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Changes in cardiovascular risk factors with participation in a 12-week weight loss trial using a commercial format



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ABSTRACT

Objective: This study assessed changes in cardiovascular disease risk factors among participants in a 12-week behavioral weight loss intervention featuring a commercial format.

Method: 132 participants were enrolled in a randomized controlled trial of a 12-week group-based lifestyle intervention that involved two structured food plan conditions. Of them, 112 (100 women and 12 men, *mean* $BMI = 31.44 \pm 2.18 \text{ kg/m}^2$) completed the program with post-treatment assessments. Weight and changes in risk factors (cholesterol, triglycerides, fasting blood glucose, and blood pressure) were assessed at pre- and posttreatment. Additionally, changes for each risk factor were examined among participants with baseline values of risk factors beyond recommended cut points.

Results: With no weight loss differences between conditions, analyses used the combined sample. Participants lost 3.74 ± 3.16 kg ($4.37 \pm 3.71\%$ of baseline weight), and exhibited significant decreases in triglyceride, total cholesterol and LDL-cholesterol levels. There were trends toward reductions in fasting glucose, systolic blood pressure, and HDL cholesterol. Among participants with elevated baseline values, significant reductions were seen on all risk factors, with the exception of HDL cholesterol.

Discussion: Modest weight loss achieved via a relatively brief, non-intensive intervention using a commercial format can yield significant improvements in cardiovascular disease risk factors, particularly among individuals with initially higher-risk values.

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1. Introduction

Rising obesity rates remain a significant public health concern (Flegal, Carroll, Ogden, & Curtin, 2010). There is considerable evidence linking obesity to adverse medical outcomes, including cardiovascular disease, diabetes, stroke, respiratory problems, and certain forms of cancer (Bray, 2004; Pi-Sunyer, 2009). However, modest reductions in body weight of 5 - 10% can improve health indices, including blood pressure, fasting glucose, and blood lipids (Look AHEAD Research Group, & Wing, 2010; Stevens et al., 2001) even if the individual remains obese (Knowler et al., 2002).

Pharmacological and surgical treatments for obesity are effective but costly and invasive. Intensive behavioral programs represent the first line of treatment for overweight/obesity, but are typically not available outside of academic centers. In contrast, commercial weightloss programs are widely available, well known to most adults,

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non-invasive, and relatively low-cost. Millions of Americans enter commercial programs annually, and research suggests that individuals who participate in such interventions can expect to lose approximately 5% of their body weight at one year and maintain a weight loss of approximately 3% at two years (Rock et al., 2010; Tsai & Wadden, 2005). Further, existing trials typically report outcomes among participants who complete 12 months of treatment, despite the fact that the average length of participation in a commercial program is considerably shorter (Heshka et al., 2003; Jebb et al., 2011; Rock, Pakiz, Flatt, & Quintana, 2007). A recent examination of retention rates within a commercial program found that over 58% of participants completed 12 weeks or less of the intervention (Finley et al., 2007).

Although commercial programs are commonly used to treat overweight/obesity, relatively little is known about their short-term impact on weight and associated health outcomes. To our knowledge, only one study of a 12-week commercial program has been conducted, and health outcomes were not reported (Rippe et al., 1998). There remains a strong need for examination of weight and health outcomes of interventions whose duration more closely resembles the typical length of participation. Thus, the purpose this study was to examine weight loss and changes in cardiovascular disease risk factors (e.g.,

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blood pressure, cholesterol, triglycerides, and fasting glucose) among men and women participating in a relatively brief (12-week) intervention for overweight/obesity featuring a commercial format.

2. Method and procedures

2.1. Participants

Participants were men and women (ages 25–65) with a body mass index (BMI) of 27–35 kg/m². Major exclusion criteria included recent history of cardiovascular disease or cancer, Type I or Type II diabetes or glucose intolerance, unstable thyroid disease, gastrointestinal disorders, recent surgery, and orthopedic conditions likely to limit physical activity. Participants were excluded if they were taking over-the-counter or prescription medications likely to affect weight, were currently enrolled in a weight loss program, had lost >5 lb (2.3 kg) in the previous 30 days, or had undergone weight loss surgery. The Medical University of South Carolina (MUSC) Institutional Review Board approved all study procedures.

2.2. Measures

Participants' weight was assessed at baseline and after Week 6 and Week 12 of the intervention using a Mettler Toledo Panther digital scale. Blood pressure and fasting blood samples were obtained at baseline and at Week 12. MUSC Laboratory Services analyzed blood samples for fasting glucose, triglycerides, total cholesterol, LDLcholesterol, and HDL-cholesterol.

2.3. Weight loss intervention

Participants were enrolled in a 12-week trial comparing the impact of two forms of a commercial weight loss program on weight and health outcomes (O'Neil, Theim, Boeka, Johnson, & Miller-Kovach, 2012). Both programs used systems in which foods were assigned point values based on their nutritional and/or caloric content. The standard program emphasized high-fiber, low-fat food choices, while the second program encouraged consumption of foods low in energy density and high in macronutrient-associated satiety. Participants were provided with an individualized daily intake goal estimated to provide 1200cal. An identical physical activity plan was provided to both groups. A formula based on each participants' body weight, the amount of time spent exercising, and their desired level of intensity was used to calculate a daily points value for activity (i.e., estimation of calories burned). Participants in both interventions attended the same weekly 45-minute group-based meetings (attended by up to 40 participants) delivered via the format used commercially. Meetings were led by experienced group leaders and held at the MUSC Weight Management Center.

2.4. Statistical analyses

Data were analyzed using SPSS 17.0 statistical software. Change scores relative to baseline were computed for each participant's weight and cardiovascular risk factors at Week 12 and their significance assessed via paired sample t-tests. Pearson bivariate correlations were used to assess the relations between percent weight loss and changes in cardiovascular risk factors. These analyses were repeated for each risk factor with analyses limited to participants whose screening values of the factor were outside of recommended limits (Genuth et al., 2003; National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III), 2002). Participants with elevated levels of fasting glucose (>100 mg/dl), blood pressure (SBP>130 mm Hg and/or DBP>85 mm Hg), triglycerides (>150 mg/dl), total cholesterol (>200 mg/dl), or LDL > 160 mg/dl), or low HDL

(<50 mg/dl for women, <40 mg/dl for men) were designated as having "higher risk" values.

3. Results

Of 132 participants who were randomized, 112 completed assessments at baseline and at Week 12 and were included in the current analyses. Completers did not differ from non-completers with respect to gender, race/ethnicity, age, or treatment condition assignment. However, completers had a higher baseline BMI (31.5 vs. 30.3 kg/m^2) than non-completers, t = -2.32, p = .022. The sample comprised 100 women and 12 men (*mean* \pm *SD age* = 48.01 \pm 10.93, *mean BMI* = 31.44 \pm 2.18) and included Caucasian (75.0%), African-American (23.2%), and Hispanic (1.8%) participants.

The two diet conditions did not differ with respect to percent weight loss at Week 6 (p = 0.57) or at Week 12 (p = 0.76). As a result, the groups were combined for further analyses. At Week 6 the combined sample of participants had lost an average of 2.68 ± 1.92 kg (3.1% of baseline weight). At Week 12, participants exhibited weight losses of 3.74 ± 3.16 kg (4.37% of baseline weight) and a 1.32 ± 1.14 point reduction in BMI (ps < 0.001). Participants attended an average of 9.29 ± 2.4 of 12 possible meetings.

As displayed in Table 1, participants achieved significant decreases in total cholesterol, LDL-cholesterol, and triglycerides, while decreases in fasting glucose and systolic blood pressure approached statistical significance. While not desirable, a trend toward reduction of HDL was also observed. Reductions in diastolic blood pressure were not significant. Amount of weight loss was significantly associated with level of decrease in total cholesterol, LDL-cholesterol, systolic blood pressure, and HDLcholesterol. There was no relation between weight loss and decreases in fasting glucose, triglycerides or diastolic blood pressure.

As displayed in Table 2, participants with elevated total cholesterol, LDL cholesterol, triglycerides, systolic blood pressure, diastolic blood pressure, and fasting glucose achieved significant reductions in these risk factors. Among participants with higher-risk (below recommended levels) baseline HDL values, there was a marginally significant *increase* at Week 12. We then calculated the number of participants with higher-risk baseline levels of each risk factor who attained normal levels of that factor by Week 12. The results were: total cholesterol, 14/31 (34.1%); triglycerides, 12/22 (54.5%); LDL cholesterol, 6/11 (54.5%); HDL cholesterol, 5/57 (8.8%), fasting glucose, 7/8 (87.5%); and blood pressure, 9/14 (64.3%).

Within these smaller higher-risk subsamples, weight loss was significantly associated with degree of reduction in systolic BP and, to a marginally significant degree, diastolic BP. Surprisingly, among the few participants with initially elevated blood glucose levels, greater weight loss was related to a *lesser* reduction in blood glucose. However, this appeared attributable to two outliers. Change in weight was not associated with change in total cholesterol, LDL cholesterol, HDL cholesterol or triglycerides.

4. Discussion

Participants who were enrolled in a 12-week weight loss program using a commercial format lost 4.36% of baseline weight (a reduction in BMI of 1.32 ± 1.14 points), and achieved significant improvements in total cholesterol, LDL-cholesterol, and triglycerides. Changes in fasting glucose and systolic blood pressure approached significance. Among participants with high-risk levels of the cardiovascular disease factors at baseline, improvement was more striking and consistent. Significant decreases were observed in all risk factors except HDL cholesterol, where a near-significant change in the desirable direction (increase) was observed. Further, a sizeable proportion of participants were able to reduce their cardiovascular risk factor levels to within normal limits after 12 weeks of the intervention. These findings provide evidence that a relatively brief, non-intensive treatment

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