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Communication

Greater weight loss among men participating in a commercial weight loss program: a pooled analysis of 2 randomized controlled trials

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ABSTRACT

Being overweight and obese are significant health concerns for men and women, yet despite comparable needs for effective weight loss and maintenance strategies, little is known about the success of commercial weight loss programs in men. This study tests the hypothesis that men participating in a commercial weight loss program (Weight Watchers) had significantly greater weight loss than men receiving limited support from health professionals for weight loss (controls). A pooled analysis of weight loss and related physiologic parameter data from 2 randomized clinical trials was conducted. After 12 months, analysis of covariance tests showed that men in the commercial program group (n = 85) lost significantly more weight ($P < .01$) than men in the control group (n = 84); similar significant differences were observed for body mass index and waist circumference. These results suggest that participation in a commercial weight loss program may be a more effective means to lose weight and maintain weight loss.

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1. Introduction

Excess body weight is a significant health concern for both men and women in the United States, with recent data indicating that the prevalence of obesity is 35.5% among men and 35.8% among women [1]. Among men, the prevalence of obesity increased significantly over the 12-year period from 1999 through 2010 [1].

Despite comparable needs for effective weight loss and maintenance strategies for men and women, men have been underrepresented in weight loss trials. Pagoto et al [2] examined inclusion rates of males in lifestyle weight loss interventions. Their research found that 32% of trials exclusively included women, whereas only 5% exclusively included men; overall, men represented 27% of the study populations. Potential reasons for the limited engagement of men in weight loss trials include lack of attention to sex differences that influence health behavior, failure to include motivators relevant to men, inclusion of dietary restrictions, and lack of individualized feedback [3].

Abbreviations: ANOVA, analysis of variance; BMI, body mass index; DBP, diastolic blood pressure; LOCF, last observation carried forward; SBP, systolic blood pressure; WW, Weight Watchers.

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A weight loss of 5% is regarded as clinically meaningful [4] and may be achieved through a variety of behaviorally based treatments [5,6]. Weight Watchers (WW) is a community-based commercial program that uses a multicomponent approach to weight management. Participants attend weekly group meetings that are facilitated by a trained leader who has lost weight and is maintaining that loss while using the program. The program promotes a low-energy balanced diet, increased physical activity, and group support and also includes a food plan, activity plan, and cognitive skill development that is administered in a supportive environment. Consistent with other trials of weight loss, clinical studies of the WW program have primarily or exclusively enrolled women. These trials provide evidence that this program supports significant loss of weight in interventions of 6 months or less as well as in interventions spanning 1 year or more [7-10] in predominantly female populations; however, the specific effects of the program on men are unknown.

Based on combined data from available clinical studies, the purpose of this study was to test the hypothesis that weight loss and changes in related physiologic parameters at 12 months in men participating in a commercial program (WW) are larger than those in men receiving limited help for weight loss (controls).

2. Methods and materials

2.1. *Clinical trials included in the analysis*

Randomized controlled trials of the WW program that met the following criteria were included in the pooled analysis: (1) the study population included men, (2) the period of intervention was at least 1 year, and (3) the primary outcome was weight loss at 1 year or more. Two published trials met these criteria, including a multicenter study in the United States of 423 adults 18 years and older (study 1) [7] and a multicountry study of 772 adults 18 to 65 years with at least 1 risk factor for metabolic disease (study 2) [7,8].

Two additional trials enrolling men and women in a WW treatment group and reporting results at 1 year were identified, although neither was included in the pooled analysis; one lacked a control group [9], and the other allowed optional participation in a commercial weight loss program beyond the primary outcome at 12 weeks [10].

In each study, participants randomized to the commercial group had free access for 12 months to community-based weekly WW meetings; participants in the commercial group in study 2 additionally had access to WW "eSource" online resources. Participants in the control group attended 20-minute consultations with a dietitian at baseline and week 12 at which they received printed materials on weight loss/exercise and referrals to other information (study 1) or standard weight loss care from a primary health care practitioner at a general practitioner's practice with advice based on national clinical guidelines for treatment (study 2).

Study outcomes collected in the 2 trials included weight, body mass index (BMI), waist circumference, systolic blood pressure (SBP), and diastolic blood pressure (DBP). Study personnel measured weight (in street clothing on a calibrated scale in study 1; in light clothes without shoes in study 2). Height was measured without shoes at the baseline visit in both studies. Waist circumference measurements were taken at the end of inspiration (in study 1 at the uppermost lateral border of the ilium, in study 2 midway between the top of the iliac crest and the most inferior part of the rib cage). The outcomes were collected at baseline, 6 months (24 weeks), and 12 months (52 weeks). Person-level data were obtained from the principal investigators of each study.

2.2. *Outcome measures*

The primary outcome measure in the pooled analysis was weight change in men over a period of 12 months. Secondary outcomes included changes over 12 months in BMI, waist circumference, and SBP and DBP.

2.3. *Statistical analyses*

The primary outcome was analyzed by intention to treat with the last observation carried forward (LOCF) based on weight at 6 months for individuals missing weight data at 12 months. The LOCF method was used to assess weight loss for consistency with previous analyses of the commercial weight loss programs. Other methods including the maximum likelihood and multiple imputation methods provide alternate approaches for treating missing data in weight loss studies, particularly when effect size is small [11].

The commercial program and control groups were compared at baseline using a 2-factor analysis of variance (ANOVA) with study indicator and treatment group as factors. Change at 12 months was analyzed using a 2-factor analysis of covariance with study indicator and treatment group as factors and baseline measurement as a covariate. A study indicator was included in the analyses based on identification of differences in baseline values across the studies. Initial analyses of all parameters, which included an interaction term for treatment group and study indicator, showed no significant interaction, and so the interaction term was dropped from the models. Binary regression models, which included study indicator and baseline weight, were used to estimate the risk ratios of at least 5% and 10% weight change. Statistical significance was set at $P < .05$. All analyses were conducted using STATA version 10 (College Station, TX, USA).

3. Results and discussion

A total of 169 men participated in the 2 trials (n = 85 in the commercial program and n = 84 in the control groups). The ANOVA analyses of baseline data showed no differences between men assigned to the commercial program and those assigned to the control group; however, a significant study effect was observed for weight ($P < .05$) and BMI ($P < .001$).

At 12 months, data were available for 65 men in the commercial program group and 61 men in the control group. A lower drop-out rate was observed in study 1 (14%) than in study 2 (41%), although drop-out rates were comparable