

## PAPER

# Feasibility of a partial meal replacement plan for weight loss in low-income patients

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**BACKGROUND:** Low-income patients are disproportionately affected by obesity. Routine care is available to this population at the Venice Family Clinic (VFC) in Los Angeles. The current study examined the effectiveness of nutrition clinic utilizing meal replacements (Slim-Fast, Slim-Fast Foods Co., FL, USA) in low-income patients over a 6-month period compared with the routine care by their primary care physician (PMD) prior to enrolling in the nutrition clinic at similar time intervals

**METHODS:** In total, 63 patients (51 F; 49 ± 0.8 yo) who had been followed at the VFC by their PMD for at least 6 months were enrolled in this study. Patients had a body mass index (BMI) of 40 ± 1.1 kg/m<sup>2</sup>, were 72% Hispanic, 25% Caucasian, and 3% African American. They had the following co-morbidities: hypertension (HTN) 45%, diabetes mellitus II (DM II) 50%, gastroesophageal reflux disease (GERD) 34%, osteoarthritis 51%, and hypercholesterolemia 48%. All patients were provided with meal replacements to be taken twice a day and were instructed to consume one complete low calorie meal per day. Weights at the first visit to the nutrition clinic, 1, 3, and 6 months after enrollment in nutrition clinic were compared to their weights at the same time intervals during routine visits to their PMD prior to enrollment in the nutrition clinic.

**RESULTS:** There was no significant weight change during the 6 months prior to enrollment in the nutrition program despite receiving care by a PMD. At 6 months after participating in the nutrition program, there was a mean decrease of 7% body weight with a reduction in BMI from 40–37 kg/m<sup>2</sup> ( $P \leq 0.05$ ).

**CONCLUSION:** Implementation of nutrition clinic utilizing meal replacements in this low-income patient population was effective in achieving a significant reduction in weight over 6 months of treatment.

*International Journal of Obesity* (2004) 28, 1575–1579. doi:10.1038/sj.ijo.0802792

Published online 5 October 2004

**Keywords:** meal replacement; weight loss; low income; nutrition

## Introduction

The epidemic of obesity in the United States affects low-income and minority populations disproportionately by comparison to the general population.<sup>1</sup> According to the most recent National Health and Nutrition Examination Survey (NHANES 1999–2000), the prevalence of obesity in Hispanics and non-Hispanic African Americans is higher than Caucasians.<sup>2</sup> For instance, The incidence of obesity among African-American women is 40.4% (95% CI 38.3–42.6%), and 26.1% (95% CI 23.9–28.2%) in Hispanic women compared to 20.5% (95% CI 19.6–21.4%) in Caucasian women.<sup>2</sup> Thus, even though the rate of obesity has uniformly increased over the past two decades in America,<sup>3</sup> there is a steep ethnic gradient disfavoring minorities.

This phenomenon is compounded by the fact that low-income uneducated populations notoriously consume high-energy foods, containing added sugars and fats.<sup>4</sup> Thus, the higher incidence of obesity in low-income individuals may be explained in part by poor diet choices. Providing affordable and convenient food alternatives to this patient population coupled with energy-reduced diets could result in successful weight loss.

Meal replacements have been shown to be effective for weight loss and weight maintenance in obese patients.<sup>5–9</sup> In addition, meal replacements are safe in obese diabetic patients.<sup>9</sup> However, meal replacements have not been investigated in low-income populations. Partial meal replacement plans (PMR) have been defined previously.<sup>6</sup> A PMR is a plan where one or more meals are replaced by a commercially available, vitamin and mineral fortified-calorie-reduced products and at least one daily meal consisting of regular food.<sup>6</sup> PMR plans may be an affordable and practical approach for the management of obesity in

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Received 4 March 2004; revised 6 June 2004; accepted 27 June 2004; published online 5 October 2004

low-income individuals. The current study was designed to examine the effectiveness of nutrition clinic utilizing meal replacements at a clinic that delivers care to low-income patients. Data obtained prospectively at base line, 1, 3, and 6 months was compared to data from the same patients during routine primary care visits prior to enrolling in the nutrition program at similar time intervals.

### Research methods and procedures

This study was conducted according the protocol approved by both UCLA and the Venice Family Clinic Institutional Review Board.

### Site

The Venice Family Clinic (VFC) was founded in 1970 and is the largest free clinic in the United States. To the larger community, the clinic has proven itself to be an innovative, efficient and viable response to the need for primary health care services for the working uninsured low-income patients of Venice, California and surrounding communities. The clinic serves 65% of patients who have jobs that do not provide affordable health care and 84% of its patient population live below poverty level.

The nutrition clinic was initiated in October of 2001 to meet the demands of the increasing number of obese patients in the primary care setting unable to reach satisfactory weight control with their regular primary care visits. All referrals were made within the VFC. Patients referred to the nutrition clinic were patients who were already being followed by a primary care physician (PMD) at this site for primary care issues such as diabetes or hypertension (HTN). Most referrals were limited to morbidly obese patients.

One physician (SH) and multiple volunteers provided weight management to this patient population. Clinic visits to the nutritional clinic took place once a week in a 4-h period.

### Study design

Our database consists of over 200 patients who have been referred to the nutrition clinic for weight management. Since the clinic was initiated, all patients were followed prospectively for a period of 6 months by the same physician. In order to assess the effectiveness of our program, we analyzed our data prospectively collected at the beginning of the program (baseline), 1, 3 and 6 months in our patient population. However, because we did not have a control group, we elected to retrospectively review the charts on all of our patients who had been seen by their PMD for at least 6 months prior to starting the nutrition program. We then compared data prospectively collected at base line, 1, 3 and 6 months to data retrospectively reviewed at similar time intervals on the same patients.

In our database, we identified 63 patients who had been followed by PMDs in the clinic for at least 6 months prior to the referral to the nutrition clinic. Data on these patients were then collected for demographic information as well as statistical analysis.

### Diet

The meal replacement was provided by Slim-Fast Foods Co. (Ultra Slim-Fast with Soy Protein; 170 calories, 15 g protein). All patients consumed two meal replacements and one portion-controlled meal per day. The total caloric intake for each patient was  $\geq 800$  to  $\leq 1800$  calories per day. The protein intake was 0.5–1 g/kg of lean body weight. Meal replacements were provided to all patients at each visit and sufficient meal replacements were supplied until their next scheduled appointment. Patients met with volunteer dietitians on occasional basis and were counseled on low-fat, low-carbohydrate diets.

Meal plans for calorie-controlled diets both in English and Spanish, incorporating the use of meal replacements, and portion-controlled meals were designed for simplicity of implementation as previously described.<sup>10–12</sup>

Patients were counseled regarding exercise at the beginning of the program. All patients were instructed to increase daily activity by walking at least three times a week for 30 min as well as isometric exercise as tolerated.

### Follow-up

The same physician saw all patients the first week after beginning of the program and then every 4–6 weeks depending on their degree of success. Patients who were not losing weight were asked to come to clinic more frequently.

### Statistical analysis

PRISM statistical Analysis software (Graphad Soft-ware, Inc., San Diego, CA, USA) was used for statistical analysis. Data are expressed as means  $\pm$  s.e.m.

Differences comparing two groups were evaluated by Student's *t*-test. Differences in percentages were assessed by  $\chi^2$ . Tukey's multiple comparison test evaluated multiple group differences. Statistical significance was established at  $P \leq 0.05$ .

### Results

Patient's demographics are depicted in Table 1. All patients in our study were, on the average, morbidly obese (body mass index (BMI)  $\geq 40$  kg/m<sup>2</sup>). Men were taller and heavier than women, but with similar BMIs. Patient's co-morbid conditions are depicted on Table 2. Men were more commonly affected by diabetes and HTN, while osteoarthritis and hypercholesterolemia occurred more frequently in

women. The majority of our patient population was Hispanic comprising 72%, while Caucasians (25%) and African American (3%) made up the balance of the population. All patients were low-income and received their medical care at the Venice Free Clinic.

No changes in weight at 6, 3, or 1 month were noted prior to implementation of the nutrition clinic (Figures 1 and 2). There was a trend towards weight loss in comparing the weight at baseline to 1, 3 and 6 months after implementation of the program. However, this difference did not reach

**Table 1** Patient demographics

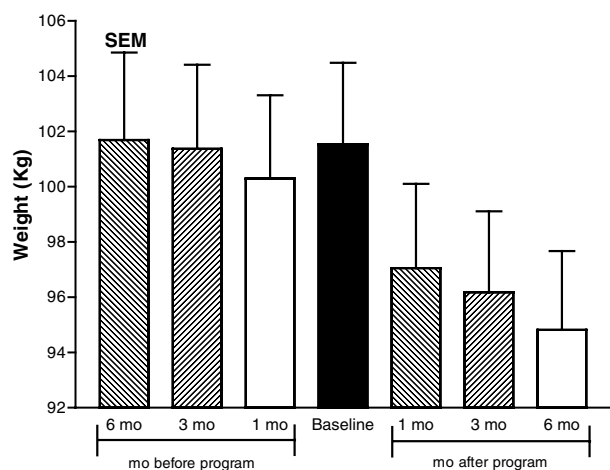
	Total population	Female	Male
Number	63	50	13
Age (y)	49.1 ± 0.8	48.6 ± 1.6	49.0 ± 1.9
Weight (lb)	225.0 ± 3.6	214 ± 7.0	250 ± 8.0**
Height (m)	62.5 ± 0.3	61.1 ± 0.5	63.1 ± 1.4**
BMI (kg/m <sup>2</sup> )	40.0 ± 1.1	41.0 ± 1.3	39.0 ± 1.4
Body fat (%)	40.0 ± 0.5	41.0 ± 0.8	33.4 ± 1.2**

\*\*P ≤ 0.01 female vs male.

**Table 2** Co-morbidities

	Total population	Female	Male
Number	63	50	13
HTN	45%	44%	47%*
DM	50%	40%	50%**
GERD	33%	32%	33%
Osteoarthritis	50%	52%	47%*
Depression	36%	38%	34%
Hypercholesterolemia	47%	50%	41%**

\*P ≤ 0.05; \*\*P ≤ 0.01.

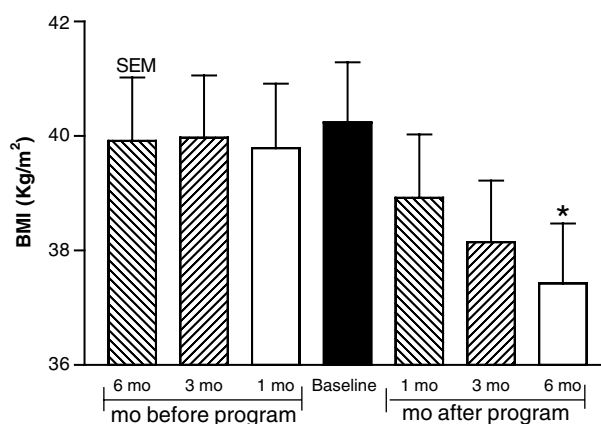


**Figure 1** Weight changes over the study period. Each bar represents the mean ± s.e. of weight change (in kg) of all of our patients (N = 63) at each given time.

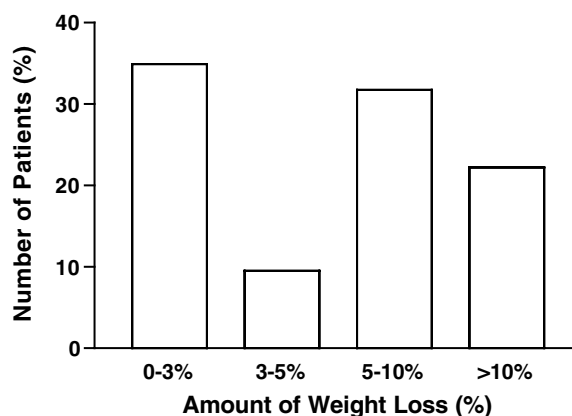
statistic significance (Figure 1). Following initiation of the program, there was a trend towards a decrease in BMI at 1 and 3 months. At 6 months after initiation of the nutrition program there was a 7.5% decrease in BMI compared to baseline. A reduction in BMI from 40 to 37 kg/m<sup>2</sup> was observed at a 6-month follow-up compared to base line (P ≤ 0.05; Figure 2).

The majority of patients (44.5%) were unable to lose more than 5% of body weight at a 6-month follow-up compared to baseline. However, a significant percentage of patients (32%) were able to lose 5–10% of body weight at a 6-month follow-up compared to baseline. Notably, 22% of patients were able to lose more than 10% (Figure 3).

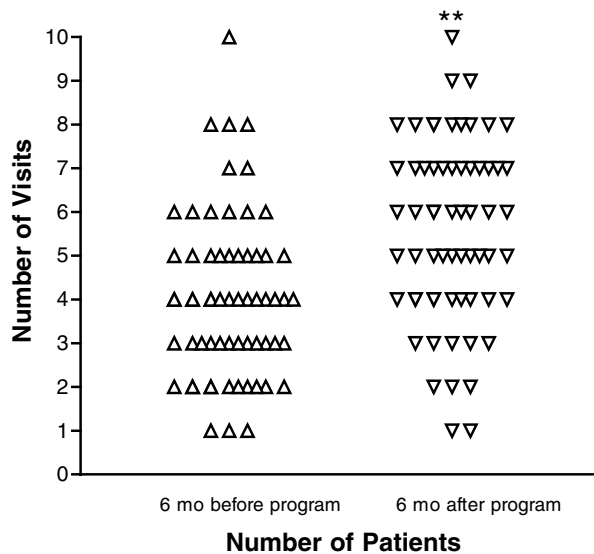
The average number of visits over 6 months prior to the initial visit to the nutrition clinic at baseline was 4.0 ± 0.24. The number of visits from baseline to 6 months after



**Figure 2** BMI changes over the study period. Each bar represents the mean ± s.e. of BMI of all of our patients (N = 63) at each given time (\*P ≤ 0.05 base line vs 6 months).



**Figure 3** Percent of patients achieving various degrees of weight loss from base line to 6 months after initiating the nutrition program. Each bar represents the percent of patient achieving the given percent weight loss from their initial weight at baseline.



**Figure 4** Number of visits 6 months prior to the implementation of the program and 6 months following initiation of the program. Each point represents an individual patient. The number of visits 6 months before the nutrition program was  $4.0 \pm 0.24$ , and  $5.6 \pm 0.26$  after the program (\*\* $P \leq 0.001$ ).

implementation of the program was  $5.6 \pm 0.26$  ( $P \leq 0.001$ , Figure 4).

## Discussion

The epidemic of obesity in the United States extends to every group in America including minorities and underserved populations. An alarming 80% prevalence of obesity has been reported in patients seen by PMDs at public hospitals serving indigent populations.<sup>13</sup> Weight-loss programs may be difficult to implement for indigent patients due to the high cost, time constraints, and the resulting high rates of dropout. A recent study targeting inner-city women in New Jersey reported a 10% reduction in weight in only 18% of the participants and a high drop out rate as a result of a small fee required in a subset of patients in the study.<sup>14</sup> Poverty and low-education status directly correlate with obesity.<sup>4</sup> Furthermore, energy-rich foods composed of sugars and fats are cheaper and more available to low-income patients.<sup>4</sup> As a result, low-income patients with limited resources are disproportionately affected by obesity.

For the clinically severe obese patient ( $BMI \geq 40$  or  $\geq 35$  kg/m<sup>2</sup> with co-morbid conditions), nonsurgical treatments are, in the majority of cases, unable to help patients maintain a significantly reduced body weight over the long-term and attaining a sustain ideal body weight in this patient population is unrealistic.<sup>15</sup> However, a small reduction in body weight ( $\geq 10\%$ ) has been shown to have major health benefits as a result of amelioration of obesity related co-morbid conditions.<sup>1</sup> Additionally, a 7% reduction in body

weight by diet and exercise reduced in incidence of diabetes by 58% in patients with impaired glucose tolerance tests.<sup>16</sup> Thus, achieving moderate weight loss in low-income patients should have a substantial health impact.

Meal replacements are a cost-effective approach to weight loss in this population, since the cost of meal replacements is less than the food these individuals typically purchase. Moreover, a PMR plan may potentially eliminate poor food choices in this patient population, while effectively reducing total calories consumed per day.

In the present report, we provide initial evidence of the practicality of this approach. Implementation of a PMR plan resulted in a 7.5% decrease in BMI over a period of 6 months compared to the baseline level and the stable level while receiving routine medical care over the 6 months prior to entering the nutrition clinic. A BMI reduction of 40 to 37 kg/m<sup>2</sup> was observed. This study demonstrates in a preliminary manner that meal replacements may be an effective tool for weight management in low-income populations with comparable results in series previously reported in nonindigent patients.<sup>6</sup>

Our study design had the particular advantage that each subject served as his or her own control over a 6-month period of time in the same clinical setting. The VFC provided the referrals to the nutrition clinic from the existing VFC patient population and all of these patients were being treated by their PMD.

The number of visits to the PMD in the 6-month period prior to enrollment into our program was  $4.0 \pm 0.24$  over a 6-month period and 6 months following initiation of our program was  $5.6 \pm 0.26$ . Thus, patients had an average of 1.6 more visits overall following implementation of the program vs regular visits with their PMD. Consequently, the observed reduction in BMI in our study may be the result of implementation of meal replacements, the increased number of visits alone or both. Further randomized studies need to be conducted to eliminate this potential bias, which is inherent in our study design.

Adherence to dietary treatments is notoriously difficult. In our patient population, we anticipated greater difficulties in maintaining adherence since the nutrition clinic was offered only once a week in the evenings. However, retention on the study was higher than expected by comparison to the average clinic statistics for a typical primary care clinic. We believe that the high retention rate on study was due to two factors. First, most of the patients seen at the VFC have obesity-related co-morbid conditions requiring frequent visits for follow-up on their condition and or adjustment in their medications. Second, the VFC has an aggressive retention patient program where if a patient misses one appointment, they are placed in a long waiting list to be seen again. Thus, when patients at the VFC are given an appointment they rarely miss it. Since this rule was applied to the study clinic, we had an above average rate of compliance. Given the difficulties encountered by our patient population and the fact that our patients did not

receive any form of compensation for their participation other than the meal replacements, adherence to our program was remarkable.

A diet plan utilizing meal replacements, with an emphasis on avoidance of 'high-energy foods' simplified calorie counting, reduced confusion, and was well accepted in our patient population. With a multitude of ethnic groups in the Los Angeles area, designing culturally specific diets was not practical. Future research comparing this simple method to the traditional exchange diets used by dietitians is required to assess the comparative efficacy of this simplified program, but it was apparently successful and had the practical advantage that it could be implemented by the physicians in the clinic.

The present study also had several weaknesses. First, the number of patients studied ( $n=63$ ) was relatively small. However, even with this small number of patients, we were able to appreciate significant weight loss in our patients. As an initial report, it provides evidence of the practicality of this approach in weight management. Studies with larger numbers of patients will need to be conducted. Secondly, we did not have an appropriate control group. Only 63 of all the patients prospectively followed at 6 months had been seen by a VFC PMD for at least 6 months prior to implementation of the program. Additionally, not all of the patients had visits at exactly, 6, 3, or 1 month. Thus, these intervals were approximated to best match data prospectively collected. As a result, a lesser number of visits were observed prior to implementation of the program. Future randomized-control-trial studies need to be conducted to resolve this issue. The VFC is a well-established setting for primary care delivery to low-income patients. Other settings, with less structural health care for low-income patients, may not experience the same results utilizing meal replacements as compliance may be an important factor as previously reported.<sup>14</sup> Finally, we have only reported the effects of the intervention on weight loss, and not on amelioration of obesity-related co-morbid conditions. The study design for this initial feasibility trial was not large enough to enable us to examine the effects of weight loss on co-morbidities. However, the weight loss we observed in our study is similar to other well-controlled studies, which have demonstrated amelioration of obesity-related co-morbid conditions or prevention in the incidence of DM II in patients with glucose intolerance test with the same degree of reduction in body weight.<sup>6,16</sup>

The present report provides initial evidence to support that a PMR plan, known to be effective in other group of patients,<sup>6</sup> may be feasible in a low-income population that carry a disproportionate burden of a disease with limited resources. The present study is the first report investigating meal replacements in low-income patients with promising results. The low-cost meal replacements make this office-

based practical regimen attractive among lower-income patients who commonly have to resort to poor choice eating habits. Further studies for longer periods of time are warranted given these encouraging preliminary results both to assess weight maintenance and the effects on common co-morbid conditions.

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