

Randomized Trial of a Multifaceted Commercial Weight Loss Program

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Abstract

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Objective: To test whether a commercial weight loss program promotes greater weight loss in overweight or obese women compared with control conditions and to describe the effect on plasma lipids, carotenoids, hormones, and fitness.

Research Methods and Procedures: Overweight or obese women were randomized to commercial weight loss program or control conditions ($n = 35$ each).

Results: At randomization, participants were 41.1 (11.4) (mean [standard deviation]) years, BMI 34.0 (3.5) kg/m^2 , and weight 92.0 (11.1) kg. At 6 months, change in weight by intent-to-treat (ITT) analysis was -7.2 (6.7) kg and -7.8% (7.2%) in the intervention group vs. -0.3 (3.9) kg and -0.3% (4.5%) in the control group ($n = 35$ for each; $p < 0.01$). One-year ITT analysis revealed significantly greater change in weight, percent weight, BMI, and waist and hip circumferences in the intervention vs. control group. Completers at 1 year exhibited change in weight of -7.3 (10.4) kg for the intervention group ($n = 32$) vs. -0.7 (5.6) kg for controls ($n = 33$) ($p < 0.01$), and -7.8% (11.1%) weight change for the intervention group vs. -0.7% (6.2%) for controls ($p < 0.01$). High-density lipoprotein (HDL) cholesterol concentration increased significantly in the intervention group. Fasting serum insulin decreased in the intervention but increased in the control group at 6 months

($p < 0.01$), remaining different at 1 year ($p = 0.05$).

Discussion: The commercial program successfully facilitated weight loss, which was notably maintained at 1 year, and promoted favorable changes in plasma lipid and hormone concentrations.

Key words: insulin, energy density, weight reduction, cholesterol, clinical trials

Introduction

The prevalence of obesity among U.S. adults has increased dramatically over the last few decades (1,2). The majority of the U.S. adult population are currently considered overweight or obese ($\text{BMI} \geq 25 \text{ kg/m}^2$), and approximately one third are considered obese ($\text{BMI} \geq 30 \text{ kg/m}^2$) (2). The disease burden associated with overweight or obesity is considerable and is attributable primarily to increased risk for type 2 diabetes, gallbladder disease, coronary artery disease, hypertension, osteoarthritis, and several types of cancer (3,4).

Numerous studies have tested a variety of strategies and interventions to promote weight loss and maintenance in the general population of overweight and obese women. Findings from those studies, and data collected from individuals who have lost weight and successfully maintained the loss, provide insight about which strategies are likely to be most successful (5,6). For example, one of the most consistent observations is that successful weight loss with maintenance of that loss is characterized by regular physical activity (5,7), in addition to some sustained effort to regulate food choices. The ultimate determinant of weight change is energy intake relative to expenditure (6), so a reduction in intake relative to expenditure is the primary dietary factor that must be addressed to promote weight loss. Energy density of the diet has emerged as a dietary characteristic that can be manipulated to maintain volume, satiety and satiation, while minimizing the discomfort of restricting energy intake. Strategies that reduce the energy density of the diet (e.g., increased intake of vegetables, fruit, and fiber) may help to maintain meal satiety at a lower level of energy intake (8).

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Providing prepackaged prepared foods within the context of a nutritionally complete meal plan also has been shown to be superior in promoting weight loss when compared with standard dietary and behavioral counseling. In a randomized trial, Metz et al. (9), in a study that involved 302 overweight or obese adults with hypertension, dyslipidemia, or type 2 diabetes, demonstrated that meals based on prepackaged prepared items promoted greater weight loss than a standard diet prescription. After 1 year, weight change was -5.8 (6.8) [mean (standard deviation)] kg with the prepared meal plan vs. -1.7 (6.5) kg with standard diet prescription among overweight or obese men and women with hypertension or dyslipidemia, and a similar difference was observed among individuals with type 2 diabetes (-3.0 [5.4] kg vs. -1.0 [3.8] kg, respectively). In a study targeting 163 overweight or obese individuals who were otherwise healthy, food provision was similarly observed to be superior to standard weight loss counseling or behavioral interventions. At the 6- and 18-month follow-up, providing prepackaged foods (free or at minimal cost) increased average initial weight loss by 50% (from 8 to 12 kg) at 6 months and by $>100\%$ 1 year later (from 3.3 to 6.9 kg) (10).

Previous studies suggest that commercial weight loss programs have the potential to promote a degree of weight loss that equals or exceeds traditional counseling or medical interventions (11). One commercial program, the Jenny Craig (JC)¹ program, incorporates several features that have independently been observed to promote weight loss and maintenance (individual counseling, low-energy density diet, prepackaged foods, and increased physical activity), but this multifaceted intervention has not been previously tested in a randomized trial.

The first aim of this study was to test, in a proof-of-principle randomized controlled trial, whether the multifaceted JC intervention, a commercial diet and lifestyle modification program to promote weight loss, is associated with a greater degree of weight loss and maintenance of that loss in overweight or obese women, compared with control conditions. This study used a randomized study design, with subjects assigned to the commercial weight loss program or a usual care control group. The second study aim was to describe the effect of participation in the weight loss program (vs. control conditions) on plasma lipids [fasting total plasma cholesterol and triglycerides, low-density lipoprotein (LDL) cholesterol, and high-density lipoprotein (HDL) cholesterol], plasma carotenoids (a biomarker of vegetable and fruit intake), selected hormonal factors [fasting serum insulin and sex-hormone binding globulin (SHBG)], and

cardiopulmonary fitness. Data collected at baseline and the 6- and 12-month follow-up time-points are presented in this report.

Research Methods and Procedures

Subjects

Participants in this study were overweight or obese women in San Diego who met the following inclusion criteria: Age 18 years and older; initial BMI ≥ 25.0 kg/m² (overweight or obese) (6) and < 40 kg/m², and a minimum of 15 kg over ideal weight as defined by the 1983 Metropolitan Life Insurance tables (12); willing and able to participate in clinic visits and JC facility interactions at specified intervals and to maintain contact with the investigators for two years; willing to allow blood collections; and capable of performing a simple step test for assessing cardiopulmonary fitness. Those who were unable to be physically active because of severe disability (e.g., severe arthritic conditions) or who reported a history or presence of a comorbid disease for which diet modification and increased physical activity might be contraindicated were not included, as well as those who reported being currently pregnant or breastfeeding or planning a pregnancy within the next 2 years. Current active involvement in another diet intervention study or organized weight loss program; and having a history or presence of a significant psychiatric disorder or any other condition that, in the investigator's judgment, would interfere with participation in the trial also disqualified women from participating.

A total of 276 women were screened by telephone. Of those screened by telephone, 98 apparently met the inclusion criteria and were invited to a screening clinic visit. At this clinic visit, the ability to participate in mild and moderate physical activity was assessed with the Physical Activity Readiness and Health History Questionnaire, a standard procedure for screening participants for community-based programs involving physical activity (13). At this clinic visit, 28 women were determined to be ineligible (Figure 1). A total of 70 women were enrolled in the study and were randomized.

This study was reviewed and approved by the Human Research Protections Program at the University of California, San Diego, and all study participants provided written informed consent.

Procedures

Information about demographic characteristics was collected by telephone at the time of recruitment and as part of the initial interview. Before the initial clinic visit, participants received detailed instructions on how to prepare for a clinic visit and the interview, and written questionnaires were completed at the clinic visits. Trained staff obtained anthropometric measures, BMI was calculated with these

¹ Nonstandard abbreviations: JC, Jenny Craig; LDL, low-density lipoprotein; HDL, high-density lipoprotein; SHBG, sex-hormone binding globulin; EDE-Q, Eating Disorder Examination-Questionnaire; BDI, Beck Depression Inventory.

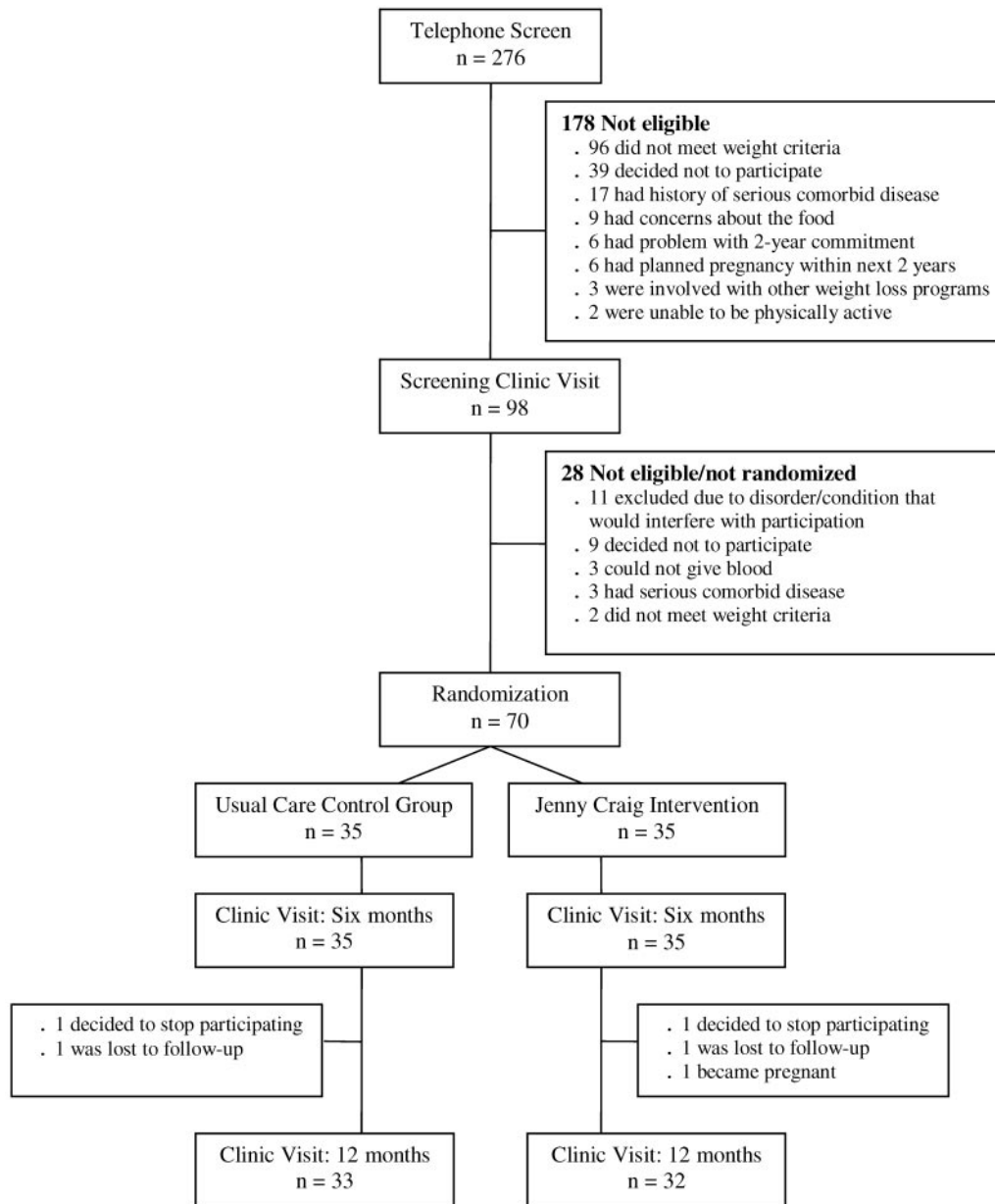


Figure 1: Flow of participants in the trial.

measurements, and a step test was conducted with each participant at the baseline and 6- and 12-month clinic visits.

After enrollment and successful completion of the baseline data collection and assessment activities, participants were stratified by BMI (25.0–29.9 vs. ≥ 30.0 kg/m²) and age (≤ 40 and >40 years) and randomly assigned to one of the two study groups. The intervention arm consisted of referral to a conveniently located community-based JC facility, including the establishment of an initial appointment to begin the program. Subjects assigned to the commercial weight loss program intervention received all program materials, including prepackaged prepared foods as needed to achieve a meal plan, free-of-charge.

The core components of the JC weight loss program are described as addressing food, body, and mind. Interactions between corporate-trained and supervised staff and the clients consist of weekly one-to-one contacts with a counselor who is described as a consultant, with follow-up telephone and e-mail contacts and web site/message board availability.

The food component consists of prescribing an energy-reduced diet (typically 1200–2000 kcal/d, individualized based on energy requirements) that includes prepackaged prepared food items that incorporate (and are accompanied by) increased vegetables, fruit, and other additional strategies to reduce the energy density of the diet. The prepack-

aged foods are generally provided at the weekly interactions at a community-based facility, and food selections are determined by the preferences of the client and how the products fit into a nutritionally complete meal plan. Notably, these foods provide only the core of the prescribed meal plan, rather than the entire prescribed daily intake. In addition to non-prepackaged food choices to be included in meals and snacks, such as vegetables, fruit, and dairy products, strategies addressed in the food component include counseling for making appropriate food choices in situations apart from the context of prepackaged foods (e.g., eating in restaurants, eating when traveling, meals and snacks based on usual food choices). The approach is tailored, so that clients can choose regular foods when preferred, an option that is discussed during counseling sessions. In general, clients are initially encouraged to follow a menu plan that includes prepackaged foods in each meal and snack. The average energy contribution of the prepackaged foods during that initial period is 820 kcal/d, so that within a prescribed energy intake of 1200 to 2300 kcal/d, the prepackaged food would provide 35% to 68% of energy for clients who choose not to deviate from the plan. Regular foods, such as vegetables, fruit, cereal/grain foods, low-fat dairy products, lean meat or equivalent, and unsaturated fat sources, are prescribed to achieve the total prescribed energy intake. When the client is halfway to goal weight, a meal plan based on prepackaged foods 5 days of the week is recommended. When the goal weight is achieved, transition to a meal plan that is based entirely on regular (not JC) food is implemented, although clients have the choice of including one prepackaged-based meal per day through transition.

Increased physical activity (the body component) is another aspect of this commercial program, with specific goal-setting and follow-through that are determined on the basis of the readiness, capabilities, and preferences of the client. In general, the goal is 30 minutes of physical activity on 5 or more days of the week. Finally, the mind component describes the cognitive aspects of promoting weight loss and maintenance, including self-acceptance, improved body image, and interpretation of one's attitudes, behavior, and thinking patterns, as these factors can be monitored and/or modified to promote successful weight loss and maintenance. For example, the dichotomous thinking pattern associated with dieting behavior is challenged, and healthy stress management and motivational factors are addressed. The program uses extensive written materials and other media, such as compact discs that promote cognitive restructuring and increased physical activity and videotapes to facilitate structured exercise activities.

Participants assigned to the usual care control group were provided consultation, at baseline (after randomization) and again at 16 weeks, with a research staff dietitian, who also provided publicly available print material that described

dietary and physical activity guidelines to promote weight loss and maintenance. The dietitian initially discussed the interpretation of the participant's anthropometric data and the concepts of healthy weight and energy balance. Baseline energy requirements for weight maintenance were then calculated, and an energy intake level (accompanied by a menu plan based on food groups) to achieve a weight loss of 10% over a 6-month period was prescribed, involving a deficit of 500 to 1000 kcal/d, as per current recommendations (6). Specific sample meal plans and recommendations to increase physical activity were provided to each participant. Written materials and resources for useful strategies and skills, such as reading food labels, estimating serving sizes, and eating outside the home, were provided, as well as information for healthy food choices (e.g., the U.S. Department of Agriculture Food Guide Pyramid). Progress was reviewed and concepts and strategies were further discussed in the follow-up counseling session.

Measurements

Data collection (anthropometric measures, biochemical laboratory assays, questionnaires, and step test) for all subjects occurred at three clinic visits: at baseline and 6 and 12 months. Information about demographic characteristics and weight history was collected only at baseline.

Anthropometric measures consisted of height, weight, and waist and hip circumferences. The 3-minute step test was used to detect possible changes in aerobic fitness of study participants. This test measures heart rate during the first 30 seconds of recovery from stepping. Step tests are useful for field-testing subjects, and although they are less accurate than measuring maximal oxygen uptake ($VO_2\max$), they have high reliability and are sensitive to change (14).

At each clinic visit, a blood sample was collected by venipuncture. Blood samples collected at the clinic visit were immediately placed on ice, protected from light, and separated within 1 hour after collection, using centrifugation at 2300g at 4 °C for 10 minutes. Plasma and serum aliquots were stored at -80 °C in cryogenic tubes until analysis. Measurements of plasma cholesterol, triglycerides, and HDL cholesterol were accomplished using enzymatic methods with the Kodak Ektachem Analyzer system (Johnson & Johnson Clinical Diagnostics, Rochester, NY). LDL cholesterol values were calculated by the Friedewald equation (15). Standard reference materials from the manufacturer were used to validate analytical precision of these procedures, and the laboratory participates in the American College of Pathologists quality assurance program to monitor precision and reliability for these lipid measures.

Plasma carotenoid concentrations, as a biomarker of vegetable and fruit intake, were measured by high performance liquid chromatography, using a previously described method (16). Carotenoids measured with this method include α -carotene, β -carotene, β -cryptoxanthin, lycopene,

and lutein plus zeaxanthin, which quantify >90% of the carotenoids present in the circulation in humans. The variable described as plasma total carotenoids in the present study is the summed total of the quantified carotenoids. Accuracy was assessed by periodic analysis of National Institute of Standards and Technology standard reference material, and a pooled plasma sample was analyzed with batches of study samples to monitor analytical precision, with a day-to-day coefficient of variation of ~7%. Also, the laboratory participates in the National Institute of Standards and Technology round robin quality assurance program to monitor precision and reliability of these carotenoid measurements.

A double antibody radioimmunoassay, with <0.2% cross-reactivity with human proinsulin, was used for the analysis of fasting serum insulin (Linco Research, Inc., St. Charles, MO). The intra-assay coefficient of variation is 3.2%, and the inter-assay coefficient of variation is 3.9%. The method used for SHBG analysis was a time-resolved fluoroimmunoassay (Delphia SHBG, E G & G, DSL, Webster, TX), and the laboratory inter-assay coefficient of variation is 5.94%.

Eating, shape, and weight concerns and attitudes were assessed at baseline and 6 and 12 months with the Eating Disorder Examination–Questionnaire (EDE-Q). This assessment tool allows examination of attitudes about eating and body weight and shape as potential predictors of response and also enables the examination of the effect of the intervention on these attitudes. The 39-item EDE-Q is a self-report version of the EDE (17), which has been described in detail and compared with the EDE in previous studies (18,19). Scores obtained from the two instruments are generally correlated, and the self-report instrument is considered acceptable for assessing general features of eating and weight psychopathology. The EDE-Q asks questions such as, “Have you gone for long periods of time (8 hours or more) without eating anything to influence your shape and weight?” and “Have you felt fat?” over the preceding 28-day period. It allows quantifiable data to be collected so that the degree of eating pathology across a continuum of disturbance may be assessed with four subscales (restraint, eating concern, shape concern, and weight concern) and a global score, which is the mean of these four subscales. In the present study, the variable of interest was the global EDE-Q score. A global score of 4 or higher is considered to be indicative of a clinical eating disorder (20).

The 21-item Beck Depression Inventory (BDI) was used to assess self-reported presence and degree of depressive symptoms (19). This self-report questionnaire asks questions about feelings such as sadness, pessimism, suicidal thoughts or wishes, worthlessness, and loss of interest. The BDI is a widely used inventory that is considered an acceptable instrument to assess severity of depressive symptoms (21). A score of 0 to 13 indicates normal ups and

downs, 14 to 19 corresponds to mild mood disturbance, 20 to 28 is indicative of moderate depression, and a score of 29 to 63 represents severe depression (22).

Analysis

Data for continuous variables were log-transformed to improve normality in independent *t* tests. Demographic and anthropometric variables were compared between the two groups at baseline using two-sample *t* tests for continuous variables or χ^2 tests for categorical variables. Changes in anthropometric measures (change in weight, BMI, waist and hip circumferences, and percentage weight change) were compared between the two groups at 6 months and at 12 months using two-sample *t* tests. Changes in step test (heart rate/30 seconds) and changes in BDI and EDE-Q scores in the two study groups were also compared using two-sample *t* tests. The dropout rate was low [none at 6 months and 5 (7%) at 12 months], and we performed both an intent-to-treat and completers analysis on the 12-month data, substituting baseline values for any subjects for whom 12-month data were missing.

Changes in the biochemical variables (lipids, carotenoids, and hormonal factors) were examined using several approaches. First, means for these variables at baseline were compared between the two groups using two-sample *t* tests. Two subjects who had been assigned to the intervention group exhibited plasma triglyceride concentrations that exceeded 3 standard deviations from the mean at least at one time-point, so data from those subjects were excluded from the analysis of triglyceride concentration. Paired *t* tests for within-group changes for these variables were conducted as the primary approach to analysis. Changes in these variables in the intervention vs. control groups were also compared using two-sample *t* tests. Also, study group means at 6 and 12 months were compared using two-sample *t* tests. Because the values for SHBG concentration exhibited substantial variability, we examined whether weight loss (at least 5% of initial weight) was associated with change in this hormonal factor regardless of group assignment. All analyses were conducted using SAS (version 9.1, Cary, NC).

Results

Table 1 summarizes characteristics of the two study groups at baseline. There were no significant differences in anthropometric measurements, step test, BDI and EDE-Q scores, and demographic characteristics at baseline. BMI at study entry ranged from 26.9 to 40.2 kg/m² (mean, 34.0 kg/m²), and weight at baseline ranged from 72.7 to 121.4 kg (mean, 92.0 kg). Fifty-seven percent of the women were non-Hispanic white, 23% were Hispanic, 10% were African-American, 3% were Asian-American, and 7% were other ethnicity. Two of the women were smokers. Half of the women reported >15 years of education.

Table 1. Comparability of groups at baseline for the intervention and usual care control groups ($n = 35$ for each)*

Variables	Intervention group [mean (standard deviation)]	Usual care control group [mean (standard deviation)]
Age (yrs)	42 (11)	40 (12)
Education (yrs)	15.2 (2.5)	15.2 (3.0)
Body mass index (kg/m ²)	34.2 (3.7)	33.8 (3.4)
Weight (kg)	94.4 (12.2)	89.6 (9.4)
Waist circumference (cm)	113.0 (10.6)	110.2 (11.6)
Hip circumference (cm)	123.5 (9.1)	120.0 (6.5)
Step test (heart rate per 30 seconds)	57.1 (9.2)	53.9 (7.2)
Eating Disorder Examination-Questionnaire global score	2.0 (0.9)	2.1 (0.9)
Beck Depression Inventory	6.6 (5.8)	8.1 (7.0)
	<i>n</i> (%)	<i>n</i> (%)
Race/ethnicity		
White non-Hispanic	20 (57)	20 (57)
Hispanic	5 (14)	11 (31)
African-American	6 (17)	1 (3)
Asian-American	1 (3)	1 (3)
Other	3 (9)	2 (6)
Marital status		
Married	19 (54)	26 (74)
Single	7 (20)	4 (11)
Divorced/separated	9 (26)	5 (14)

* None of the variables differed significantly between groups at baseline, 2-sample t tests for continuous variables, or χ^2 tests for categorical variables.

All of the enrolled and randomized women completed a baseline and 6-month clinic visit, and 65 of the 70 women enrolled (32 intervention and 33 control group subjects) completed a 12-month clinic visit. Of the five women who did not complete the 12-month clinic visit, two decided to stop participating, two were lost to follow-up, and one became pregnant. These 65 women had a mean age of 41 years (range, 19–65 years), and the median age was 44 years. The five women who did not complete their 12-month clinic visit did not differ from the 65 who remained in the study at 1 year in baseline weight, BMI, waist and hip circumferences, and BDI and EDE-Q scores. During the trial, one participant assigned to the commercial weight loss program was diagnosed with gallstones; she remained in the study, and the condition was surgically treated.

Table 2 shows details of change in anthropometric measures and step test in the two groups, applying an intent-to-treat approach. Because none of the subjects dropped out of the study between baseline and 6 months, the intent-to-treat analysis as shown is identical to a completers analysis for

the 6-month time-point. Results of the intent-to-treat analysis are shown for the 12-month data, although because of the low dropout rate of only 7% between 6 and 12 months, the differences between completers and intent-to-treat are quite small and do not affect the significance of the intervention effect.

At 12 months, the completers in the intervention group had lost an average of 7.3 kg, 9.0 cm of waist circumference, and 6.7 cm of hip circumference over the year, whereas the control group women had lost only 0.7 kg, 0.2 cm of waist circumference, and 0.3 cm of hip circumference (Table 3). None of the changes in the control group women is significantly different from zero, although the corresponding changes in the intervention group women are all significant ($p < 0.01$).

The two groups did not differ on their EDE-Q and BDI scores, with both groups showing very small improvements on each measure (data not shown). The intervention group women showed a greater improvement in their step test performance, indicated by a larger heart rate decrease, between baseline and 6 months than did the comparison group

Table 2. Results of analysis of differences in changes over time: intent-to-treat analysis*

	Intervention group		Usual care control group	
	6 months (n = 35)	12 months (n = 35)	6 months (n = 35)	12 months (n = 35)
Change in weight (kg)†	-7.2 (6.7)	-6.6 (10.2)	-0.3 (3.9)	-0.7 (5.5)
Change in percent weight†	-7.8 (7.2)	-7.1 (10.8)	-0.3 (4.5)	-0.7 (6.0)
Change in BMI (kg/m ²)†	-2.6 (2.5)	-2.4 (3.8)	-0.2 (1.5)	-0.3 (2.1)
Change in waist circumference (cm)†	-7.1 (8.4)	-8.2 (10.5)	-1.1 (6.5)	-0.2 (7.0)
Change in hip circumference (cm)†	-5.7 (5.1)	-6.2 (7.8)	-0.3 (3.3)	-0.3 (5.0)
Change in step test (heart rate per 30 seconds)‡	-6.4 (6.4)	-4.1 (6.8)	-2.9 (6.3)	-3.4 (6.3)

* Values are mean (standard deviation) for intent-to-treat analysis, with baseline values substituted for missing values among those who did not complete the 12-month clinic visit.

† $p < 0.01$ between groups at both 6 and 12 months.

‡ $p < 0.05$ between groups at 6 months only.

($p < 0.05$), but this difference was not sustained at 12 months. Importantly, at both follow-up time-points, the intervention group lost significantly more weight, BMI, and waist and hip circumferences than the usual care control group ($p < 0.01$).

As shown in Table 4, the two groups did not differ at baseline in their lipid concentrations, individual or total plasma carotenoid, or insulin or SHBG concentrations. Women assigned to the commercial weight loss program intervention experienced increases in plasma concentrations of α -carotene, β -carotene, lycopene, and HDL cholesterol ($p < 0.01$ paired t tests) between baseline and 12 months (Table 4). The usual care control group did not show any change in HDL cholesterol or α -carotene concentrations,

although the β -carotene and lycopene concentrations also increased in the control group women. Total carotenoids, α -carotene, and β -carotene increased more in the intervention group than in the usual care control group between baseline and 6 months ($p < 0.05$), but the difference was not sustained over 12 months. Triglyceride and SHBG concentrations did not change differentially between groups, but fasting insulin concentration showed a larger decrease in the intervention group than in the control group at 6 months (a decrease of 5 μ U/mL in the intervention group vs. an increase of 1.7 μ U/mL in the usual care control group, $p < 0.05$) and a marginally larger decrease in the intervention group than in the usual care control group at 12 months ($p = 0.05$). Using a two-sample t test to compare 12-month data,

Table 3. Changes in body measurements in the two groups compared with baseline scores, completers only*

	Intervention group		Usual care control group	
	6 months (n = 35)	12 months (n = 32)	6 months (n = 35)	12 months (n = 33)
Change in weight (kg)†	-7.2 (6.7)	-7.3 (10.4)	-0.3 (3.9)	-0.7 (5.6)
Change in percent weight†	-7.8 (7.2)	-7.8 (11.1)	-0.3 (4.5)	-0.7 (6.2)
Change in BMI (kg/m ²)†	-2.6 (2.5)	-2.6 (3.9)	-0.2 (1.5)	-0.3 (2.1)
Change in waist circumference (cm)†	-7.1 (8.4)	-9.0 (10.6)	-1.1 (6.5)	-0.2 (7.3)
Change in hip circumference (cm)†	-5.7 (5.1)	-6.7 (7.9)	-0.3 (3.3)	-0.3 (5.2)
Change in step test (heart rate per 30 seconds)‡	-6.4 (6.4)	-4.5 (7.0)	-2.9 (6.3)	-3.6 (6.5)

* Values are mean (standard deviation) for completers at 6 and 12 months.

† $p < 0.01$ between groups at both 6 and 12 months.

‡ $p < 0.05$ between groups at 6 months only.

Table 4. Carotenoid, lipid, and hormone measurements across time for the study groups

Variable	Intervention group			Usual care control group		
	Baseline (<i>n</i> = 35)	6 months (<i>n</i> = 35)	12 months (<i>n</i> = 32)	Baseline (<i>n</i> = 35)	6 months (<i>n</i> = 35)	12 months (<i>n</i> = 33)
Alpha-carotene (μM)*	0.12 (0.14)	0.13 (0.11)	0.18 (0.15)†	0.13 (0.11)	0.09 (0.07)‡	0.16 (0.14)
Beta-carotene (μM)*	0.48 (0.65)	0.73 (0.73)‡	0.67 (0.57)†	0.46 (0.39)	0.42 (0.32)	0.50 (0.31)†
Lutein (μM)	0.36 (0.19)	0.38 (0.23)	0.40 (0.23)	0.37 (0.16)	0.40 (0.16)	0.41 (0.17)
Lycopene (μM)	0.71 (0.35)	0.69 (0.27)	0.94 (0.35)†	0.77 (0.24)	0.74 (0.23)	1.03 (0.32)†
Beta-cryptoxanthin (μM)	0.15 (0.13)	0.20 (0.16)‡	0.15 (0.07)	0.16 (0.10)	0.18 (0.15)	0.16 (0.10)
Total carotenoids (μM)*	1.82 (1.2)	2.12 (1.18)	2.33 (1.04)	1.90 (0.81)	1.81 (0.65)	2.26 (0.69)
HDL cholesterol (mg/dL)	50 (15)	51 (13)	61 (15)†	52 (13)	53 (11)	56 (17)
LDL cholesterol (mg/dL)	113 (40)	109 (32)	104 (26)	121 (35)	119 (26)	120 (31)
Total cholesterol (mg/dL)	189 (37)	181 (33)	188 (30)	193 (42)	196 (34)	196 (37)
Triglycerides (mg/dL)§	112 (52)	98 (42)	107 (59)	99 (50)	102 (51)	102 (50)
Sex hormone binding globulin (nM)	56.4 (49.6)	72.7 (59.3)	72.8 (50.7)	68.9 (74.5)	79.4 (69.3)	69.8 (43.2)
Insulin ($\mu\text{U}/\text{mL}$)*	22.7 (12.3)	17.7 (9.9)‡	18.8 (10.8)	17.9 (8.4)	19.6 (10.0)	19.7 (9.2)

HDL, high-density lipoprotein; LDL, low-density lipoprotein. Values are mean (standard deviation).

* Intervention group showed significantly greater change between baseline and 6 months than did the usual care control group ($p < 0.05$, independent t test).

† Significant change from baseline to 12 months, within-group paired t test.

‡ Significant change from baseline to 6 months, within-group paired t test.

§ Excluding data from two intervention group subjects who exhibited plasma triglyceride concentrations that exceeded three standard deviations from the mean at least at one time-point.

|| Intervention group showed marginally greater change between baseline and 12 months than did the usual care control group ($p = 0.05$, independent t test).

LDL cholesterol concentration was significantly different between the two groups (averaging 120 vs. 104 mg/dL in the control and intervention groups, respectively). SHBG increased in women who lost $\geq 5\%$ of initial weight at 12 months (21.4 [62.2] nmol/L) and decreased in those whose weight was stable or increased (-4.7 [44.5] nmol/L), regardless of group assignment ($p = 0.077$).

Discussion

Results from this study demonstrate that a commercial diet and lifestyle modification program that incorporates several specific strategies (individual counseling, low-energy density diet, prepackaged foods, and increased physical activity) successfully facilitated a weight loss of $\sim 8\%$ of initial weight that was notably maintained at 1 year. Favorable changes in plasma lipid and hormone concentrations were observed in association with participation in the commercial weight loss program. Further, increased plasma

carotenoid concentrations were observed in the program participants, indicating increased consumption of vegetables and fruit. This multifaceted approach has not been previously tested in a randomized trial.

The need for and importance of controlled trials to assess the efficacy of commercial weight loss programs was a major conclusion reported by Tsai and Wadden as a result of their systematic review of the literature (23). A large proportion of the overweight or obese individuals in the United States enroll in commercial weight loss programs, and scientific evidence on which to judge the efficacy of these programs has been meager. As noted in their report (23), evidence to support the use of commercial and self-help weight loss programs is suboptimal, and at the time of that review, only one randomized controlled trial of a commercial weight loss program had been reported.

In previous studies (9,10), prepackaged meals and snacks in a nutritionally complete meal plan have been shown to be superior in promoting weight loss when compared with

usual care diet instruction or standard behavior therapy. Portion control and structure are among the reasons that have been proposed to explain the usefulness of this strategy (10). In the present study, we observed an average weight loss of -7.2 kg at 6 months and -7.3 kg at 1 year among completers in response to a multifaceted commercial weight loss program that included prepackaged foods, with similar results using an intent-to-treat analysis due to the low drop-out rate. This represents a reduction in body weight of 8%, which is considered clinically significant due to changes in risk factors for chronic disease that are associated with this degree of weight loss (6). Maintenance of this weight loss was observed over a 1-year period, which suggests that lifestyle changes, such as increased physical activity and food choices that promote weight management, were adopted by the program participants. At 1 year, waist circumference remained significantly reduced in the commercial weight loss program participants compared with the control group, indicating a sustained reduction in abdominal obesity.

A key aspect of the approach to dietary guidance in the JC program is to encourage increased intake of vegetables and fruit, as one approach to reducing the energy density of the diet. The increase in plasma carotenoids observed in this study confirms this change in diet composition. Increased plasma carotenoids, particularly α -carotene, have been consistently associated with higher levels of dietary intake of vegetables and fruit in observational studies (24,25), and tissue concentrations have been shown to increase in response to feeding or prescribing these foods (26,27) and in diet intervention studies that successfully promote increased vegetable and fruit intake (28,29).

This trial is testing the effect of the multifaceted commercial weight loss program in its entirety, and this study was not designed to test the relative contributions of the various components of the commercial weight loss program. Contributions of the various components of the intervention to the weight loss and maintenance that was observed remain to be determined.

Several favorable changes in lipids and hormonal factors were observed in response to participation in the commercial weight loss program. HDL cholesterol concentration increased in the subjects assigned to the program, as has been previously observed in response to weight loss interventions that emphasize both diet and exercise (30). Women assigned to the commercial program also exhibited a significant and sustained reduction in fasting serum insulin concentration, which is considered a surrogate for insulin resistance (31). The improvement in the step test that was observed at 6 months indicates increased regular physical activity by the commercial weight loss program participants.

Obesity is associated with decreased serum SHBG concentration, which increases the bioavailable estrogen frac-

tion and may contribute to the observed relationship between obesity and risk for hormone-related cancers (3,32,33), and in previous studies, weight loss has been shown to promote an increase in SHBG levels. For example, Mingrone et al. (34) examined the effect of weight reduction on SHBG concentration in 52 obese women who were either prescribed an energy-restricted diet or were provided gastric surgery to facilitate reduced energy intake. Both subgroups demonstrated an increase in SHBG concentration (averaging 25% in association with diet alone and 34% in association with the surgical procedure), and the effect correlated with both total weight loss and percentage body fat. In the present study, we did not observe a difference in SHBG response in the study arms, although women across both study arms who had a greater degree of weight loss exhibited increased SHBG concentration. The small sample size, heterogeneity of the sample, and resulting large variance for this factor likely explain why group assignment was not associated with a difference in SHBG response.

One participant in this trial developed gallstones during the study, but current scientific evidence suggests that pre-existing obesity, rather than the intervention or study participation, is the most likely causal factor (35). Indeed, lifestyle changes to promote weight loss at a moderate rate (as prescribed in the JC intervention) are recommended to reduce risk of gallstones (36,37).

There are several limitations of this study. The sample size was small, and the study was powered to detect differences in weight change between the groups, rather than differences in the biochemical and hormonal factors that were examined. As a proof-of-principle study, the purpose was to determine whether the commercial program was effective in promoting weight loss and maintenance, rather than to address cost-effectiveness or disentangle the effects of the various components of the program, as noted above. The results may not be generalizable to all overweight or obese women because the sample was comprised of individuals who agreed to participate in a randomized controlled trial. As follow-up continues, some attenuation of the program effects may occur.

The choice of control group also affects the interpretation of these data. A more intensive intervention for the control group, particularly one with more frequent contact and counseling, may have resulted in a similar degree of weight change in the two study arms. The control group in this study was provided an intervention that would be a likely first step for the overweight or obese individual seeking guidance for weight loss and could be covered by health insurance programs. Intensive behavioral or medical weight loss interventions with frequent long-term contact are not available for most individuals and in most communities, nor are they covered by typical healthcare plans. A comparison

of the commercial weight loss program to a more intensive intervention that does not incorporate prepackaged foods would be of interest.

Results from the large Diabetes Prevention Program study, which utilized an individual counseling intervention aimed at achieving and maintaining a reduction of at least 7% of initial body weight through a reduced-calorie, low-fat diet and physical activity of moderate intensity for at least 150 minutes/wk, are relevant (38). In that large study ($n = 3234$), the intensive lifestyle intervention promoted an average weight loss of 5.6 kg in participants assigned to the lifestyle intervention group at an average follow-up of 2.8 years. In another large study that is ongoing (the Look AHEAD [Action for Health in Diabetes] Study), the effects of a similar intensive weight loss and physical activity intervention are being examined (39). In the Look AHEAD Study, the intervention is similar to that utilized in the Diabetes Prevention Program but is based primarily on group (rather than individual) treatment during the first year and includes liquid meal replacements and the option of weight loss medication after the first 6 months with selected individuals.

In summary, results from this study suggest that a commercial weight loss program that promotes diet and lifestyle modification successfully facilitates weight loss, which is notably maintained at 1 year. Program participation promoted favorable changes in plasma lipid and hormone concentrations, and changes in plasma carotenoids suggest increased vegetable and fruit intake, a strategy that reduces the energy density of the diet.

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