

A 54-Month Evaluation of a Popular Very Low Calorie Diet Program

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Background. Thirty-three percent of the adult American population over the age of 20 is obese. Many attempts to treat this increasingly occurring problem have had poor results. Both achieving weight loss and maintaining weight loss are difficult; however, current treatments appear more effective in achieving weight loss than in maintaining weight loss. The current study followed a cohort of patients to analyze weight maintenance and predictors of weight maintenance in a 26-week, formula-based, very low calorie diet program.

Methods. The study population consisted of a consecutive sample of 145 overweight patients who entered a very low calorie diet program and were contacted at 54 months after program entry.

Results. For men, the average initial weight loss at program termination was 27.2 kg (22% of original weight) and for women, 19.3 kg (18.8% of original weight). At 54 months after program entry, the average maintained loss was 5.1 kg (4.3% of original weight), at a cost of

\$630 per kg of long-term weight loss. There was no significant difference in maintained weight loss between men and women. Twenty-six percent of patients maintained a medically significant weight loss of 10% of entry weight. Subjects who exercised regularly maintained an average of 9.6 kg compared with 1.3 kg for nonexercisers. Those who attended the program for a longer period, and exercised more, maintained their weight better. The 54-month weight loss was similar to that seen at 30 months but markedly less than that at 18 months.

Conclusions. Very low calorie diet programs have limited long-term success that may not justify the risk of adverse effects and high costs. Longer program attendance and continued exercise are associated with improved weight maintenance. Evaluation of dietary programs should be based on a sample of consecutive patients followed for a minimum of 2 years after program completion.

Key words. Obesity; weight loss; reducing diet; very low calorie diet. (*J Fam Pract* 1995; 41:231-236)

The incidence of obesity in the western world is increasing and has reached epidemic proportions.¹⁻⁴ The medically obese segment of the United States population consists of the 34 million Americans who are more than 20% overweight.⁵ At this level of obesity, health hazards occur, such as diabetes, arthritis, hyperlipidemia, cardiovascular disease, pulmonary disorders, certain types of cancers, and restricting disabilities.^{6,7} Even though these patients are often motivated to lose weight, finding a successful and

lasting treatment is an ongoing quest.⁸⁻¹⁰ A therapeutic candidate is a very low calorie diet (VLCD).¹¹⁻¹³ These diets contain 800 kilocalories (3360 joules) per day or less and are usually part of a multimodal program that provides behavioral therapy, nutritional education, exercise instruction, and professional supervision. Despite the money spent on these types of programs (\$1.6 billion in 1990 alone),¹⁴ the research on long-term results is inadequate.^{9,13}

The Federal Trade Commission published guidelines for substantiation of weight-loss claims. The conditions for validating claims require sampling based on all patients entering the program, monitoring results for a minimum of 2 years after program completion, and documenting the amount and duration of the average weight loss maintained.¹⁵

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Recently, we published a study conforming to these guidelines in a 30-month follow-up evaluation of consecutive patients enrolled in a VLCD program.¹⁶ The current report is an extended evaluation of this population at 54 months after program entry and is the largest number of successive patients treated with VLCD studied in long-term follow-up.

Methods

Study patients participated in a weight-loss clinic administered by a for-profit hospital in Orange Park, Florida. The clinic offered the OPTIFAST Core Program (Sandoz Nutrition Co, Minneapolis, Minn). Details of the program have been previously described elsewhere.¹⁷ The program is designed to last 26 weeks. After an introductory week, patients consume a high-protein supplement of either 420 kilocalories (1764 joules) or 800 kilocalories (3360 joules) for the next 12 weeks. Over the subsequent 6 weeks, patients are gradually reintroduced to food. During the final 7 weeks, patients consume a regular diet of 1200 to 1400 kilocalories (5040 to 5880 joules). During the 26-week program, closed groups of 12 to 18 patients meet weekly for 1 hour of behavioral modification, nutritional education, exercise instruction, and emotional support. A supervising physician takes an initial history, does a physical examination, and sees the patient weekly for 20 weeks of the program. Laboratory testing is done at the beginning of the program and during the low-calorie portion of the program.

We reviewed the charts of 306 consecutive patients entering the OPTIFAST program for demographic characteristics, height, weight at time of entry, length of program attendance, and weight at time of program exit. No patients were excluded during the initial screening process. At 30 months after program entry, we surveyed these patients. Results were published on the 255 responding patients.¹⁶

At 54 months after program entry, these 255 patients were sent a second letter and questionnaire requesting their weight without shoes, exercise duration, participation in other weight-loss programs, and satisfaction with the OPTIFAST program. Those not responding were contacted by telephone. There were 93 patients who could not be contacted because of change of address or telephone number, or failure to return calls. Seventeen patients who were contacted refused to participate. These patients, who had consented to an interview in the previous study, responded with hostility or expressed disappointment but did not clarify their reasons for nonparticipation. Data were collected on 145 patients. Two women were excluded from analysis because of marked statistical

Table 1. Characteristics of Participants in Very Low Calorie Diet Program vs Nonparticipants at 54 Months After Entry in Study

Variable	Participants*	Nonparticipants†	P Value
	Mean (SD) (n=143)	Mean (SD) (n=110)	
Age, y	45.6 (9.6)	41.4 (10.0)	<.001
Weeks attended program	17.7 (6.4)	17.2 (6.6)	NS
Entry weight, kg	107 (21.6)	109.2 (21.9)	NS
Entry BMI	37.5 (5.3)	39.1 (7.2)	.05
Total weight lost, kg	21.4 (11.3)	20.9 (9.2)	NS

*Patients followed up 54 months after entry in the program.

†Patients studied 30 months after entry in the program but not participating in the 54-month follow-up.

‡BMI was calculated as weight(kg)/height(m²).

SD denotes standard deviation; BMI, body mass index.

variation from the rest of the study group (greater than the 99.99th percentile). Inclusion of the two patients strongly skewed the results against weight loss maintenance, possibly inducing a type 1 error. In comparison with the study group at 54 months (Table 1), those not included in the 54-month analysis were younger at program entry (41.4 vs 45.6 years, $P<.001$) and had a higher entry body mass index (39.1 vs 37.5, $P=.05$). There were no significant differences in entry weight (107 ± 21.6 vs 109.2 ± 21.9 kg), weeks attended (17.2 vs 17.7), or amount of weight initially lost (20.9 vs 21.4 kg).

Patients were divided into four groups based on the program phase they were in when they left the program. Group 1 dropped out during the first 13 weeks of the program (supplemented fasting phase) in which the patients consumed only supplement. Group 2 dropped out during the next 6 weeks (refeeding phase) while food was reintroduced. Group 3 withdrew during the next 4 weeks (stabilization phase) while on a low-calorie diet without supplement. Group 4 consisted of program graduates, those who remained through at least week 24. These definitions of the groups have been described previously by others.¹⁷

For each patient, the percentage of initial weight that was lost and then regained as well as the percentage of the initial weight that was lost and maintained at 54 months of follow-up was calculated. These percentages were then averaged. Ideal body weight at the midpoint of the medium frame for sex and height were obtained from the 1983 Metropolitan Life Insurance Company tables. Body mass index (BMI) was calculated as weight(kg)/height(m²). Patients were considered mildly obese if the BMI was between 27 and 30 (20% to 40% overweight); moderately obese if between 30.1 and 35 (41% to 100% overweight); and severely obese with a BMI greater than 35 (more than 100% overweight).¹⁸ For accuracy and conformity with other studies of self-reported weights, 2.3 kg was added to follow-up weights.^{17,19}

Table 2. Characteristics of Subjects of Very Low Calorie Diet Program at 54 Months After Program Entry, by Sex (n=143)

Variable	Men	Women	All Patients
	Mean (SD)	Mean (SD)	Mean (SD)
Age, y	46.5 (9.7)	45.2 (9.6)	45.6 (9.6)
Weeks attended program	18.6 (5.6)	17.6 (6.4)	17.9 (6.2)
Entry weight, kg	123.3 (22.6)	100.7 (17.2)*	107.7 (21.6)
Entry BMI†	38.8 (6.0)	37.2 (5.0)	37.7 (5.4)
Total weight lost at end of 26-week program, kg	27.2 (10.9)	19.7 (8.6)*	21.4 (13.0)
Weight at 54 months after entry in program, kg	117.6 (20.7)	95.9 (21.7)*	102.6 (23.6)
Amount of weight loss preserved at 54-month post-entry follow-up, kg	5.7 (12.9)	4.8 (15.5)	5.1 (14.7)

* $P < .001$.†BMI was calculated as weight (kg)/height (m^2).

SD denotes standard deviation; BMI, body mass index.

Statistical and graphics computation was performed using StatView 4.01 for the Macintosh (Abacus Concepts, Berkeley, Calif). An unpaired t test compared patients participating at 54 months ($n=143$) with nonparticipating patients ($n=110$) for baseline characteristics. Data for men and women participating at 54 months were tested using a two-tailed unpaired means test by sex. Weight loss data at 54 months were analyzed using a paired t test statistic. Categorical data comparing BMI at three measurement points (program exit, 30 months, and 54 months) were matched using χ^2 . All results were considered significant at $\alpha = .05$.

Results

Demographics and Retention

Table 2 presents the entry characteristics of the patients who were followed up through 54 months. Men represented 31% of the patients. At the conclusion of the pro-

gram, the men had lost an average of 27.2 kg, or 22% of their entry weight. Women had lost 19.3 kg, or 18.8% of their entry weight. The difference in this initial weight loss was significant ($P < .001$). Weight loss preserved at 54 months was no longer significantly different between men and women (5.7 ± 12.9 kg vs 4.8 ± 15.5 kg). Correcting for body habitus and sex difference, BMI was not significantly different for men and women.

For analysis, patients were grouped according to the phase they were in when they exited the program: 45% of the men and 43% of the women who started the program completed it. Sixty-one percent of the entrants stayed in the program for at least 19 weeks until they were no longer consuming the VLCD supplement.

Weight Loss

Table 3 shows the initial and maintained weight losses of all patients at the time they exited the program. The mean initial weight loss was 21.4 ± 13 kg, or 19.6% of entry weight. Average weight losses were greater for those who attended the program longer. At 54 months after program entry, the average maintained weight loss was 5.1 ± 14.7 kg, or 4.3% of entry weight. Program graduates maintained a weight loss of 7.3 ± 14.9 kg, or 6.3% of entry weight. The average patient had regained 87.6% of the weight originally lost. Those who completed 19 weeks of the program had regained 79.5% compared with program graduates, who had regained 76.8%. These weight regains, while similar to those for the 30-month follow-up results of 86.2%, 77.7%, and 67.3%, were significantly different for the total study group ($P < .001$), for the 19-week group ($P = .05$), and for program graduates ($P < .001$). Weight losses of 5 kg, 10 kg, and 20 kg were initially lost by 98%, 89%, and 55%, respectively, and maintained at 54 months by 18%, 17%, and 14%, respectively.

When the participants entered the program, it was advertised that 85% would lose 18.2 kg and that 60%

Table 3. Weight Loss Data on Subjects Followed Up at 54 Months After Entry into Very Low Calorie Diet Program

Group	Weeks Attended	No. of Patients	Initial* Weight Loss, mean kg (SD)	54-Month Weight Loss, mean kg (SD)	Initial* Weight Loss Regained by 54 Months, % (SD)	Initial* Weight Loss Maintained at 54 Months, %† (SD)
1	1-12	22	11.2 (8.2)	-2.0 (12.1)	124.6 (155.0)	-1.9 (12.3)
2	13-18	34	18.9 (6.1)	4.9 (13.5)	89.7 (81.6)	3.7 (13.2)
3	19-22	23	21.8 (7.4)	6.2 (16.7)	79.5 (106.0)	5.7 (13.4)
4	23-26	64	27.1 (8.4)	7.3 (14.9)	76.8 (57.8)	6.3 (13.3)
All	1-26	143	21.4 (13.0)	5.1 (14.7)	87.6 (92.6)	4.3 (13.3)

*At termination from the 26-week weight-loss program.

† $\geq 10\%$ is required in order to maintain health benefits.

SD denotes standard deviation.

would maintain the lower weight they achieved.²⁰ This amount was lost by 59.6% of the patients and maintained by 11%.

Admission BMI classified 2.8% of patients as mildly obese, 34.3% as moderately obese, and 62.2% as severely obese. At the 54-month follow-up, these percentages were 10.5%, 28.7%, and 54.5%. Nonobese weight was maintained by 6.3%. These differences are significantly different ($P < .001$).

When overweight individuals lose 10% of their body weight, health benefits occur.²¹ This medically significant weight loss was achieved by 90% of participants and maintained by 26% at 54 months.

Predictors of Maintenance and Reported Patient Satisfaction

Exercise was associated with improved weight maintenance. Among those who stated at the 54-month follow-up that they exercised regularly, the average weekly exercise reportedly lasted 90 minutes. The initial weight loss at program termination for those exercising was 20.3 ± 8.9 kg and for nonexercisers, 21.8 ± 11 kg. The exercisers maintained a 54-month weight loss of 9.6 ± 14.8 kg. The nonexercisers maintained 1.3 ± 14.3 kg at 54 months. This positive effect of exercise was significant ($P < .001$).

After leaving this program, 52 patients (36%) tried other weight-loss programs. These programs included self-help ($n=20$), VLCD ($n=23$), over-the-counter weight-loss aids ($n=3$), multiple ($n=2$), gastric surgery ($n=1$), and unspecified ($n=4$). Patients attending other weight reduction programs reported an average weight of 100.7 ± 20.3 kg, while those not attending other programs reported an average weight of 100.8 ± 24.1 kg. There was no significant difference between these groups in reported weight at 54 months.

Patients were asked whether the program helped their sense of well-being. At 54 months, 41.7% reported a positive effect, 35.4% were negative, and 22.9% were neutral.

Discussion

The National Institutes of Health recently convened a second conference to evaluate the available methods of weight loss and control.⁹ The incidence of obesity is increasing and now affects almost one third of all Americans. The panel members called for more data on all aspects of obesity, including evaluations of the long-term results of various methods for weight loss.

Very low calorie diet programs should be scrutinized

for long-term efficacy, as they are expensive and may be dangerous if not used in a responsible manner.^{12,13} The cost of the initial weight loss for these patients was \$120.43 for each kilogram, and at 30 months, \$395.73 for each kilogram maintained. The estimated cost at 54 months for the 143 patients is \$630 for each kilogram of weight loss maintained. Short-term data on patients completing VLCD programs demonstrate initial weight loss of 15 kg to 32 kg and 0% to 78% weight loss maintenance at 18 months.^{13,15,22} Results are markedly different when patients are evaluated 2 years or more after program completion, when weight loss maintenance of 0% to 48% is found.²³⁻²⁸ Most studies suffer from small study populations, lack of uniform data collection, low percentage of follow-up, or failure to evaluate consecutive patients.¹³ With the exception of a 47% follow-up rate, this study does not suffer from these limitations.

The 145 patients in this study had also been evaluated at 30 months after program entry.¹⁶ Comparison of these data shows that the majority of weight regain occurs by 30 months. The average patient regained another 3.6 ± 9.6 kg between the 30- and 54-month evaluation. This slowing of the rate of weight regain after diet programs has been noted by others²⁹ and is consistent with the "set point" theory of obesity.^{22,30} Comparison of the studies also showed a small but significant shift between 30- and 54-month BMI categories.

Medically significant weight loss of 10% of original weight decreased from 90% at the time of program termination to 26% at 54 months. Untreated patients are expected to gain approximately 1 kg per year.¹³ Based on the controversial theory that higher mortality may occur in obese patients with greater fluctuations in weight,^{9,31-34} it is uncertain whether the rapid regain of weight negated the benefits of residual weight loss.

As others have noted,^{28,35-38} exercise continues to be a key component in maintaining weight loss. Exercise affects a wide range of physiological, behavioral, and psychological variables.^{38,39} Our exercising patients reported averaging 90 minutes of strenuous activity per week. An exercise prescription may be counterproductive if too strenuous. Perri et al⁴⁰ found that a prescribed goal of 180 minutes per week of brisk walking or stationary cycling may be too difficult and may lead to negative self-perception and interfere with other self-management strategies.

Because only 5% of weight-loss program participants will initiate exercise based solely on instruction to do so,³⁹ it is important that the exercise initially be supervised. The patients in our study who remained in the program for at least 19 weeks, which included the period of supervised exercise instruction, were far more likely to continue exercising than were those who did not (59% vs 13%). It is

uncertain whether this finding represents the effect of supervision or of differing motivation.

Over the 4 years of follow-up, 36% of the patients tried other weight-loss programs. This high number is not surprising, since obese patients are often dieting.⁴¹ The discovery that there was no difference in the follow-up weights of those who did not try other programs does not guarantee endless cycles of weight loss and regain. It is possible that patients who regain their weight and then lose it with the aid of another program are better prepared to maintain the low weight because of what they have learned about maintaining weight loss. Relapses are a natural part of the cyclical pattern of change and may represent incremental learning instead of failure.^{42,43} Other investigators believe that patients are endlessly fighting obesity because of genetic susceptibility,⁴⁴ inability to change their "set point,"²² or a tendency to revert to former behaviors when under stress.¹⁰

Conclusions

These data provide valuable information to health care providers and patients involved in these programs. Longer program attendance and continued exercise are associated with improved weight maintenance. The present study validates the recommendation of the Federal Trade Commission. Weight loss treatments of all types, including VLCD, should be evaluated on samples of all patients entering the program followed for a minimum of 2 years following program completion.¹⁵ As theories lead to new strategies of weight loss, programs under development should compile accurate outcome data on all participants.

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