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Weight Loss With Self-help Compared With a Structured Commercial Program
A Randomized Trial

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A N INCREASING NUMBER OF MEN and women in the United States are attempting to lose weight.[1,2] Formal diet and exercise programs provide weight loss treatment to approximately 13% of these women and 5% of the men.[3] However, obese participants in diet and exercise programs rarely achieve a body mass index (BMI, calculated as weight in kilograms divided by the height in meters squared) in the normal range (20-25) and because weight lost is often regained, there is a perception that nothing is accomplished by participation in such programs. Nevertheless, numerous studies have documented improvements in indicators of health with modest weight loss,[4-7] which, if maintained over several years, may be clinically significant.

Commercial weight loss programs have been recommended as the second step in a graded, 4-step model for weight management[5,8] but their efficacy has rarely been rigorously evaluated.[9-13] We conducted a 2-year, mul-

Context Although commercial weight loss programs provide treatment to millions of clients, their efficacy has not been evaluated in rigorous long-term trials.

Objective To compare weight loss and health benefits achieved and maintained through self-help weight loss vs with a structured commercial program.

Design and Setting A 2-year, multicenter randomized clinical trial with clinic visits at 12, 26, 52, 78, and 104 weeks conducted at 6 academic research centers in the United States between January 1998 and January 2001.

Participants Overweight and obese men (n=65) and women (n=358) (body mass index, 27-40) aged 18 to 65 years.

Intervention Random assignment to either a self-help program (n=212) consisting of two 20-minute counseling sessions with a nutritionist and provision of self-help resources or to a commercial weight loss program (n=211) consisting of a food plan, an activity plan, and a cognitive restructuring behavior modification plan, delivered at weekly meetings.

Main Outcome Measures Weight change was the primary outcome measure. Secondary outcomes included waist circumference, body mass index, blood pressure, serum lipids, glucose, and insulin levels.

Results At 2 years, 150 participants (71%) in the commercial group and 159 (75%) in the self-help group completed the study. In the intent-to-treat analysis, mean (SD) weight loss of participants in the commercial group was greater than in the self-help group at 1 year (−4.3 [6.1] kg vs −1.3 [6.1] kg, respectively; $P<.001$) and at 2 years (−2.9 [6.5] kg vs −0.2 [6.5] kg, respectively; $P<.001$). Waist circumference ($P=.003$) and body mass index ($P<.001$) decreased more in the commercial group. Changes in blood pressure, lipids, glucose, and insulin levels were related to changes in weight in both groups, but between-group differences in biological parameters were mainly nonsignificant by year 2.

Conclusion The structured commercial weight loss program provided modest weight loss but more than self-help over a 2-year period.

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ticenter randomized trial to evaluate the largest provider of commercial weight loss services in the United States.[14] A report of the 6-month results of this trial has been published previously.[15]

METHODS

Study Design

The study was a randomized, parallel-group, 2-year trial conducted at 6 US clinical centers (see author affiliations on the first page) between January 1998 and January 2001 with scheduled visits to the study center at weeks 0, 12, 26, 52, 78, and 104. The number of participants to be enrolled was selected to provide a power of 0.84 to detect a difference of 2.5 kg between treatment and control groups in the amount of weight lost at the end of 2 years based on an estimated SD of 6.5 kg in change scores, with a type I error rate of .05, 2-tailed, if 120 participants remained in each group.

Study Participants

Participants were recruited from existing clinic records or by advertising a long-term nonmedication weight loss study for moderately overweight persons. All participants provided written informed consent. A medical history was taken and physical examination and electrocardiography were performed at the screening visit. Men and women with a BMI of 27 to 40, aged 18 to 65 years, including persons with health problems for which weight reduction is a medically accepted therapy, were eligible for the study.

Exclusion criteria were fasting glucose higher than 140 mg/dL (7.8 mmol/L), triglycerides higher than 1000 mg/dL (11.3 mmol/L), liver function test results (aspartate aminotransferase, alanine aminotransferase, alkaline phosphatase, lactate dehydrogenase, γ-glutamyltransferase, and bilirubin) more than 2 times the upper normal limit, and serum creatinine higher than 1.4 mg/dL (124 μmol/L).

Also excluded were potential participants using systemic or inhaled corticosteroids or lithium, having a history of alcohol abuse within the past year, or having a history or presence of a sig-

nificant psychiatric disorder or any condition that, in the investigator's judgment, would interfere with participation in the trial. Potential participants who initiated a new drug therapy within 30 days of randomization, who were already participating in a weight loss program, or who took prescription weight loss or investigational medications within 90 days of randomization were also excluded. If clinically significant abnormalities were found at screening, individuals were referred to their personal physician. The protocol was reviewed and approved annually by the institutional review board at each site.

Randomization

After all screening test results were reviewed and the candidate's eligibility confirmed, a randomization envelope prepared by the data coordinating center was opened and the participant was assigned to self-help or the commercial program (**FIGURE 1**). Participants were block randomized as determined by a random number table. A different block and randomization sequence was prepared for each site. Participants and investigators at each site were blind to the assignment condition until the envelope was opened.

Treatments

Participants assigned to the self-help group received 20-minute consultations with a dietitian at the week 0 (baseline) and week 12 visits and were given publicly available printed material orienting them to dietary principles and exercise guidelines for safe weight loss.[16,17] Other resources such as public library materials, Web sites, and telephone numbers of health promotion organizations offering free weight control information were drawn to their attention.

Participants assigned to the commercial program were given vouchers entitling them to attendance at sessions of Weight Watchers, and the locations of available sites of this commercial program were reviewed with them. The vouchers enabled participants to attend sessions at no cost and, during the study

Figure 1. Flow of Participants in the Trial
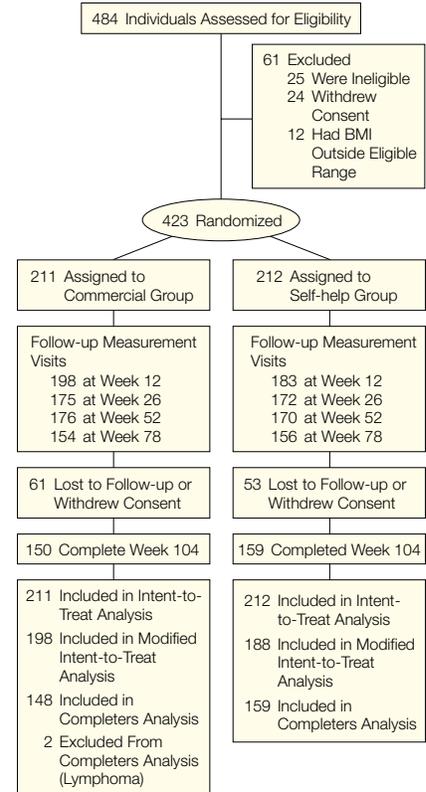
BMI indicates body mass index.

period, had a retail value of approximately $9 per voucher. The commercial program consists of a food plan, an activity plan, and a behavior modification plan focused primarily on cognitive restructuring. The food plan is a nutritionally balanced, moderate-deficit diet designed to produce a weight loss of up to 0.9 kg/wk. The activity plan follows current National Institutes of Health guidelines.[18] Weekly group meetings of approximately an hour's duration are led by successful program graduates who act as role models and provide written educational materials, a weekly weigh-in, and social support.

Compliance with treatment assignment in the commercial group was assessed at each clinic visit by self-reported attendance at group meetings. The use of concomitant medications for weight loss, including herbal preparations, was recorded.

Outcome Measures

The primary outcome measure was change in body weight measured at each visit. Secondary measures to assess change in adiposity were BMI, waist circumference (at weeks 26, 52, and 104), and body fat measured by bioimpedance analysis (Tanita Bodyfat Analyzer, model TBF 105 or 305, Tanita Corporation, Arlington Heights, Ill). Other secondary measures were blood pressure (measured at each visit); total cholesterol, high-density lipoprotein (HDL) cholesterol, triglycerides, insulin, and glucose (measured at 1-year intervals); and quality of life measured using the Medical Outcomes Study Short-Form 36 Health Survey (SF-36)[19] and Impact of Weight on Quality of Life Questionnaire (IWQOL-Lite)[20] scales.

Adverse events, vital signs, and a standard panel of 20 biochemical indicators were monitored for safety. Blood samples were sent to a commercial laboratory (Quest Diagnostics, San Juan Capistrano, Calif) except for insulin levels, which were assayed at the New York Obesity Research Center, New York City.

Statistical Analysis

Differences between the treatment groups at randomization and characteristics of completers vs dropouts were tested using independent *t* tests for continuous variables and the Fisher exact test for categorical variables. Values are presented as mean (SD) except where otherwise noted. Statistical significance was set at $P < .05$.

Three analyses were performed on weight change and related outcome variables: an intent-to-treat (ITT) analysis including all randomized participants (missing values were imputed by last-observation-carried-forward or linear interpolation and participants who made no follow-up visits were assumed to remain at baseline value); a modified ITT analysis including all participants who made at least 1 clinic visit after randomization; and a completers analysis using only participants who completed the study.

A mixed-model repeated-measures analysis of covariance was used to assess the significance of changes in the outcome variable, with treatment group, clinic site, visit, and visit × group interaction as fixed effects, and initial weight as a covariate (Proc Mixed, SAS version 8, SAS Institute Inc, Cary, NC). Similar mixed regression models were used for analysis of changes in secondary outcome measures. Initial values of variables such as age, sex, and BMI were included as covariates if they contributed significantly to the model.

In the completers analysis of biological indices participants taking blood pressure, lipid, or glucose lowering medication were excluded from analyses on those measures, respectively, but included in all others. Analyses on changes in biological indices were run once including all values and a second time excluding values more than 3 SDs from the mean. Results were similar in all substantive aspects and the latter are presented here as being more typical of the interventions. The relation between weight changes and biological indicators of health was examined by including weight change and interactions of weight change and treatment group in linear regression models.

For the tabulation of cases by percentage of weight lost, separate χ^2 tests were conducted for year 1 and year 2 to test the hypothesis that the distributions in the self-help group were not different from those in the commercial group. Following rejection of the null hypothesis, frequencies within each percentage of weight loss category were tested against the null hypothesis that successes were distributed in the same proportion as the number of participants in the 2 groups.

RESULTS

Participant Characteristics

Characteristics of participants at baseline are shown in **TABLE 1**. Two participants developed lymphoma during the trial and were excluded from the completers analysis. Two participants assigned to the commercial group re-

Table 1. Baseline Characteristics of Participants by Randomization Group*

Variables	Mean (SD)	
	Commercial Group (n = 211)‡	Self-help Group (n = 212)§
Age, y	45 (10)	44 (10)
Women, No. (%)	173 (82)	185 (87)
Smokers, No. (%)	21 (10)	19 (9)
Height, cm	167 (8)	166 (8)
Weight, kg	94.2 (13.1)	93.1 (14.4)
Body mass index†	33.8 (3.4)	33.6 (3.7)
Fat, %‡	44 (8)	45 (9)
Waist, cm	101 (12)	99 (12)
Blood pressure, mm Hg		
Systolic	123 (14)	121 (12)
Diastolic	79 (8)	79 (9)
Glucose, mg/dL	92 (14)	89 (12)
Insulin, IU/L	18 (9)	18 (10)
Cholesterol, mg/dL		
Total	214 (38)	209 (36)
HDL	50 (12)	49 (13)
HDL/total cholesterol ratio	0.24 (0.06)	0.24 (0.06)
Triglycerides, mg/dL	155 (99)	141 (82)

Abbreviation: HDL, high-density lipoprotein.
SI conversion factors: To convert cholesterol to mmol/L, multiply values by 0.0259; to convert glucose to mmol/L, multiply values by 0.0555; to convert insulin to pmol/L, multiply values by 6.945; to convert triglycerides to mmol/L, multiply values by 0.0113.
*There were no statistically significant differences between the commercial and self-help groups.
†Body mass index is measured as weight in kilograms divided by height in meters squared.
‡For fat %, n = 197, waist, n = 209, glucose and lipids, n = 210.
§For fat %, n = 194, waist, n = 209, triglycerides and insulin, n = 211.

Table 2. Change in Weight, Body Mass Index, and Waist Circumference by Analysis Method and Treatment Group

	Change, Mean (SE)								
	Intent-to-Treat Analysis			Modified Intent-to-Treat Analysis			Completers Analysis		
	Commercial Group (n = 211)*	Self-help Group (n = 212)†	Between-Group *P* Value	Commercial Group (n = 198)*	Self-help Group (n = 188)†	Between-Group *P* Value	Commercial Group (n = 148)*	Self-help Group (n = 159)†	Between-Group *P* Value
Weight, kg									
Year 1	−4.3 (0.4)	−1.3 (0.4)	<.001	−4.5 (0.5)	−1.4 (0.5)	<.001	−5.0 (0.5)	−1.4 (0.5)	<.001
Year 2	−2.9 (0.5)	−0.2 (0.4)	<.001	−2.7 (0.5)	−0.1 (0.5)	<.001	−3.0 (0.6)	−0.1 (0.6)	<.001
Body mass index‡									
Year 1	−1.6 (0.2)	−0.5 (0.2)	<.001	−1.7 (0.2)	−0.6 (0.2)	<.001	−1.9 (0.2)	−0.6 (0.2)	<.001
Year 2	−1.1 (0.2)	−0.2 (0.2)	<.001	−1.1 (0.2)	−0.1 (0.2)	<.001	−1.2 (0.2)	−0.1 (0.2)	<.001
Waist, cm§									
Year 1	−4.1 (0.6)	−1.6 (0.6)	.003	−4.4 (0.7)	−1.8 (0.7)	.007	−4.9 (0.8)	−1.9 (0.8)	.005
Year 2	−2.4 (0.6)	−0.6 (0.6)	.02	−2.3 (0.7)	−0.2 (0.7)	.03	−2.6 (0.7)	−0.2 (0.7)	.02

*For the commercial group, all values are different from baseline at *P*<.001 for weight and body mass index. For change in waist circumference, *P*<.01 vs baseline for year 1 and *P*<.04 vs baseline for year 2.
†For the self-help group, all year 1 values are different from baseline at *P*<.01 except for waist change under completers analysis (*P*<.02); all year 2 values are not significantly different from baseline (*P*>.05).
‡Body mass index is measured as weight in kilograms divided by height in meters squared.
§Because some waist measurements were not taken at baseline, n = 209 in both groups for the intent-to-treat analysis and n = 146 for commercial and n = 157 for self-help for the completers analysis.

ported using a weight loss medication and were excluded from completers efficacy analyses. In the self-help group almost all participants reported attempting to change diet and increase physical activity, 14 reported using weight loss medications, another 6 tried herbal products, 10 enrolled in some form of structured commercial program (TOPS [Take Off Pounds Sensibly], Jenny Craig, 5 in Weight Watchers), and 9 mentioned following an alternative diet plan (protein, Atkins, the Zone) at some point during the 2-year study. All were retained in the analyses.

Participants who dropped out of the study were younger (age, 42.0 [10.6] vs 45.8 [9.9] years), had a higher BMI (34.3 [3.5] vs 33.4 [3.5]), greater percentage of body fat (46.6% [8.8%] vs 44.1% [8.3%]), were more likely to be smokers, and reported slightly lower income than participants who completed the study (for all comparisons *P*<.05). The characteristics of dropouts did not differ by treatment group.

Safety Parameters

Bonferroni-adjusted statistical tests on the standard safety panel of 20 biochemistry analytes at randomization found only 1 difference: mean alanine aminotransferase values in the commercial group were statistically higher than in the self-help group, although

Figure 2. Mean Weight Changes by Group

No.	0		52	78	104
Self-help	212	172	170	156	159
Commercial	211	175	176	154	150
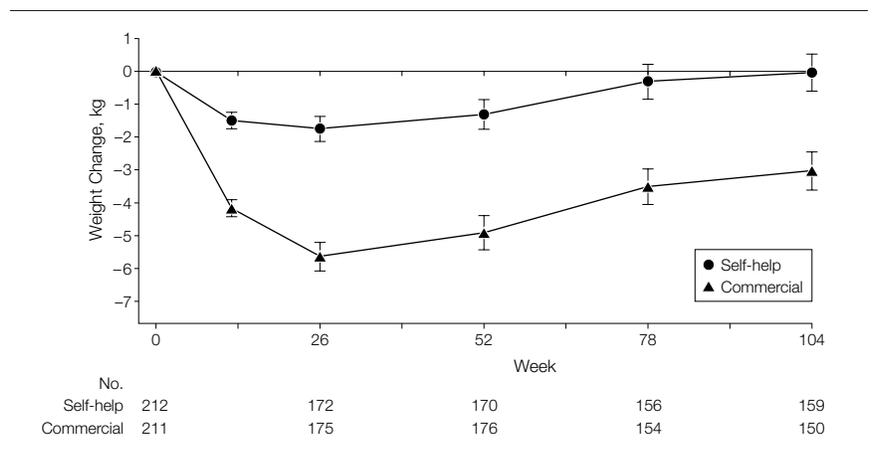
Error bars indicate SEM.

both were within the normal range and the difference is not clinically significant (25.7 [13.8] vs 21.7 [11.2] U/L, *P*<.001). There were no clinically significant changes in safety parameters over the course of the study in either group and no participants were removed from the study for adverse changes in biochemistry parameters.

Weight, BMI, Body Fat, and Waist Circumference Outcomes

Participants' change in weight ranged from −28 to +12 kg in the commercial group and −26 to +15 kg in the self-help group at 1 year, and −23 to +21

kg in the commercial group and −26 to +30 kg in the self-help group at the end of year 2.

Results of ITT, modified ITT, and completers analyses of weight changes and related body composition variables are shown in **TABLE 2**. Because of the low attrition rate, the results are not greatly different among these 3 analyses.

Mean weight changes from baseline for each of the clinic visits for all participants who made the visit are shown in **FIGURE 2**. At each visit, weight in the commercial group was significantly lower than at baseline and the amount of loss was greater than in the self-

help group. Weight in the self-help group was significantly less than baseline weight until week 52 but not thereafter. There were differences among sites in the amount of weight loss ($P<.01$); however, the magnitude of the difference in weight loss between commercial and self-help groups at the 6 sites was similar (the treatment $\times$ site interaction was not significant). The difference from baseline decreased over time in both groups after week 26 ($P<.001$) and the rates of regain were not different (the treatment $\times$ time interaction was not significant). Amount of weight lost by men compared with women was not significantly different, although the average weight of men

was greater at baseline (106.7 [11.9] vs 91.2 [12.7] kg; $P<.001$). Weight loss and gain as a percentage of initial weight at 1 and 2 years is shown in **TABLE 3**.

Compliance with treatment assignment in the commercial group was assessed by self-reported attendance at meetings. The median number of sessions attended for 6-month periods ending at weeks 26, 52, 78, and 104 were 21, 19, 17, and 13, respectively. Weight loss differed as a function of self-reported attendance level ($P<.05$) (**FIGURE 3**). Some weight regain was seen between year 1 and 2 at all attendance levels ($P<.001$).

Analysis of changes in BMI yielded results similar to those for weight loss. Af-

ter 1 year 56% and after 2 years 52% of the commercial group participants were more than 1 BMI unit below starting BMI, compared with 31% after 1 year and 29% after 2 years in the self-help group. The differences between commercial and self-help groups in waist circumference reduction at 1 and 2 years were statistically significant (Table 2). The amount of reduction declined over time in both groups but a difference of about 2 cm remained at the end of 2 years. There were also significant differences between commercial and self-help groups in average amount of fat loss maintained over the last 18 months (3.2 [6.3] kg vs 1.6 [6.4] kg, respectively; $P=.04$). Mean fat loss by men was not significantly different from that of women.
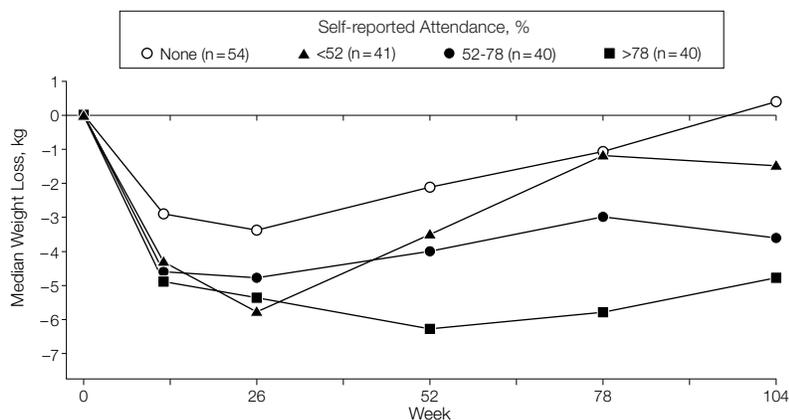
Biological Indices and Quality of Life Scales

Although there were sustained differences in mean weight loss between the 2 groups over the duration of the study, the wide range in degree of individual success in each group and the low correlation between amount of weight loss and improvement in biological parameters resulted in mainly nonsignificant differences between treatment groups (**TABLE 4**). Two indices, diastolic blood pressure and serum insulin, were statistically improved in the commercial group compared with self-help at year 1 but only insulin was significantly different at year 2. Total cholesterol and the HDL/total cholesterol ratio improved in both groups, whereas fasting glucose levels increased in both groups.

Weight changes were reliably correlated with changes in all 8 biological indices in the commercial group and in 5 of the 8 indices in the self-help group (all $P<.05$). Changes in waist circumference were also significantly related to changes in all indices (all $P<.02$). Change in total cholesterol and triglycerides was 3 or more times as large per unit change in waist circumference for men as for women.

There were no significant differences between groups in amount of improvement on quality of life scales. Weight loss and percentage of weight

Table 3. Weight Change as a Percentage of Initial Weight, by Treatment Group*

	Year 1†			Year 2‡		
	No. (%)			No. (%)		
	Commercial Group (n = 172)	Self-help Group (n = 170)	P Value	Commercial Group (n = 148)	Self-help Group (n = 159)	P Value
Decrease from initial weight, %						
≥10	37 (21)	15 (9)	.002	24 (16)	9 (6)	.005
>5-<10	29 (17)	19 (11)	.15	27 (18)	24 (15)	.57
0-5	68 (39)	57 (33)	.37	42 (28)	46 (29)	>.99
Increase from initial weight, %						
0-5	32 (19)	60 (35)	.003	38 (26)	50 (31)	.41
>5-<10	5 (3)	17 (10)	.01	15 (10)	15 (9)	.71
≥10	1 (1)	2 (1)	. . .	2 (1)	15 (9)	.003

*Percentages may not sum to 100% due to rounding. Ellipsis indicates numbers too small to perform statistical analysis.
† For year 1, $\chi_2^2 = 27.6$; $P<.001$ for hypothesis of similar frequency distribution in the 2 groups.
‡ For year 2, $\chi_5^2 = 18.4$; $P = .002$ for hypothesis of similar frequency distribution in the 2 groups.

Figure 3. Median Weight Loss in the Commercial Group by Self-reported Attendance

loss were positively correlated with improvements in all scales of the SF-36 at both year 1 and year 2 in both groups (data not shown). Using a Bonferroni-adjusted significance level of $P = .006$, at 1 year weight loss was significantly correlated with improvements in scales for general physical health ($r=0.25$) and vitality ($r=0.26$). At year 2, scales for physical function ($r=0.22$) and vitality ($r=0.21$) were significantly correlated with weight loss. A similar pattern was seen for scales of the IWQOL-Lite (data not shown). Weight strongly predicted total score and all subscale scores, with the strongest relationships for public distress, physical function, and total score. The relationship was in the expected direction, with lower weight predicting better quality of life, and this did not differ by treatment.

COMMENT

The self-help group was able to lose and maintain approximately 1.3 to 1.4 kg for the first year, after which weight tended to increase until it returned to baseline at 2 years. The commercial group maintained a weight loss of 4.3 to 5.0 kg at the end of the first year and was 2.7 to 3.0 kg lower than baseline weight at the end of the second year. Participants who attended 78% or more of the commercial group sessions main-

tained a mean weight loss of almost 5 kg at the end of the 2-year study. These weight losses were achieved despite a general tendency to gain weight during most of the adult lifespan.[21] After 2 years, 52% of the commercial group and 29% of the self-help group had a BMI 1 unit or more below baseline BMI, an amount that the Institute of Medicine report on obesity treatment described as significant long-term weight loss.[22] Waist circumference, an independent cardiovascular risk factor,[23,24] was also reduced in the commercial group by about 4.5 cm at 1 year and 2.5 cm at 2 years. It is noteworthy that these results were obtained not in academic or research settings but in the context of a regular ongoing commercial program.

The correlations of changes in biological parameters with weight changes were generally similar to those seen in other studies with modest amounts of weight loss.[4,25-29] The magnitude of the group change may depend on characteristics of the study sample at randomization and the precise nature of the intervention (eg, diet, exercise, sodium content of diet, amount of weight lost). The reasons for the low correlations of individual improvement in biological indices with amount of weight lost are not known. Additional analyses are being conducted to establish whether

individual participant factors, such as the nature of the dietary and lifestyle changes, might account in part for the degree of improvement.

Despite sustained differences in mean weight loss between the 2 groups, the mean improvement in most biological parameters was not statistically different. In part, this is a statistical issue because the study was powered to detect differences in weight loss, not biological indices. However, the wide variability in attendance at the commercial sessions and success at weight loss highlights the importance of compliance with the assigned treatment. In this case, attendance at group meetings may provide the conditions necessary to produce and sustain weight loss and may increase the likelihood of improvements in biological indicators. However, even among those with the highest degree of adherence, there was weight regain during the second year of the study.

Self-selection bias—the tendency for successful participants to remain in the trial—may be a factor influencing these weight loss results, although that influence is likely to be relatively small because the high retention rate (73% after 2 years) limited the opportunity for self-selection to occur. Also, the correlation between attendance and success at weight loss is supported by other

Table 4. Changes in Biological Indices by Year and Treatment Group

	Change, Mean (SE)					
	Year 1			Year 2		
	Commercial Group	Self-help Group	Between-Group *P* Value	Commercial Group	Self-help Group	Between-Group *P* Value
Blood pressure, mm Hg						
Systolic	−0.6 (0.9)	0.2 (0.8)	.53	−2.2 (1.1)*	−2.4 (1.0)*	.93
Diastolic	−0.4 (0.6)	1.4 (0.6)*	.02	−0.6 (0.7)	0 (0.6)	.51
Glucose, mg/dL	3.5 (0.6)*	3.6 (0.6)*	.90	5.2 (0.7)*	4.6 (0.7)*	.47
Insulin, IU/L	−2.0 (0.5)*	−0.3 (0.5)	.01	0.6 (0.6)	2.3 (0.6)*	.04
Cholesterol, mg/dL						
Total	−8.7 (1.7)*	−9.5 (1.7)*	.73	−10.4 (2.0)*	−11.3 (1.9)*	.74
HDL	2.0 (0.7)*	0.8 (0.7)	.17	0.5 (0.8)	0.6 (0.8)	.92
HDL/total cholesterol ratio	0.02 (0.003)*	0.020 (0.003)*	.43	0.02 (0.003)*	0.02 (0.003)*	.99
Triglycerides, mg/dL	−7.8 (3.7)*	1.5 (3.8)	.08	−0.3 (4.0)	−0.1 (3.9)	.97

Abbreviation: HDL, high-density lipoprotein.
SI conversion factors: To convert cholesterol to mmol/L, multiply values by 0.0259; to convert glucose to mmol/L, multiply values by 0.0555; to convert insulin to pmol/L, multiply values by 6.945; to convert triglycerides to mmol/L, multiply values by 0.0113.
*Value is significantly different from baseline at $P<.05$.

research showing that length of the treatment period, and consequently the number of intervention meetings, has an independent effect on success.[30] It is also possible that characteristics of individuals willing and motivated to participate in long-term randomized clinical trials may have influenced the trial results. Finally, it should be emphasized that this study reports on a particular commercial program with many unique aspects. Our results should not be taken as representative of all commercial programs, many of which use other interventions, such as proprietary liquid formulas or diets that are not balanced.

In summary, this 2-year trial provides information on weight loss in an ongoing structured commercial weight loss program in comparison with self-help attempts to lose weight. The results show that this program provides modest weight loss but is more effective than brief counseling and self-help for overweight and obese adults.

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