Effect of a Free Prepared Meal and Incentivized Weight Loss Program on Weight Loss and Weight Loss Maintenance in Obese and Overweight Women

A Randomized Controlled Trial

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Context The prevalence of overweight and obesity in the United States remains high. Commercial weight loss programs may contribute to efforts to reduce the prevalence of overweight and obesity, although few studies have examined their efficacy in controlled trials.

Objective To test whether a free prepared meal and incentivized structured weight loss program promotes greater weight loss and weight loss maintenance at 2 years compared with usual care.

Design, Setting, and Participants A randomized controlled trial of weight loss and weight loss maintenance in 442 overweight or obese women (body mass index, 25-40) aged 18 to 69 years (mean age, 44 years) conducted at US institutions over 2 years with follow-up between November 2007 and April 2010.

Intervention The program, which involves in-person center-based or telephone-based one-to-one weight loss counseling, was available over a 2-year period. Behavioral goals were an energy-reduced, nutritionally adequate diet, facilitated by the inclusion of prepackaged food items in a planned menu during the initial weight loss phase, and increased physical activity. Participants assigned to usual care received 2 individualized weight loss counseling sessions with a dietetics professional and monthly contacts.

Main Outcome Measures Weight loss and weight loss maintenance.

Results Weight data were available at 24 months for 407 women (92.1% of the study sample). In an intent-to-treat analysis with baseline value substitution, mean weight loss was 7.4 kg (95% confidence interval [CI], 6.1-8.7 kg) or 7.9% (95% CI, 6.5%-9.3%) of initial weight at 24 months for the center-based group, 6.2 kg (95% CI, 4.9-7.6 kg) or 6.8% (95% CI, 5.2%-8.4%) for the telephone-based group, and 2.0 kg (95% CI, 0.6-3.3 kg) or 2.1% (95% CI, 0.7%-3.5%) for the usual care control group after 24 months ($P < .001$ for intervention effect).

Conclusion Compared with usual care, this structured weight loss program resulted in greater weight loss over 2 years.

Trial Registration clinicaltrials.gov Identifier: NCT00640900

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THE PREVALENCE OF OVERweight and obesity in the United States remains high. National survey data for 2007-2008 indicate that 33.8% of adults are obese (body mass index [BMI; calculated as weight in kilograms divided by height in meters squared] ≥30), and the prevalence for overweight and obesity combined (BMI ≥25) is 68.0%.[1] Obesity is associated with an increased risk for numerous medical problems, especially hypertension, diabetes, dyslipidemia, and the metabolic syndrome.[2] Other comorbidities associated with overweight and obesity include gallbladder disease, sleep apnea, osteoarthritis, hyperuricemia, and lower quality of life.[3-5] Excess mortality associated with obesity is primarily attributable to cardiovascular disease, diabetes, kidney disease, and several types of cancer.[6,7]

Given the magnitude of the problem, clinical and public health guidelines recommend screening and prescribing treatment programs for those who are already overweight or obese.[8,9] Although commercial weight loss programs are popular, there is a paucity of scientific evidence on which to judge their efficacy.[10] Only a few studies[10-12] suggest that some programs have the potential to promote a degree of weight loss that equals or exceeds office-based counseling or medical interventions.

The first aim of this study was to test in a randomized controlled trial whether participation in a free prepared meal and

For editorial comment see p 1837.

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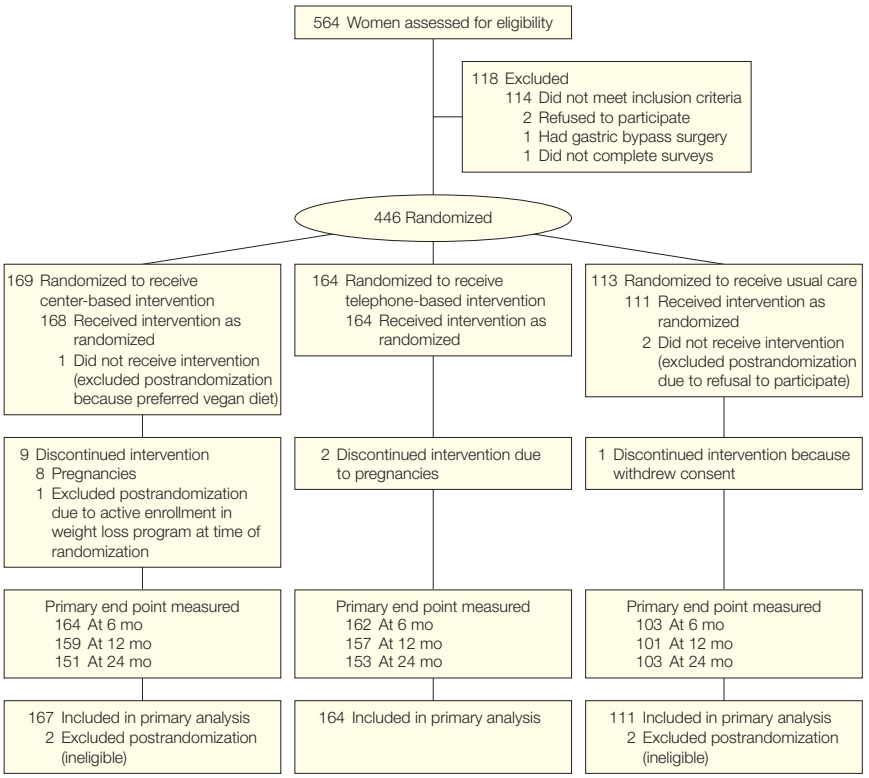
Figure 1. Flow of Participants Through Trial



incentivized center-based or telephone-based intervention promotes greater weight loss and weight loss maintenance at 2 years in overweight or obese women compared with usual care. A secondary aim of the study was to describe the effect of participating in the program (vs usual care) on selected biochemical factors, cardiopulmonary fitness, quality of life, and eating attitudes and behaviors. Biochemical factors under study include plasma lipids (fasting levels of total cholesterol and triglycerides, low-density lipoprotein cholesterol, and high-density lipoprotein cholesterol), C-reactive protein (CRP), and plasma carotenoids, a biomarker of intake of fruits and vegetables.

METHODS

Participants were enrolled at 4 study sites (University of California, San Diego; University of Arizona, Tucson; University of Minnesota, Minneapolis; and Center for Health Research, Kaiser Permanente Center Northwest, Portland, Oregon). Participants were recruited using list serves and flyers distributed by the research staff at each site. Eligibility criteria included age 18 years or older; BMI of 25 to 40 and a minimum of 15 kg over ideal weight as defined by the 1983 Metropolitan Life Insurance tables[13]; not pregnant or breastfeeding or planning to become pregnant in the next 2 years; willing to participate in any of the 3 study groups over a 2-year period; no eating disorders, food allergies, or intolerances; and willing and able to perform a simple step test for assessing cardiopulmonary fitness. Women at BMI levels of greater than 40 were excluded because such extreme obesity is associated with more serious comorbid conditions and is more likely to require a higher intensity and more supervised clinical approach to weight loss and exercise. The sample was limited to women because men comprise the minority of enrollees in weight loss programs. Current active involvement in another diet intervention study or organized weight loss program or 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.

Information about demographic characteristics, including race/ethnicity (by prespecified categories), was collected by self-report from participants at baseline. The purpose was to describe the characteristics of the sample population.

Participants were randomly assigned in a 3:3:2 allocation to the center-based intervention, the telephone-based intervention, or the usual care group (FIGURE 1). Four participants found to be ineligible postrandomization were excluded from the analysis. A Web-based data application was run at each clinical site by research staff that used a randomization sequence generated by the study statistician. Center-based intervention participants were assigned to a conveniently located center and an initial appointment to begin the program. Participants assigned to the telephone-based study group were contacted to initiate telephone interactions. All participants were provided a small monetary compensation ($25) for each completed clinic visit, but no reimbursement was provided for participation in the intervention or counseling sessions. The institutional review boards at all of the institutions involved approved the protocol prior to study initiation. All participants provided written informed consent.

Intervention

Participants assigned to the center-based or telephone-based study groups received all program materials, including free-of-charge prepackaged prepared foods as needed to achieve a meal plan. Interactions between corporate-trained and supervised staff and the participants consisted of brief weekly one-to-one contacts with an in-person or telephone counselor, with follow-up tele-

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phone and e-mail contacts and Web site or message board availability. Counselors were instructed to provide the program as designed for a regular paying client, although they were not blinded to the identity of study participants. Free-of-charge counseling sessions were offered to participants for the entire 2-year period.

The diet component of the program consisted of a nutritionally adequate, low-fat (20%-30% of energy), reduced-energy diet (typically 1200-2000 kcal/d) that included prepackaged prepared food items with increased amounts of vegetables and fruits to reduce the energy density of the diet. The approach was tailored so that participants could choose regular foods when preferred. Participants were encouraged during the initial period to follow a menu plan with prepackaged foods, which would provide 42% to 68% of energy for those who choose not to deviate from the plan. Regular foods, such as vegetables, fruit, cereal or grain products, low-fat dairy products, lean meat or the equivalent, and unsaturated fat sources were recommended to achieve the total prescribed energy intake. Over time, participants were transitioned to a meal plan based mainly on food not provided by the commercial program, although participants could choose to include 1 prepackaged meal per day during weight loss maintenance. Prepared foods and counselors were provided by Jenny Craig Inc (Carlsbad, California).

Increased physical activity was another program component; the goal was 30 minutes of physical activity on 5 or more days per week. Program material and counseling addressed attitudes about weight, food, and physical activity and included recipes and guidance for eating in restaurants, CDs and DVDs to increase physical activity, and online tools and support.

Participants assigned to the usual care group were provided consultation with a research staff dietetics professional, who provided publicly available print material that described dietary and physical activity guidelines to promote weight loss and maintenance at baseline (after randomization) and again at 6 months. Energy intake level to achieve a weight loss of 10% over a 6-month period was prescribed, aiming for a deficit of 500 to 1000 kcal/d.[14] Sample meal plans based on food groups, recommendations to increase physical activity, and written materials and resources for strategies and skills (eg, reading food labels, estimating serving sizes, eating outside the home) were provided. This 1-hour session was followed by monthly check-in via e-mail or telephone, and progress and strategies were discussed in a follow-up counseling session at 6 months.

Assessment of Study Outcomes

Anthropometric measures (height, weight, waist circumference) and responses to questionnaires (the Beck Depression Inventory,[15] the Short Form 36 Quality of Life Questionnaire,[16] and the Eating Disorder Examination Questionnaire[17]) were collected by institution research staff (usually unblinded) at clinic visits at enrollment and every 6 months over a 2-year period. The 3-minute step test was used to assess aerobic fitness. This test measures heart rate during the first 30 seconds of recovery from stepping, and although less accurate than measuring maximal oxygen uptake, the test has high reliability and is sensitive to change.[18]

Laboratory Measurements

High-sensitivity CRP was assayed using the SPQ High Sensitive CRP Assay kit (DiaSorin Inc, Stillwater, Minnesota), a polystyrene-enhanced turbidimetric in vitro immunoassay.[19,20] Leptin was measured at the Laboratory for Clinical Biochemistry Research at the University of Vermont, in Colchester, using Luminex technology and Human Serum Adipokine Panel B LINCOplex Kit (Linco Research Inc, St Charles, Missouri). Plasma levels of total cholesterol, triglycerides, and high-density lipoprotein cholesterol were measured using enzymatic methods with the Kodak Ektachem Analyzer system (Johnson & Johnson Clinical Diagnostics, Rochester, New York). Low-density lipoprotein cholesterol values were calculated using the Friedewald equation.[21] Plasma carotenoid concentrations were measured by high-performance liquid chromatography.[22]

Statistical Analysis

Power calculations based on pilot data[12] assumed a 1-year mean (SD) effect size of 6.6 (10.2) kg in the intervention groups vs 0.7 (5.5) kg in the control group. Fewer control (n=110) than intervention (n=165 per group) participants were required based on these unequal variances. Allowing for up to 33% attenuation in weight loss between year 1 and 2, and a 25% dropout rate at year 2,[11] we had 83% power to detect an intervention effect. Analyses of anthropometric data were conducted as intent to treat, using baseline value substitution as the primary approach. This approach assumes that those who did not complete clinic visits or dropped out returned to their baseline weight (based on the usual recidivism after weight loss).[23] We also conducted intent-to-treat analysis using multiple imputation. Furthermore, we report mean weights for completers at each time point, recognizing a likely bias because dropouts may exhibit more nonadherence and weight rebound. Statistical significance was set at a 2-sided *P* value of less than .05 without adjustment for multiple comparisons.

The primary outcome was weight loss over time based on an interaction between treatment group and time. Linear mixed models (with baseline and usual care as the reference category) were used to analyze weight trajectories and other primary and secondary outcomes by group over time, including group, time, and their interaction as predictors. Models were used to test for differences by group at baseline and by time for usual care. The interaction term modeled the intervention effect. A subject-specific intercept representing baseline levels of the outcome was included as a random effect in each model. All analyses were conducted using SAS version 9.2 (SAS Institute Inc, Cary, North Carolina).

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Table 1. Demographic Characteristics of Study Participants (N = 442)

	Intervention Type		
	Center-Based (n = 167)	Telephone-Based (n = 164)	Usual Care (n = 111)
Age, mean (SD), y	44 (10)	44 (10)	45 (11)
Race/ethnicity, No. (%)			
Non-Hispanic white	113 (67.7)	130 (79.3)	83 (74.8)
Hispanic	24 (14.4)	18 (11.0)	18 (16.2)
Black	18 (10.8)	12 (7.3)	8 (7.2)
Other[a]	12 (7.2)	4 (2.4)	2 (1.8)
Education, No. (%)			
≤High school	23 (13.8)	14 (8.5)	15 (13.5)
Some college	74 (44.3)	73 (44.5)	42 (37.8)
College graduate	34 (20.4)	40 (24.4)	21 (18.9)
Graduate school	36 (21.6)	37 (22.6)	33 (29.7)
Clinical site, No. (%)			
University of Arizona	42 (25.1)	39 (23.8)	29 (26.1)
Kaiser Permanente Center for Health Research	40 (24.0)	40 (24.4)	25 (22.5)
University of California, San Diego	44 (26.3)	43 (26.2)	30 (27.0)
University of Minnesota	41 (24.6)	42 (25.6)	27 (24.3)

[a]Included Native American, Asian American, Pacific Islander, and self-reported mixed or other race/ethnicity.

RESULTS

The study sample consisted of 442 women aged 18 to 69 years with a mean age of 44 years, and a race/ethnicity distribution of non-Hispanic white (n=326 or 73%), Hispanic (n=60 or 14%), and black (n=38 or 9%) (TABLE 1). No differences in baseline characteristics across the study groups were observed. Participants were recruited between November 2007 and March 2008 and were followed up for 2 years ending in April 2010. Weight data at 24 months were available for 407 women (92.1% of the study sample). Attrition did not differ by study group (Figure 1 and TABLE 2).

Although weekly counseling sessions were available for participants in the intervention groups throughout the 2-year period, not all participants used them. When we polled these partici-

Table 2. Anthropometric Data[a]

	Mean (95% Confidence Interval)							
	Intent-to-Treat Analysis (N = 442)				Women With Measured Weight Data			
	Baseline	6 mo	12 mo	24 mo	Baseline	6 mo	12 mo	24 mo
	Center-Based Intervention							
	(n = 167)	(n = 167)	(n = 167)	(n = 167)	(n = 167)	(n = 164)	(n = 159)	(n = 151)
Weight, kg	92.2 (90.7 to 93.7)	83.0 (81.4 to 84.5)	82.1 (81.3 to 84.6)	84.8 (83.0 to 86.5)	92.2 (90.6 to 93.6)	82.8 (81.3 to 84.4)	81.5 (79.8 to 83.2)	83.8 (82.0 to 85.7)
WC, kg		–9.2 (–9.9 to –8.4)	–10.1 (–11.2 to –9.0)	–7.4 (–8.7 to –6.1)		–9.4 (–10.1 to –8.6)	–10.6 (–11.7 to –9.5)	–8.2 (–9.5 to –6.8)
BMI	33.8 (33.3 to 34.4)	30.5 (29.9 to 31.0)	30.2 (29.6 to 30.8)	31.2 (30.5 to 31.8)	33.8 (33.3 to 34.3)	30.4 (29.9 to 31.0)	30.0 (29.4 to 30.7)	30.8 (30.2 to 31.5)
Waist, cm	108.9 (107.6 to 110.3)	99.6 (98.2 to 101.0)	98.0 (96.5 to 99.5)	101.5 (100.0 to 103.0)	108.9 (107.6 to 110.3)	99.4 (98.0 to 100.8)	97.2 (95.7 to 98.6)	100.3 (98.7 to 101.8)[c]
	Telephone-Based Intervention							
	(n = 164)	(n = 164)	(n = 164)	(n = 164)	(n = 164)	(n = 162)	(n = 157)	(n = 153)
Weight, kg	92.9 (91.1 to 94.7)	84.6 (82.8 to 86.4)	84.4 (82.3 to 86.5)	86.6 (84.4 to 88.9)	92.9 (91.1 to 94.7)	84.5 (82.7 to 86.3)	83.8 (81.7 to 85.9)	86.1 (83.8 to 88.4)
WC, kg		–8.3 (–9.1 to –7.5)	–8.5 (–9.7 to –7.2)	–6.2 (–7.6 to –4.9)		–8.4 (–9.2 to –7.6)	–8.9 (–10.1 to –7.6)	–6.7 (–8.2 to –5.2)
BMI	33.8 (33.3 to 34.3)	30.8 (30.3 to 31.4)	30.7 (30.1 to 31.4)	31.5 (30.4 to 32.2)	33.8 (33.3 to 34.3)	30.8 (30.2 to 31.4)	30.5 (29.8 to 31.2)	31.3 (30.6 to 32.0)
Waist, cm	108.5 (106.9 to 110.0)	100.0 (97.5 to 101.4)	99.9 (98.5 to 101.6)	102.0 (100.0 to 103.9)	108.5 (106.9 to 110.0)	99.9 (98.4 to 101.4)	99.1 (97.4 to 100.8)	100.8 (98.8 to 102.8)
	Usual Care							
	(n = 111)	(n = 111)	(n = 111)	(n = 111)	(n = 111)	(n = 103)	(n = 101)	(n = 103)
Weight, kg	91.0 (89.0 to 92.9)	88.1 (86.0 to 90.2)	88.5 (86.3 to 90.8)	89.0 (86.7 to 91.3)	91.0 (89.0 to 92.9)	87.4 (85.3 to 89.6)	87.7 (85.4 to 90.0)	87.8 (86.3 to 91.1)
WC, kg		–2.9 (–3.8 to –2.0)	–2.4 (–3.6 to –1.2)	–2.0 (–3.3 to –0.6)		–3.1 (–4.1 to –2.2)	–2.7 (–3.9 to –1.4)	–2.1 (–3.6 to –0.7)
BMI	34.0 (33.4 to 34.6)	32.9 (32.2 to 33.6)	33.2 (32.4 to 33.9)	33.4 (32.5 to 34.2)[b]	34.0 (33.4 to 34.6)	32.7 (33.2 to 34.7)	32.9 (32.1 to 33.7)	33.0 (32.5 to 34.2)
Waist, cm	108.3 (106.6 to 110.0)	104.0 (102.3 to 105.7)	103.2 (101.4 to 105.0)	103.7 (101.9 to 105.6)	108.3 (106.6 to 110.0)	103.4 (101.7 to 105.1)	102.0 (100.1 to 103.9)	102.7 (100.8 to 104.6)

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); WC, weight change.
[a]Baseline values were substituted for any missing measures for the intent-to-treat analysis. For the usual care group, $P<.001$ for time trend compared with baseline except as indicated. For the 2 intervention groups, $P<.001$ for group × time intervention effect compared with usual care (mixed models) except as indicated.
[b]$P=.002$.
[c]$P=.001$.

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pants at follow-up clinic visits between 18 months and 24 months, 35.9% of center-based (n=60) and 23.8% of telephone-based (n=39) participants did not speak with their counselors at all during that interim period. On the other end of the spectrum, 24.6% of center-based (n=41) and 39.2% of telephone-based (n=61) participants spoke with their counselors weekly during that period.

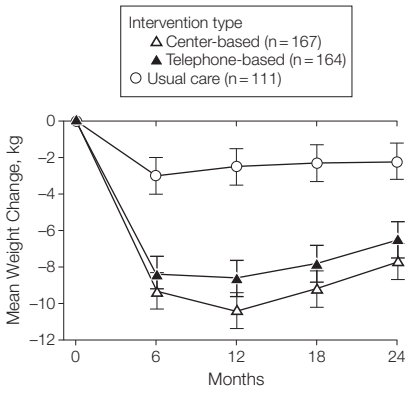
In the intent-to-treat analysis using baseline value substitution (Table 2), women in the center-based group lost a mean of 10.1 kg (95% confidence interval [CI], 9.0-11.2 kg) or 10.9% (95% CI, 9.7%-12.1%) of initial weight by 12 months and maintained an average weight loss of 7.4 kg (95% CI, 6.1-8.7 kg) or 7.9% (95% CI, 6.5%-9.3%) of initial weight at 24 months. Participants in the telephone-based group lost a mean of 8.5 kg (95% CI, 7.2-9.7 kg) or 9.2% (95% CI, 7.8%-10.6%) of initial weight by 12 months and maintained an average weight loss of 6.2 kg (95% CI, 4.9-7.6 kg) or 6.8% (95% CI, 5.2%-8.4%) of initial weight at 24 months. Participants in the usual care group lost a mean of 2.4 kg (95% CI, 1.2-3.6 kg) or 2.6% (95% CI, 1.4%-3.8%) of initial weight at 12 months and maintained a loss of 2.0 kg (95% CI, 0.6-3.3 kg) or 2.1% (95% CI, 0.7%-3.5%) of initial weight at 24 months ($P<.001$ compared with the intervention groups). We had no a priori hypothesis regarding differences between the center-based and telephone-based intervention groups, and the study was not powered to identify weight differences between these 2 groups. Attenuation of weight loss between 12 months and 24 months was 27% in each intervention group and 17% in the usual care group ($P=.003$).

Results from the multiple imputation intent-to-treat analysis were qualitatively similar to those obtained from the primary analysis (FIGURE 2). Data for women for whom weight was measured (rather than imputed) show similar differences across the groups (Table 2).

By study end, more than half in either intervention group (62% of center-based [n=103] and 56% [n=91] of telephone-based participants) had a weight loss of at least 5% compared with 29% (n=32) of usual care participants ($P<.001$). More than twice the proportion of participants in the center-based and telephone-based intervention groups compared with participants in the usual care group (37% [n=124] vs 16% [n=18]) had a weight loss of 10% or more of baseline weight at 24 months ($P<.001$).

All 3 study groups showed improved cardiopulmonary fitness at 24 months (54 [95% CI, 53-55] to 49 [95% CI, 48-50]; $P<.001$) (usual care group in TABLE 3 and intervention groups in

Figure 2. Weight Change by Group by Multiple Imputation



The error bars indicate 95% confidence intervals.

Table 3. Cardiopulmonary Fitness and Psychosocial and Laboratory Measures for the Usual Care Group[a]

	Usual Care (n = 111)			
	Baseline	6 mo	12 mo	24 mo
Cardiopulmonary fitness measures				
Step test, No.	111	99	90	93
Heart rate, /30 s	54 (53-56)	49 (47-50)	49 (47-51)	50 (48-52)
P value		<.001	<.001	<.001
Psychosocial measures, No.	111	102	98	103
SF-36 Physical QOL	85 (82-87)	83 (80-86)	82 (80-85)	82 (79-85)
P value		.21	.07	.18
SF-36 Mental QOL	81 (78-83)	79 (76-82)	78 (74-81)	78 (74-81)
P value		.15	.03	.06
Eating Disorder Examination	2.4 (2.2-2.5)	2.4 (2.2-2.6)	2.1 (2.0-2.3)	2.1 (1.9-2.3)
P value		.32	.07	.007
Beck Depression Inventory	5.7 (4.7-6.7)	6.0 (4.6-7.5)	6.0 (4.5-7.5)	6.1 (4.6-7.5)
P value		.42	.32	.54
Laboratory measures				
Blood sample, No.	111	101	94	96
Total carotenoids, μmol/L	1.8 (1.6-1.9)	1.7 (1.6-1.9)	1.8 (1.6-2.0)	1.8 (1.6-2.0)
P value		.49	.55	.83
Total cholesterol, mg/dL	200 (194-206)	196 (188-203)	192 (185-199)	186 (176-195)
P value		.15	.02	<.001
LDL cholesterol, mg/dL	122 (116-128)	127 (122-134)	114 (108-121)	114 (105-122)
P value		.12	.03	.02
HDL cholesterol, mg/dL	54 (51-56)	47 (44-49)	55 (52-58)	51 (48-54)
P value		<.001	.38	.02
Triglycerides, mg/dL	118 (108-129)	108 (97-119)	114 (104-124)	121 (110-133)
P value		.07	.49	.42
Leptin, ng/mL	37.3 (34.3-40.1)	31.7 (28.7-34.7)	32.9 (29.4-36.4)	32.7 (29.3-36.1)
P value		<.001	.006	.001
C-reactive protein, mg/L[b]	2.5 (1.4-5.7)	2.8 (1.1-4.7)	2.5 (1.3-5.0)	2.4 (1.1-5.7)
P value		.07	.06	.54

Abbreviations: HDL, high-density lipoprotein; LDL, low-density lipoprotein; QOL, quality of life; SF-36, Short Form 36.
SI conversion factors: To convert carotenoids to μg/dL, divide by 0.01863; C-reactive protein to nmol/L, multiply by 9.524; HDL, LDL, and total cholesterol to mmol/L, multiply by 0.0259; triglycerides to mmol/L, multiply by 0.0113.
[a] Values are expressed as mean (95% confidence interval) unless otherwise indicated. The *P* values represent time trend compared with baseline.
[b] Values expressed as median (interquartile range).

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TABLE 4), but no significant intervention effect was observed. Both intervention groups reported improved physical (86 [95% CI, 85-88] vs 82 [95% CI, 79-85]; $P = .007$) and mental (79 [95% CI, 77-81] vs 78 [95% CI, 74-81]; $P = .04$) quality of life at 12 months compared with usual care. The Eating Disorder Examination Questionnaire global scores improved from baseline to 24 months in each group (2.3 [95% CI, 2.2-2.4] at baseline vs 2.1 [95% CI, 2.0-2.2] at 24 months; $P = .007$), but there was no significant intervention effect. An intervention effect was seen in improved depression scores at 12 months (5.4 [95% CI, 4.6-6.1] for the intervention groups vs 6.0 [95% CI, 4.5-7.5] for the usual care group; $P = .01$) but not at 24 months.

Levels of CRP were reduced more at trial end in both intervention groups than in the usual care group (median of 1.9 mg/L [interquartile range, 1.0-3.7 mg/L] [Table 4] vs 2.4 mg/L [interquartile range, 1.1-5.7 mg/L] [Table 3], respectively; $P = .003$). Total

Table 4. Cardiopulmonary Fitness and Psychosocial and Laboratory Measures for the 2 Intervention Groups[a]

	Center-Based Intervention (n = 167)				Telephone-Based Intervention (n = 164)			
	Baseline	6 mo	12 mo	24 mo	Baseline	6 mo	12 mo	24 mo
Cardiopulmonary fitness measures								
Step test, No.	167	163	157	143	164	150	143	139
Heart rate, /30 s	53 (52-55)	47 (46-48)	47 (46-49)	48 (47-49)	55 (53-56)	48 (47-50)	49 (48-50)	49 (47-50)
P value		.16	.16	.20		.16	.16	.20
Psychosocial measures, No.	167	164	156	149	164	162	155	150
SF-36 Physical QOL	84 (82-86)	88 (86-90)	88 (86-90)	85 (82-87)	84 (82-87)	85 (82-87)	84 (82-87)	83 (80-86)
P value		.01	.007	.40		.01	.007	.40
SF-36 Mental QOL	80 (78-82)	82 (80-85)	83 (80-85)	79 (77-82)	77 (75-80)	81 (78-83)	76 (73-79)	75 (72-79)
P value		.008	.04	.35		.008	.04	.35
Eating Disorder Examination	2.3 (2.1-2.4)	2.2 (2.1-2.3)	2.0 (2.1-2.3)	2.0 (1.9-2.2)	2.4 (2.2-2.5)	2.3 (2.1-2.4)	2.2 (2.1-2.4)	2.2 (2.0-2.3)
P value		.08	.75	.90		.08	.75	.90
Beck Depression Inventory	6.6 (5.6-7.5)	4.3 (3.5-5.1)	4.6 (3.7-5.5)	5.4 (4.3-6.4)	6.6 (5.7-7.5)	4.9 (4.0-5.8)	6.1 (4.5-7.5)	7.0 (5.7-8.3)
P value		.001	.01	.30		.001	.01	.30
Laboratory measures								
Blood sample, No.	167	164	158	147	164	161	155	141
Total carotenoids, μmol/L	1.7 (1.6-1.8)	2.4 (2.2-2.5)	2.3 (2.2-2.5)	2.3 (2.1-2.4)	1.7 (1.5-1.8)	2.0 (1.8-2.1)	2.1 (1.9-2.3)	2.0 (1.9-2.2)
P value		<.001	<.001	<.001		<.001	<.001	<.001
Total cholesterol, mg/dL	195 (190-201)	187 (181-192)	189 (183-195)	185 (180-190)	194 (189-200)	186 (180-191)	188 (182-193)	181 (176-187)
P value		.21	.76	.36		.21	.76	.36
LDL cholesterol, mg/dL	117 (112-122)	120 (114-125)	111 (106-117)	116 (110-122)	114 (110-119)	119 (114-124)	119 (103-114)	110 (104-116)
P value		.64	.70	.16		.64	.70	.16
HDL cholesterol, mg/dL	56 (54-59)	46 (44-48)	57 (54-59)	53 (51-56)	57 (55-60)	45 (43-47)	59 (56-61)	55 (53-57)
P value		.02	.66	.83		.02	.66	.83
Triglycerides, mg/dL	107 (101-114)	106 (97-115)	104 (97-112)	112 (103-120)	112 (108-129)	106 (98-115)	103 (93-113)	119 (96-141)
P value		.29	.96	.69		.29	.96	.69
Leptin, ng/mL	37.9 (35.5-40.3)	23.3 (21.4-25.2)	23.8 (21.6-26.0)	28.4 (25.7-31.1)	38.8 (36.2-41.4)	24.7 (22.5-26.9)	26.1 (23.5-28.5)	30.7 (27.8-33.6)
P value		<.001	<.001	.02		<.001	<.001	.02
C-reactive protein, mg/L[b]	3.0 (1.7-5.9)	2.3 (1.2-4.1)	1.8 (0.9-4.0)	2.1 (1.0-4.1)	3.3 (2.0-5.2)	2.4 (1.4-4.7)	1.8 (1.0-3.8)	1.8 (1.0-3.7)
P value		.17	<.001	<.001		.17	<.001	<.001

Abbreviations: HDL, high-density lipoprotein; LDL, low-density lipoprotein; QOL, quality of life; SF-36, Short Form 36.
SI conversion factors: To convert carotenoids to μg/dL, divide by 0.01863; C-reactive protein to nmol/L, multiply by 9.524; HDL, LDL, and total cholesterol to mmol/L, multiply by 0.0259; triglycerides to mmol/L, multiply by 0.0113.
[a] Values are expressed as mean (95% confidence interval) unless otherwise indicated. The *P* values represent group × time intervention effect compared with usual care (mixed models).
[b] Values expressed as median (interquartile range).

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plasma carotenoids increased more by study end in the intervention groups (2.1 µmol/L; 95% CI, 2.0-2.2 µmol/L) than in the usual care group (1.8 µmol/L; 95% CI, 1.6-2.0 µmol/L) ($P<.001$). Total cholesterol concentration decreased from a baseline value of 196 mg/dL (95% CI, 193-199 mg/dL) to 184 mg/dL (95% CI, 180-188 mg/dL) at 24 months in all 3 study groups ($P<.001$) but no intervention effect was observed. Leptin concentration showed an intervention effect of 24.9 ng/mL (95% CI, 23.3-26.5 ng/mL) at 12 months compared with the usual care group level of 32.9 ng/mL (95% CI, 29.4-36.4 ng/mL) ($P<.001$) and 29.5 ng/mL (95% CI, 27.6-31.5 ng/mL) at 24 months vs 32.7 ng/mL (95% CI, 29.3-36.1 ng/mL), respectively ($P=.02$).

COMMENT

Findings from this study suggest that this incentivized structured weight loss program with free prepared meals can effectively promote weight loss compared with the usual care control group. Importantly, weight loss was largely maintained at 2-year follow-up. We observed an average 1-year weight loss of approximately 10% and an average 2-year weight loss of approximately 7% in response to the weight loss program intervention, which is a degree of weight reduction that has been shown to significantly reduce the risk of diabetes and cardiovascular disease risk factors in large randomized studies.[24,25] The low dropout rate and small amount of missing data in our study minimize ambiguity in drawing inferences. For clinical practitioners, the evidence suggests that the structured program as applied in this study provides another route for their overweight or obese patients to achieve and maintain weight loss through behavioral changes for at least a 2-year period. Moreover, several components of this structured program have been independently observed to promote weight loss and the maintenance of weight loss, including person-to-person behavioral counseling,[9] low-energy density diet,[26] prepackaged foods,[27,28] and increased physical activity.[29]

In a randomized controlled trial of another US weight loss program (N=423), Heshka et al[11] reported an average weight loss of 4.6% at 1 year and 3.1% at 2 years in the group assigned to that program in a last observation carried forward intent-to-treat analysis. Results also can be compared with the Diabetes Prevention Program study (N=3234), in which participants assigned to the intensive lifestyle intervention group achieved an average weight loss of 5.6 kg (5.9% of weight) at 2.8 years.[25] In the Look AHEAD (Action for Health in Diabetes) study (N=5145), a weight loss and physical activity intervention that included liquid meal replacements and the option of weight loss medications, an average weight loss of 8.6% of initial weight at 1 year and 4.7% at 4 years was achieved.[24,30,31]

In our small, single-site pilot study (N=70) for this trial, we compared the effect of the center-based intervention with a usual care group to provide data for power calculations. In that study, baseline value substitution intent-to-treat analysis showed an average 12-month weight loss of 7.1% of initial weight in the intervention group.[12] Findings from the present trial provide further evidence for the effectiveness of the center-based intervention across several geographical regions and centers in a larger sample, but also provide new information about the effectiveness of the telephone-based intervention.

The improvement in levels of high-sensitivity CRP in the intervention groups reflects the effect of weight loss on this inflammatory marker.[32] A differential lipid response was not observed across the study groups despite differing degrees of weight loss. Notably, the women in this study sample were generally not dyslipidemic. As previously observed, high-density lipoprotein cholesterol often is reduced in response to initial weight loss but rebounds at later time points.[33] The increase in plasma carotenoids (a marker of vegetable and fruit intake) in participants in the intervention groups is an important indicator of diet quality as well as energy density of the diet.[34-36] In contrast with some other weight loss programs, this structured weight loss program uses foods in prepackaged meals and snacks to facilitate a structured meal plan rather than a composite formula beverage. This strategy results in a dietary pattern associated with reduced risk for cardiovascular disease and stroke.[37-39]

There are several limitations of this study. First, as a proof-of-principle study, the purpose was to determine whether the program is effective in promoting weight loss and weight loss maintenance so the intervention and prepackaged foods were provided without cost to the participants. For paying patients in this structured commercial program, enrollment fees for a year-long premium program are $359, plus the cost of food. In the United States, the cost of program-provided foods for a 7-day menu of prepared foods averages $100 per week. The average cost varies due to personal tastes, incidence of dining out, travel, and phase of the program. The menu is supplemented with fruits, vegetables, and dairy foods at an approximate cost of $20 to $25 per week. For the first year of the program, participant food costs would have averaged $85 per week for a total of $4080 for the year. For the second year of the program, when participants transitioned to their own foods, food costs would have averaged $45 per week for a total of $2160 for the year. This compares with data from the Consumer Expenditure Survey, which estimates that US consumers typically spend $124 per week on food.[40]

Thus, a major issue is the generalizability of these findings to the average patient. The results may be related in part to the economic benefits to the participants of providing food, as well as reimbursement for participating in clinic visits, and the low dropout rate in this study contrasts with the high attrition rates reported among weight loss program cohorts.[41-43]

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Second, individuals who agree to participate in a randomized controlled trial are likely to be a highly motivated subset of the population. Third, the weight loss program counselors were unblinded, which may have influenced their behavior and effectiveness, although they were instructed to provide the program and services as designed to be delivered to paying customers. Fourth, 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, so disparate intensity in the intervention and control groups also likely influenced the findings. Some attenuation of the program effects may occur over time, although the improvement in cardiopulmonary fitness suggests that participants are maintaining higher levels of physical activity, which is associated with better maintenance of weight loss.[44]

Person-to-person behavioral counseling interventions involving frequent contact are associated with optimal weight loss, although these are difficult to incorporate into medical practice.[9] With scientific evidence for efficacy, such weight loss programs may be appropriate to include in health care systems and/or employer health promotion initiatives.

In summary, results from this study suggest that a free prepared meals and incentivized structured weight loss program that promotes diet and lifestyle modification successfully facilitated weight loss and weight loss maintenance compared with a control group. Program participation promoted favorable changes in biological factors associated with risk for cardiovascular disease. Health care practitioners, when applying these findings to the care of the average patient, also may note that effectiveness likely relates to motivation and adherence.

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Author Contributions: Dr Rock had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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Independent Statistical Analysis: Shirley W. Flatt, MS, a senior statistician at the University of California, San Diego, performed the statistical analysis with consultation provided by Loki Natarajan, PhD, a faculty biostatistician.

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Additional Information About Trial Registration: The clinical trials registry was initiated by the investigators in early November 2007, before any patient enrollment. When informed at that time that this was a responsibility of the industry sponsor, the responsibility of completing the registration process was reassigned. The registration was in process until March 2008, when it was finalized. The delay was not purposeful and is attributable to inexperience and personnel support limitations. This had no effect on screening, recruitment, enrollment, and management of study participants due to the limited number of geographical sites involved, exclusion and inclusion criteria, and a relatively small total sample size compared with other large-scale population-based clinical trials.

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