CLINICAL RESEARCH STUDY

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Outcomes from a Medical Weight Loss Program: Primary Care Clinics Versus Weight Loss Clinics

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ABSTRACT

BACKGROUND: Few studies have focused on weight loss programs implemented in community-based primary care settings. The objective of this analysis was to evaluate the effectiveness of a weight loss program and determine whether physicians in primary care practices could achieve reductions in body weight and body fat similar to those obtained in weight loss clinics.

METHODS: Analyses were performed on chart review data from 413 obese participants who underwent weight loss at a primary care (n = 234) or weight loss (n = 179) clinic. Participants received physician-guided behavioral modification sessions and self-selected a diet plan partially or fully supplemented by meal replacements. A repeated-measures analysis of covariance was conducted with age and sex serving as covariates; significance was set at $P \leq .05$.

RESULTS: In 178 subjects (43%) completing 12 weeks of the program, primary care clinics were as effective as weight loss clinics at achieving reductions in body weight (12.4 vs 12.1 kg) but better with regard to reduction in body fat percentage (3.8% vs 2.7%; $P \leq .05$). Regardless of location, participants completing 12 weeks lost an average of 11.1% of their body weight. Participants selecting full meal replacement had greater reductions in weight and body fat percentage (12.7 kg, 3.5%) compared with participants selecting a partial meal replacement plan (8.3 kg, 2.3%).

CONCLUSION: Primary care physicians can successfully manage and treat obese patients using behavioral modification techniques coupled with meal replacement diets.

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KEYWORDS: Behavioral therapy; Body composition; Diet; Obesity

Consumers spend $33 billion annually for weight loss products and services,[1] yet approximately one third of adults in the United States are obese (body mass index [BMI] ≥ 30 kg/m^2).[2] Healthcare professionals are well aware of the relationship between excess body weight and cardiovascular disease, hypertension, type 2 diabetes, osteoarthritis, sleep apnea, and certain cancers.[3] Unfortunately, less than one half of obese patients report being advised to lose weight by their primary care provider,[4] an astounding statistic given the well-documented influence physician recommendations exert on patient behavior.[5,6] The low rate of primary care physicians who treat obesity is frequently attributed to limited time during office visits, lack of reimbursement, inadequate teaching materials, and poor training in nutrition or exercise counseling.[7-10]

Lifestyle modification programs, which include energy-reduced diets, have been the cornerstone of weight reduction efforts.[11] Healthcare providers relying on energy-reduced diets typically prescribe a low calorie diet providing ≥ 800 kcal/day. Studies indicate that low calorie diets provide satisfactory short-term weight loss without the adverse events often reported with very low calorie diets.[11,12] Moreover, low calorie diets incorporating partial

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meal replacements are a popular treatment option[13] and have been found to be safe and efficacious.[14-16] Studies have shown that meal replacements also result in better compliance and higher satisfaction, and are more likely to ensure adequate intake of essential nutrients compared with diets without meal replacements.[17,18] However, many of these studies took place in research settings and not primary care clinics, thus limiting their generalizability.[19]

The goal of this study was to evaluate a proprietary weight loss program that uses both partial and full low calorie diet meal replacement plans coupled with lifestyle modification counseling in the offices of primary care physicians or weight loss clinics. The first objective of the study was to determine the effectiveness of this approach to reduce total body mass and body fat in obese adults. The second objective was to determine whether trained physicians in a primary care practice setting could achieve comparable results as full-time medical weight loss centers using the same intervention. We hypothesized that physicians in both clinical settings could effectively treat patients with obesity; however, physicians at weight loss clinics could provide patients with larger weight and body fat losses compared with physicians at primary care clinics.

CLINICAL SIGNIFICANCE

- Patients participating in a nonsurgical Center for Medical Weight Loss program successfully achieve significant weight loss comparable to participants in other scientifically reviewed weight loss programs.
- Primary care clinics are equally effective at achieving weight loss in moderately obese patients using Center for Medical Weight Loss protocols as are weight loss clinics.

MATERIALS AND METHODS

Participants

We conducted a retrospective analysis of chart review data from 550 subjects treated between March 2008 and March 2010 at 8 clinics that used the same protocol for weight loss (Center for Medical Weight Loss, Tarrytown, NY). Patients who were prescribed an appetite suppressant (n = 137) as an adjunctive treatment were excluded from analyses, leaving a total sample size of 413. Before treatment, all patients underwent a comprehensive medical evaluation. Contraindications for the program included recent surgery or myocardial infarction (<6 weeks), history of hepatic or renal disease, type I diabetes, pregnancy, and significant psychologic illness or substance abuse. Before participating in the weight loss program, all participants signed an informed consent for data to be gathered for research purposes, which was approved by the institutional review board at East Carolina University.

Site Selection

Eight sites were selected along the Northeast corridor from approximately 400 clinics across the United States that offer the Center for Medical Weight Loss program: 4 primary care clinics and 4 weight loss clinics. Sites were selected on the basis of patient sample size (>100 patients), willingness to participate in the study, and use of a Valhalla Scientific Body Composition Model 2 Scale (Valhalla Scientific, San Diego, Calif) for body composition.[20]

Data Collection

Medical charts for all enrolled, obese participants (BMI ≥ 30) were reviewed by one author (WH) for demographic characteristics and body composition measurements. Weight measurements were obtained using a bioelectrical impedance scale with participants wearing light clothing and no shoes; recordings were not standardized according to time of day or hydration status of the patient. Height was measured with a standard wall-mounted stadiometer. Measurements were taken after the initial medical evaluation and again at every subsequent contact point; data collection ceased after 16 weeks or when the patient failed to attend more than 4 consecutive treatment sessions, whichever came first.

Dietary Treatment

Participants chose between 2 dietary regimens, either a traditional low calorie diet relying solely on meal replacement products or a modified low calorie diet supplementing meal replacements with 1 unpackaged 550 kcal meal (**Table 1**). Physicians directed participants to a particular regimen according to desired weight loss, severity of comorbidities, and financial resources. The prescribed caloric intake varied according to each individual's basal metabolic rate as determined by the Harris Benedict equation.[21] Each prepackaged meal consisted of 160 kcal and provided approximately 19 g of carbohydrates, 15 g of protein, and 25% of the Recommended Dietary Allowance for vitamins and minerals.

Lifestyle Modification

During the program, participants took part in weekly or bimonthly checkups incorporating physician-guided behavioral modification therapy. High-risk participants, those with comorbid conditions or medications requiring adjustment (eg, antihypertensive, insulin), were seen on a weekly basis for counseling and medical monitoring. Low-risk participants were seen every 2 weeks for counseling and consultation. Counseling sessions with the physician (15 minutes) consisted of proprietary interactive behavioral modification modules that incorporated at home questionnaires to be discussed at the following session. Modules covered a variety of topics including but not limited to meal planning, stress management, and exercise prescription.

Table 1 Overview of Treatment Protocol

	Low Calorie Diet			**Modified Low Calorie Diet**
Counseling:	Weekly physician-guided sessions			Bimonthly physician-guided sessions
Body composition:	Weekly analysis and feedback			Bimonthly analysis and feedback
Diet:	Meal Plan	BMR (kcal/d)	Calories (kcal/d)	Meal Plan
	5 meal replacements	<2000	800	550 kcal meal + 3 meal replacements
	6 meal replacements	2000-2500	960	550 kcal meal + 3 meal replacements
	7 meal replacements	2500-3000	1120	550 kcal meal + 4 meal replacements
	8 meal replacements	>3000	1280	550 kcal meal + 4 meal replacements

BMR = basal metabolic rate; Kcal = kilocalories.

Statistical Analysis

Baseline differences in physical characteristics by diet type (low calorie diet vs modified low calorie diet) and clinic setting (primary care vs weight loss clinic) were assessed by *t* tests. The main effect of the intervention on weight and percent body fat was derived from 2-way (2×2) repeated-measures analysis of covariance. The independent variables for the analyses were diet type and the clinic setting, with age and sex serving as covariates. To examine clinical significance of the intervention, participants were dichotomized into those who achieved weight loss of 5% or 10% of their weight at baseline and those who did not.[22] Pearson's chi-square tests were used to examine differences in achievement of clinical weight loss (yes/no) by intervention condition and clinic type. All analyses were conducted in SPSS 17 (SPSS Inc, Chicago, Ill), and significance was set at the .05 level.

As usual in weight loss studies,[23-25] an intention-to-treat approach was used. This method is more conservative than a traditional last-observation-carried-forward because the model assumes a dropout gains 0.075 kg/week on cessation of treatment (ie, 0.075 kg was added to the participant's final weight for each week < 12 that was completed). For reporting purposes, "completers" refers to individuals who were seen in clinic at least twice per month and who provided data after the 12th week after initiation of the protocol.

RESULTS

Participants

Participant characteristics are shown in **Table 2**. A total of 234 participated in the program at a primary care clinic, and the remaining 179 participated at a weight loss clinic. Among the participants seen at a primary care clinic, 222 selected a low calorie diet and 12 selected a modified low calorie diet; the breakdown among weight loss clinics was 153 low calorie diet participants and 26 modified low calorie diet participants ($\chi^2 = 10.72$, $P < .01$). Program completion rates between settings were similar in primary care (47%, 110/234) and weight loss clinics (38%, 68/179) ($\chi^2 = 3.36$, $P = .07$).

Weight and Body Composition Changes

Weight and body composition changes were examined in those completing the 12-week program (n = 178). For weight loss, a main effect for time was observed ($F[1,172] = 89.19$, $P < .01$) that was significantly associated with diet type ($F[1,172] = 95.91$, $P < .01$), with those on the low calorie diet experiencing greater weight loss. Sex was a significant covariate in the model ($F[1, 172] = 21.92$, $P < .01$), whereas the effect of the program on weight loss did not differ by clinic type. For weight, a main effect for time was observed ($F[1,172] = 39.34$, $P < .01$) that was significantly associated with diet type ($F[1,172] = 11.29$, $P < .01$), with those on the low calorie diet experiencing greater weight loss. Neither age nor sex was a significant covariate in the model, and the effect of the program on BMI did not differ by clinic type. For percent body fat, a main effect for time was observed ($F[1,172] = 40.52$, $P < .01$) that was significantly associated with clinic type ($F[1, 172] = 4.79$, $P < .05$). Participant sex was a significant covariate in the model ($F[1,172] = 9.64$, $P < .01$), and par-

Table 2 Demographics, Anthropometrics, and Diet of All Participants by Clinic Type

Demographic Characteristics	Primary Care Clinic (n = 234)	Weight Loss Clinic (n = 179)	*P*
Mean age (y [±SD])	54.4 (12.4)	48.8 (13.0)	<.01
Gender (n [%])			
Male	74 (32)	40 (22)	.01
Female	160 (68)	139 (78)	
Initial mean height (cm [±SD])	167.4 (10.6)	165.6 (9.1)	.07
Initial mean weight (kg [±SD])	104.6 (20.2)	109.1 (25.4)	.06
Initial mean BMI (kg/m² [±SD])	37.2 (6.3)	39.2 (7.2)	.01
Initial body fat (% [±SD])	40.8 (6.6)	42.4 (5.5)	<.01
Dietary regimen			
LCD (n [%])	222 (94.9)	153 (85.5)	<.01
MLCD (n [%])	12 (5.1)	26 (14.5)	

BMI = body mass index; SD = standard deviation; LCD = low calorie diet; MLCD = modified low calorie diet.

Table 3 Pre- and Post-intervention Weight, Body Mass Index, and Body Composition of Completers by Clinic Type

	Primary Care Clinic (n = 110)		Weight Loss Clinic (n = 68)		Combined (n = 178)			
	Pre-intervention	Post-intervention	Pre-intervention	Post-intervention	Pre-intervention	Post-intervention	MeanΔ	MeanΔ%
Weight (kg [±SD])	106.7 (21.8)	94.3 (20.0)	116.2 (29.0)	104.1 (25.9)	110.3 (25.1)	98.0 (22.9)	12.3 (5.0)	11.1 (3.8)
BMI (kg/m^2 [±SD])	38.0 (7.2)	33.4 (6.6)	41.4 (8.7)	37.1 (8.1)	39.3 (8.0)	34.8 (7.4)	4.5 (1.9)	11.4 (4.3)
Body fat (% [±SD])	40.8 (6.8)	37.0 (8.0)	43.3 (5.8)	40.5 (7.0)	41.8 (6.5)	38.3 (7.8)	3.4 (2.3)	8.8 (6.6)

BMI = body mass index; SD = standard deviation.

ticipants seen in primary care clinics realized greater declines than those seen at weight loss clinics. Mean values for the dependent variables for the completers are shown in **Table 3**.

Although achievement of 5% weight loss did not differ in participants treated at primary care (97.3%) or weight loss clinics (92.6%), a significant difference was observed between those in the low calorie diet condition (96.9%) compared with the modified low calorie diet condition (82.4%; $\chi^2 = 7.57$, $P < .01$). Significantly more participants treated at the primary care clinics (64.5%) compared with those treated at the weight loss clinics (48.5%) achieved greater than a 10% loss in baseline weight ($\chi^2 = 4.44$, $P < .05$). Participants in the low calorie diet condition (62.1%) were more likely than those in the modified low calorie diet condition (23.5%) to achieve a 10% weight loss ($\chi^2 = 9.42$, $P < .01$).

Likewise, the results of the intention-to-treat analysis on weight loss indicated that a main effect for time was observed ($F[1, 407] = 128.48$, $P < .01$), which differed by diet type ($F[1, 407] = 4.97$, $P < .05$), with those on the low calorie diet experiencing greater weight loss. Participant sex was a significant covariate in the model ($F[1, 407] = 77.54$, $P < .01$), but age was not.

A significant difference in achievement of weight loss in excess of 5% ($\chi^2 = 7.37$, $P < .01$) and 10% ($\chi^2 = 4.64$, $P < .05$) of baseline was observed across participants in the 2 clinical settings. A greater number of participants treated in the primary care clinic lost more than 5% (primary care clinic: 80.3% vs weight loss clinic: 68.7%) or 10% (primary care clinic: 41.0% vs weight loss clinic: 30.7%) of their baseline body weight than those treated in the weight loss clinics. In addition, a greater number of participants in the low calorie diet group achieved 5% (low calorie diet: 76.8% vs modified low calorie diet: 60.5%; $\chi^2 = 4.91$, $P < .05$) and 10% (low calorie diet: 38.1% vs modified low calorie diet: 21.1%; $\chi^2 = 4.34$, $P < .05$) of baseline weight loss at follow-up compared with participants in the modified low calorie diet group.

DISCUSSION

The first objective of this study was to determine the effectiveness of a proprietary low calorie diet treatment approach to reduce weight and percent body fat in obese adults treated in community-based clinical settings. Results indicate that patients participating in a Center for Medical Weight Loss program can successfully achieve significant weight loss. Successful weight loss, as defined by the Institute of Medicine of the National Academy of Sciences, is a reduction in initial body weight of 5% or more and the maintenance of this loss for at least 1 year.[22] Although the present study did not evaluate the maintenance of weight lost, 75% of participants achieved a 5% reduction in body weight under the intention-to-treat model. Alternatively, participants evaluated with the intention-to-treat model lost an average of 9.1% of their total body weight over a 12-week period, an amount comparable to that in other programs evaluating short-term weight loss.[26-28] Despite the promise of these findings, future studies should include a 1-year follow-up evaluating the ability of participants to maintain weight reductions.

The second objective of this study was to determine if trained physicians in a primary care practice setting could achieve comparable results as full-time nonsurgical medical weight loss centers using the same intervention. The results demonstrate that although participants seen in primary care clinics and weight loss clinics did not differ with regard to reductions in weight, participants seen in primary care clinics realized greater declines in percent body fat than those seen at weight loss clinics. The difference in percent body fat reductions may be attributed to the exclusion of participants on appetite suppressants and differences in obesity at baseline. Weight loss clinics tend to see more obese patients, whose treatment regimens call for more aggressive management, including the use of appetite suppressants. Although selection bias may account for the performance differential, the long-standing relationships between the primary care physicians and their patients also may have enhanced lifestyle changes, which led to more positive body composition changes. Regardless of the interpretation, a conservative conclusion is that primary care clinics are equally effective at achieving weight loss using Center for Medical Weight Loss protocols as are weight loss clinics in moderately obese patients.

The final objective of the study was to determine if patients on a traditional low calorie diet program would

experience a greater weight loss than those patients on a modified low calorie diet program. The results indicate that patients on a traditional low calorie diet program achieved greater reductions in weight and body fat than those patients on a partial low calorie diet program. Although it may not be practical for patients to rely solely on meal replacements for an extended period, a traditional low calorie diet program may be a good starting point for patients while they learn lifestyle modifications before transitioning to a partial low calorie diet program. In the long run, partial low calorie diet programs also may be a more economic approach to achieving and sustaining weight loss.

These results should be considered in light of a few limitations. First, the clinics were not randomly selected, thereby introducing the potential for selection bias. Second, the evaluation relied on methodologies that were acceptable to clinic physicians and staff but lacked the rigor that would be expected in a more controlled environment. Finally, there is no information available regarding the physical activity levels of the participants during the intervention, so we are unable to ascertain any other behavioral changes that may have affected the results of the study. Future studies might use a more rigorous research design that can control for many of these factors while maintaining the characteristics of the present study related to external validity.

CONCLUSIONS

The results of the present study extend the medical literature regarding weight loss in the outpatient setting and address some of the barriers keeping primary care practitioners from becoming actively involved in obesity management. The study evaluated a weight loss intervention in a realistic setting, patterned after everyday medical practice where physicians and patients negotiate treatment options. Our study shows that primary care clinics are equally effective at achieving weight loss using CMWL protocols as are physicians in weight loss clinics.

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