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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.

1. 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 and self-weighing) from the National Weight Control Registry [5–9]. Virtually all past intervention 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].

Abbreviations: CONSORT, Consolidated Standards Of Reporting Trials; DHQ, Diet History Questionnaire;NWCR, National Weight Control Registry.

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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 Model [21] 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.

2. 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, and 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.

3. 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 $\geq$ 20.5 kg/m [2]; and 4) ability to communicate with the research staff by telephone. Exclusion criteria included 1) history of anorexia nervosa; 2) bariatric surgery; 3) modified Charlson [29] score $\geq$ 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.

4. Methods

4.1. Participants

Fig. 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