Two-Year Results From a Multi-Site Randomized Trial of a Commercial Weight Loss Program

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ABSTRACT

Commercial weight loss programs may contribute to efforts to reduce the prevalence of obesity, although evidence of efficacy and effects on metabolic and cardiovascular risk factors is critical in evaluating the likelihood of sustained benefits. The Jenny Craig (JC) program involves individualized diet and exercise counseling (provided either in-person at community-based sites or by telephone), prepackaged foods and a low-energy density diet. The aims of this study are (1) To test, in a multi-site randomized controlled trial, whether the JC Centre-based and/or JC Direct (telephone-based) interventions promote greater weight loss and maintenance of that loss in overweight or obese women over a 24-month period compared to usual care (UC) conditions; and (2) To describe the effect of the program (vs. UC conditions) on selected biochemical factors, cardiopulmonary fitness, quality of life (QOL) and eating attitudes and behaviors. At randomization, participants (n=442) were 44(10) (mean[SD]) yrs, with BMI 33.8(3.4) kg/m2, weight 92.1(10.7) kg, and waist circumference 108.6(9.6) cm. Two-year data are available for 91% of study participants (n=406), and weight loss is -8.1(8.6), -6.7(9.3), and -2.2(7.4) kg for the JC Centre-based, JC Direct, and UC groups, an average weight reduction of -8.7%, -7.3%, and -2.4% of initial weight, respectively. The proportion of women at highest risk (CRP>3 mg/L) in the JC arms decreased significantly from 53% at enrollment to 33% at two years, but was unchanged in the UC arm. Interim analysis also shows the JC intervention to promote favorable changes in lipid, leptin and carotenoid levels, and improved cardiopulmonary fitness.

INTRODUCTION

- The prevalence of overweight and obesity in the United States remains high.
- Obesity is associated with increased risk for numerous medical problems, especially hypertension, diabetes, dyslipidemia, and metabolic syndrome.
- 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.
- A few studies suggest that some commercial programs have the potential to promote a degree of weight loss that equals or exceeds office-based counseling or medical interventions

SPECIFIC AIMS

1. To test, in a randomized controlled trial, whether participation in a free prepared meal and 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.
2. 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.

PARTICIPANTS

- Women (N=442) aged ≥ 18 years; BMI 25-40 kg/m^2, a minimum of 15 kg over ideal weight (by the 1983 Metropolitan Life Insurance tables) and able to participate in clinic visits and other study activities.
- Exclusion criteria: Severe disability that prohibits physical activity, significant comorbid disease, pregnancy or breastfeeding, current involvement in another study or weight loss program, or other factors that might interfere with participation.

STUDY DESIGN AND ACTIVITIES

- Distributed across four sites: University of California, San Diego, University of Arizona, Kaiser Portland Center for Health Research, and the University of Minnesota.
- Randomized design with three study arms (center-based, telephone-based, and usual care), allocated 3:3:2 in a permuted block design, stratified by BMI (25.0 - 29.9 vs. ≥ 30.0 kg/m^2), age (<40 vs. ≥ 40 yrs) and clinical site.
- As a proof-of-principle randomized controlled trial, participants in the structured program arms received all program activities, material and food as needed free-of-charge.
- *Center-based program:* Weekly in-person counseling, prepackaged prepared foods directly from the center, supportive materials provided, and follow-up telephone and email contacts and Web site/message board availability.
- *Telephone-based program:* Weekly one-to-one telephone counseling, prepackaged prepared foods delivered to the home every two weeks, supportive materials provided, and email contacts and Web site/message board availability for further support.
- *Usual care:* Two sessions with a dietetics professional, one at baseline and the other at 6 months follow-up, and monthly check-in by email or telephone.

MEASUREMENTS

- Data collection time points: Baseline and six, 12, 18 and 24 months
- Anthropometric measures: Height, weight, and waist and hip circumference
- Cardiopulmonary fitness: Step test
- Plasma cholesterol, triglycerides, and HDL cholesterol (LDL cholesterol calculated by the Friedewald equation)
- Plasma carotenoids (a biomarker of vegetable and fruit intake)
- C-reactive protein (CRP)
- Leptin
- Eating Disorder Examination – Questionnaire (EDE-Q): Assesses a broad range of disturbances in eating behavior and attitudes toward food, eating, shape and weight
- Beck Depression Inventory (BDI): Assesses self-reported presence and degree of depressive symptoms
- Eating Inventory: Assesses dietary restraint, disinhibition, and hunger
- SF-36 Health Survey Questionnaire: Measures quality of life and health perception (dimensions are functional status, well being, and overall evaluation of health)

Figure 1. Flow of Participants Through Trial

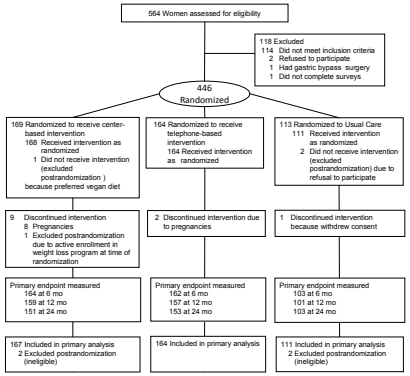

Figure 2. Weight Change by Group Multiple Imputation

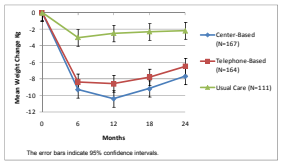

Table 1. Demographic Characteristics of Study Participants (N=442)

	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 (7.21)	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.

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)
Weight Change, kg		-9.9 to -8.4)	-10.1 (-11.2 to -9.0)	-7.4 (-8.7 to -6.1)		-10.0 (-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)[b]
	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)
Weight Change, 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)
Weight Change, 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)[c]	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 (106.8 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 to110.0)	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).
[a]Baseline values were substituted for any missing measures for the intent-to-treat analysis. For the usual care group, P<.001 for the time trend compared with baseline except as indicated. For the 2 intervention groups, P<.001 for the group X time intervention effect compared with usual care (mixed models) except as indicated.
[b]P=.002.

Table 3. Cardiopulmonary Fitness and Psychological and Laboratory Measures[a]

	Usual Care			Center-Based Intervention			Telephone-Based Intervention		
	Baseline	6 Mo	12 Mo	24 Mo	Baseline	6 Mo	12 Mo	24 Mo	Baseline	6 Mo	12 Mo	24 Mo
Cardiopulmonary fitness measures												
Step Test, No.	111	99	90	93	167	163	157	143	164	150	143	139
Heart Rate, / 30 s	54 (53-56)	49 (47-50)	49 (47-51)	50 (48-52)	53 (52-55)	47 (46-48)	48 (46-49)	48 (47-49)	55 (53-56)	48 (47-50)	49 (48-50)	49 (47-50)
P value		<.001	<.001	<.001		.16	.16	.20		.16	.16	.20
Psychosocial Measures, No	111	102	98	103	167	164	156	149	164	162	155	150
SF-36 Physical QOL	85 (82-87)	83 (80-86)	82 (80-85)	82 (79-85)	84 (82-86)	85 (84-86)	86 (86-90)	85 (82-87)	84 (82-87)	85 (82-87)	84 (82-87)	83 (80-86)
P value		.21	.07	.18		.01	.007	.40		.01	.007	.40
SF-36 Mental QOL	81 (78-83)	79 (76-82)	78 (74-81)	78 (74-81)	80 (78-82)	82 (80-85)	83 (80-85)	79 (77-82)	77 (75-80)	81 (78-83)	78 (73-79)	75 (72-79)
P value		.15	.03	.06		.006	.04	.35		.008	.04	.35
Eating Disorder Examination	2.4 (2.2-2.5)	2.4 (2.2-2.6)	2.1 (2.0- 2.3)	2.3 (1.9-2.3)	2.2 (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		.22	.07	.007		.08	.75	.90		.08	.75	.90
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)	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)	5.1 (4.5-7.5)	7.0 (5.7- 8.3)
P value		.42	.32	.54		.001	.01	.30		.001	.01	.30
Laboratory Measures												
Blood sample, No	111	101	94	96	167	164	158	147	164	161	155	141
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)	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		.49	.55	.83		<.001	<.001	<.001		<.001	<.001	<.001
Total cholesterol, mg/dL	200 (194-208)	196 (188-203)	192 (185-199)	185 (176-195)	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		.15	.02	<.001		.21	.76	.36		.21	.76	.36
LDL cholesterol, mg/dL	122 (116-128)	127 (122-134)	114 (108-121)	114 (105-122)	117 (112-122)	120 (114-125)	111 (106-117)	116 (110-122)	114 (109-119)	119 (114-124)	119 (113-114)	110 (104-116)
P value		.12	.03	.02		.64	.70	.19		.64	.70	.19
HDL cholesterol, mg/dL	54 (51-56)	47 (44-49)	55 (52-58)	51 (48-54)	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		<.001	.36	.02		.02	.66	.83		.02	.66	.83
Triglycerides, mg/dL	118 (108-129)	108 (97-119)	114 (104-124)	121 (110-133)	107 (101-114)	106 (97-115)	104 (97-112)	112 (103-120)	112 (105-120)	106 (98-115)	103 (93-113)	116 (96-141)
P value		.07	.49	.42		.29	.96	.69		.29	.96	.69
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)	37.9 (35.5-40.3)	23.3 (21.4-25.2)	23.8 (21.6-26.0)	28.4 (25.7-31.1)	36.8 (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	.006	.001		<.001	<.001	.02		<.001	<.001	.02
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)	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		.07	.09	.54		.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 ug/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. P values in usual care cells represent time trend compared with baseline, and P values in intervention cells represent group by time intervention effect compared with Usual Care (mixed models).
[b]Values expressed as median (interquartile range).

RESULTS

- At baseline, participants (N=442) averaged 44 years, with mean BMI 33.8 (3.4) kg/m^2, and weight 92.1 (10.7) kg.
- In the intent-to-treat analysis (using baseline value substitution), at 12 months and 24 months, participation in the JC intervention arms, compared to usual care, was associated with lower BMI, weight, and waist and hip circumference (P < 0.01 for all).
- By study end, more than one-half in either intervention group (62% of center-based [n=103] and 56% [n=91] of telephone-based) had a weight loss of at least 5%, compared with 29% (n=32) of usual care women (P<.0001). More than twice the proportion of the center-based intervention and telephone-based intervention groups compared with usual care group (37% [n=124] versus 16% [n=18]) had a weight loss of 10% or more of baseline weight at 24 months (P<.0001).

CONCLUSIONS

- 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.
- We observed an average 1-year weight loss of approximately 10% and an average 2-year weight loss of approximately 7%.
- Importantly, weight loss was largely maintained at 2-year follow-up.
- Health care practitioners, when applying these findings to the care of the average patient, also may note that the effectiveness likely relates to motivation and adherence.

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