key weight-loss maintenance eating strategies • Discuss using Food Guide Pyramid and food labels for menu planning
5. Strategies for Successful Weight Management	<ul style="list-style-type: none"> • Discuss behavioral weight-loss maintenance strategies, including planning eating, social situations, environmental food cues, and limiting activities while eating • Talk about portion size, liquid calories, energy density of foods, and “mindless” eating
6. Introduction to Problem Solving	<ul style="list-style-type: none"> • Discuss and practice five key steps to problem solving • Talk about long-term motivational strategies
7. Overcoming Barriers to Physical Activity and Healthy Eating	<ul style="list-style-type: none"> • Explore common barriers to healthy eating and exercise • Review strategies to enhance social support • Discuss managing negative self-talk
8. Relapse Prevention	<ul style="list-style-type: none"> • Discuss “lapses” versus “relapses” • Discuss potential relapse triggers and develop “restart” plan • Discuss stress and its effect on relapse
9. Body Image and Weight Goals	<ul style="list-style-type: none"> • Discuss body image and weight goals • Discuss body image changes over time and current status

Core biweekly phone coaching calls	
	<ul style="list-style-type: none"> Discuss strategies for challenging negative thinking patterns
10. Putting It All Together	<ul style="list-style-type: none"> Review progress made with the key strategies for successful weight-loss maintenance Discuss and re-evaluate long-term weight, exercise, and eating goals
Monthly calls (months 6 to 12)	<ul style="list-style-type: none"> Review and revise weight-maintenance goals Problem-solve barriers to healthy eating and activity Provide encouragement for maintaining weight loss
Bimonthly calls (months 13 to 24)	<ul style="list-style-type: none"> Review and revise weight-maintenance goals Problem-solve barriers to healthy eating and activity Provide encouragement for maintaining weight loss
Weekly weight reporting (months 1 to 24)	<ul style="list-style-type: none"> Weekly weight reporting (phone, email, Web site)
Bi-monthly weight graphs (months 8 to 24)	<ul style="list-style-type: none"> Mailing included weight graph, tailored letter, and small incentive (sticky note pad, pens, magnetic clips)
Weight gain trigger calls	<ul style="list-style-type: none"> Support and problem-solving calls to help participant reverse small weight gain (2 lb average)
Motivational campaigns	<ul style="list-style-type: none"> No Holiday Weight Gain Walk the North Shore
Group events	<ul style="list-style-type: none"> Two group sessions featuring outside guest speakers and phone coaches