

ORIGINAL
RESEARCH
PAPER

Effectiveness of Medifast supplements combined with obesity pharmacotherapy: A clinical program evaluation

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ABSTRACT. PURPOSE: To evaluate the long-term impact of Medifast meal-replacement supplements (MMRS) combined with appetite suppressant medication (ASM) among participants who received 52 weeks of treatment. **METHODS:** We conducted a systematic program evaluation of weight loss data from a medically-supervised weight control program combining the use of MMRS and ASM. Data were obtained and analyzed from 1,351 patient (BMI \geq 25) medical charts who had participated for at least 12 weeks of treatment. Outcomes included weight loss (kg) and percent weight loss from baseline and at 12, 24, and 52 weeks. Both completers and intention-to-treat analyses were conducted. Completers' (i.e., those with complete data for 52 weeks) outcomes were evaluated after stratification for reported adherence to the MMRS and ASM. **RESULTS:** Participants who completed 52 weeks of treatment experienced substantial weight losses at 12 (-9.4 \pm 5.7 kg), 24 (-12.0 \pm 8.1 kg), and 52 weeks (-12.4 \pm 9.2 kg) and all measures were significantly different from baseline weight ($p < 0.001$ for all contrasts) for both true completers ($n = 324$) and for ITT analysis ($n = 1,351$). Fifty percent of patients remained in the program at 24 weeks and nearly 25% were still participating at one year. **CONCLUSIONS:** This weight loss program using a combination of MMRS and ASM produced significant and sustained weight losses at 52 weeks. Results were better than those typically reported for obesity pharmacotherapy in both short- and long-term studies and also better than those reported for partial meal replacement programs. Program retention at one year was similar to that reported in many controlled drug trials and better than most commercial programs reported in the literature.

(Eating Weight Disord. 13: 95-101, 2008). ©2008, Editrice Kurtis

INTRODUCTION

The weight loss industry in the United States (US) was worth \$46.3 billion in 2004 and is projected to climb to \$61 billion by 2008 (1). Among weight loss options, approximately 7.1 million dieters in the U.S. will use the services offered by commercial weight loss (CWL) programs (1). Unfortunately, little is known about the efficacy of CWL programs and advertising claims are not regulated by the U.S. Food and Drug Administration (2). Given that consumers desire information about typical weight losses along with data on safety, costs, and program components, calls have been made for research on the efficacy of CWL programs (3).

The small number of systematic investigations of structured CWL programs suggest that they typically result in modest post-treatment weight losses and are more effective than self-help plans (2, 4-7). The current investigation provides the first systematic analysis of the long-term clinical impact of a physician-directed weight loss program combining Medifast meal replacement supplements with appetite suppressant medication among participants who received a minimum of 12 weeks of treatment. This study improves on previous research by providing data on a large, diverse sample of patients who completed a weight loss program in a clinically-representative setting (i.e., not part of a university-based treatment study) and

Key words:

Obesity, primary care, weight loss, meal replacement, pharmacotherapy.

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Received: May 18, 2007

Accepted: February 22, 2008

by examining the long-term impact of treatment. In addition, data are presented which examine the impact of treatment adherence on program clinical outcomes.

METHODS

Study overview

This study provides a systematic clinical program evaluation of weight loss data from a medically-supervised weight control clinic. Data were obtained from clinic medical charts. The objective was to determine the clinical outcomes of a combined diet and medication protocol using Medifast Meal Replacement Supplements (MMRS) in conjunction with Appetite Suppressant Medications (ASM) under medical supervision. De-identified data were analyzed by researchers from the University of Missouri - Kansas City (UMKC). The protocol for this study was approved by the Social Sciences Institutional Review Board at UMKC.

Setting and program costs

Treatment occurred at the New Dimensions Medical Group Clinic in Northern California. This clinic has been open for approximately 10 years and has provided participants with an outpatient, medically-supervised, diet and medication approach to weight control throughout that time. The clinic is owned and operated by a physician and program costs include: 1) \$150 for initial visit; 2) \$75 for one-week follow-up; 3) \$65 for monthly visits; and 4) \$92.50 to \$100 per month for Medifast supplements.

Treatment protocol

Treatment consisted of both Medifast meal replacement supplements and Medication protocol over a total of one year, but for a minimum of 12 weeks for all participants. Assessments occurred at baseline and 12, 24, and 52 weeks.

Medifast Meal Replacement Supplement (MMRS) Protocol

Patients were instructed to use a combination of three to four MMRS each day as part of a menu plan. The daily menu plan averages approximately 750 calories per day (650-850 calorie range). A sample menu plan is provided in Table 1.

The four-meal plan provided an average of 747 calories including 83 grams (g) of protein, 20 g of fat, 72 g of carbohydrate, and 24 g of dietary fiber. An optional snack in the evening

provides an additional 90 calories. In addition, the plan provided recommended levels of essential vitamins and minerals, including 1,336 milligrams (mg) of calcium, 24 mg of iron, 153 mg of vitamin C, 3.3 mg of B6, 8.7 mg of B12, 13134 international units (IU) of vitamin A, and 455 IU of vitamin D.

Appetite Suppression Medication (ASM) Protocol

The medication protocol primarily used Phentermine HCL (Fastin-30mg, Ionamin-30 mg or Adipex-37.5 mg). A 30-day prescription was issued by the treating medical practitioner to each patient for either prescription. A one week follow-up visit was scheduled to determine whether any possible medication adjustment was needed and if so, a longer acting form of ASM, Phendimetrazine (Bontril-35 mg; 1 three times daily), was prescribed individually and not in combination with any other ASM. In cases of excessive hunger, the initial starting dosage was doubled for Phentermine HCL. All patient visits occurred monthly to assess progress and to refill prescriptions. Before writing a prescription, the nurse practitioner provided appropriate information regarding dosage side effects and potential drug interactions to the patient. Approximately 10% of the patients entering the program did not qualify for ASMs. These patients received only the MMRS protocol.

Outcome measures

Participants were weighed without shoes or extra clothing using a Seco Balance Beam scale with stadiometer. All participants' heights and weights were measured and recorded by a trained medical assistant or nurse practitioner.

TABLE 1
Sample Medifast meal plan.

Meal	Content	Estimated calories (Kcal)	Estimated carbohydrates (g)
Breakfast	Medifast 55 shake	90	13
Lunch	Medifast 55 shake	90	13
Snack	Medifast 55 shake or bar	90 or 160	13 or 21
Dinner	Meat (patients chose one)		
	Ground beef (4 ounces)	290	0
	Fish (4 ounces)	132	0
	Chicken (4 ounces)	110	0
	Salad	120	13
	Vegetables (1 cup)	44	10
Snack (optional)	Medifast 55 shake	90	13

Blood pressure was measured using a standard sphygmomanometer by a physician or nurse practitioner.

Participants

Participants were part of a fee-based medical clinic for the purpose of losing weight using a diet-medication protocol. Exclusion criteria from this study included enrollment in treatment for less than 12 weeks, less than 18 years of age, current use of MAO inhibitors, cardiac disease, severe hypertension, kidney disease, renal failure, asthma, liver disease, cancer therapy and eating disorders. All exclusion criteria were assessed during the initial patient's history and physical exam and recorded in their chart. All clinical exams were conducted by a physician or nurse practitioner.

Clinical and weight loss data were derived from a total of 1,445 patient medical charts that were not excluded based on the criteria previously presented from a total sampling pool of approximately 9,948 records. Data were extracted by trained research assistants and only relevant clinical data and limited demographic information were collected in a manner so as to protect the identity of patients. Characteristics of the resulting sample of patients are presented below.

Statistical approach and preliminary analysis

Means \pm standard deviation scores or percentages were calculated for all baseline demographic and clinical variables. Data distributions were examined and outliers were evaluated. We limited analyses to those with BMI 25, i.e., those individuals who at minimum met the National Institutes of Health (NIH) definition for overweight or obese. Thus, while our total sample started at 1,445 participants, one participant did not have baseline weight and six did not have either baseline or 12-week weights, leaving 1,438 potential participants. In addition, 81 did not meet our analytic criterion of BMI ≥ 25 , leaving 1,351 individuals with complete data. By 12 weeks, those eligible for analysis lost an average of -8.9 ± 5.4 kg. By 24 weeks, 669 individuals (50% of the total sample) had valid data and lost -11.4 ± 7.4 kg, and by 52 weeks, 326 (24% of the total sample) were available for analyses and lost -12.4 ± 9.2 kg. From this group, we derived our "true completers" (i.e., those with valid weight measurements at all time periods), which resulted in a sample size of 324 individuals. It was this sample that was used to examine weight change over the course of the 52 weeks of treatment. Weight

change at each time point was evaluated using paired samples t-tests, comparing 12, 24, and 52 weeks mean weights to baseline.

We also examined weight loss outcomes using a conservative Intention-to-Treat (ITT) model used by Wadden et al. (8) and Poston et al. (9) rather than the Last-Observation-Carried-Forward (LOCF) method, which does not account for weight gain after treatment termination. This ITT approach assumes that dropouts gain 0.3 kg/month after study withdrawal. Thus, in our ITT models, 0.3 kg/month was added per month to the patient's last assessed weight. For instance, if a patient weighed 100 kg at 12 weeks but dropped out before week 24, their weight would be recorded as 101.8 kg (i.e., $0.3 \text{ kg} * 6 \text{ months} + 100 \text{ kg}$) rather than as 100 kg in the LOCF method. Similar to completers, weight change at each time point was evaluated using paired samples t-tests, comparing 12, 24, and 52 weeks mean weights to baseline.

Finally, we stratified "true completers" by their medication use and use of the supplement beverage and examined outcomes by creating dichotomous options on these variables. For example, consistent medication use was defined as using medications at all assessments, regardless of medication type while inconsistent use was not meeting this criterion. Consistent supplement use was defined as reporting consumption of at least 2 shakes per day at all assessments while inconsistent use was not meeting this criterion. Consistent medication and supplement use was defined by combining the previous two variables so that participants could either be classified as reporting: 1) consistent medication and supplement use; 2) consistent use of either medications or supplements, but not both; and 3) inconsistent medication and supplement use. Repeated-measures ANOVA (RANOVA) models were then evaluated using all four measurements as the within-subjects variable and either consistent medication use (yes or no), consistent supplement use (yes or no), or consistent medication and supplement use (i.e., the three groups defined above) and the between-subjects variables for three separate models.

RESULTS

As can be seen in Table 2, the majority of participants were women aged 30 and over who were normotensive and had average BMI's well above the NIH cutoff for obesity (BMI > 30).

TABLE 2
Baseline demographic characteristics of participants.

Variable	Total sample (N=1,351)	True completers* (N=324)	All measures not available (1,027)	p-value**
Gender (% female)	90.2	87.7	90.9	0.083
Age (%30 and over)	75.2	80.9	73.4	0.007
Height (m)	1.65±0.08	1.65±0.09	1.64±0.08	0.194
Weight (kg)	93.3±20.6	96.6±21.3	92.3±20.3	0.001
BMI (kg/m ²)	34.3±6.6	35.3±6.6	34.0±6.6	0.003
Systolic blood pressure (mmHg)	124.3±14.7	125.6±12.7	123.8±15.3	0.065
Diastolic blood pressure (mmHg)	79.3±9.3	79.7±9.5	79.2±9.2	0.363

*True completers are those individuals with valid weight measures at all four measurement periods, i.e., baseline, 12, 24, and 52 weeks.

**p-values calculated to examine differences between true completers and individuals for whom all measures were not available.

Table 2 also separates our true completers (i.e., those with all four measurements) from those who did not have all four assessments completed. On average, our completers were still more likely to be women, but more of them were aged 30 and over when compared to those with incomplete data (80.9% vs. 73.4%; $p=0.007$). In addition, true completers were heavier at baseline than those with incomplete data as demonstrated by their significantly greater weight and BMIs. There were no differences between completers and those with incomplete data with respect to systolic or diastolic blood pressure.

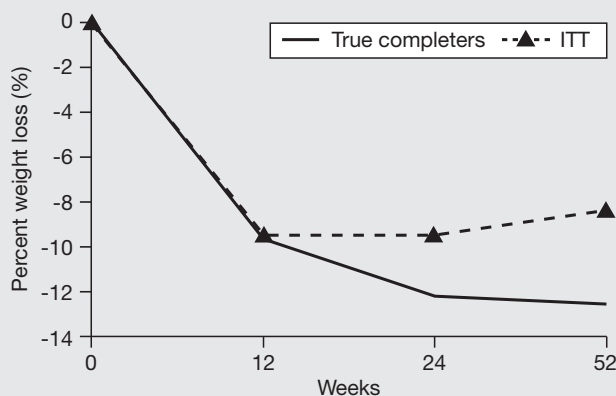
Figure 1 illustrates percent weight change among true completers (N=324) and all eligible for analysis (N=1,351) using the conservative ITT treat model from baseline to the 52-week final assessment.

As can be seen, those who completed all measures (and a full year of treatment) experi-

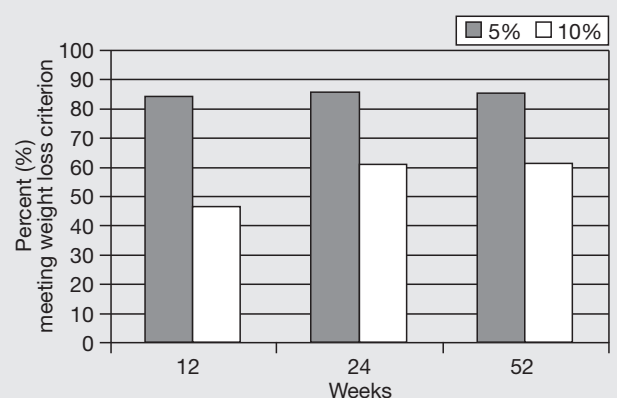
enced substantial weight losses at 12 (-9.4±5.7 kg), 24 (-12.0±8.1 kg), and 52 weeks (-12.4±9.2 kg) and all measures were significantly and clinically different from baseline weight ($p<0.001$ for all three contrasts, respectively for both true completers and for ITT). Figure 2 presents the proportions of true completers who achieved both 5% and 10% weight losses, the NIH standard for clinically significant weight loss.

The majority of participants achieved a 10% weight loss by 24 and 52 weeks and over 80% achieved at least a 5% weight loss at all three time points.

Next, we stratified the true completers by whether they reported using any medication (regardless of type) and found that 212 (65.4%) reported using medications at all assessments while 112 (34.6%) reported less consistent use of medications. Of this latter group, only one person reported never using medications and

**FIGURE 1**

Weight loss among true completers (N=324) and total sample using ITT (N=1,351).

**FIGURE 2**

Proportion of true completers who lost 5% and 10% of initial body weight at 12, 24, and 52 weeks.

that individual was left in the less consistent medication user group. We then examined weight change differences between these two groups at each measurement (i.e., 12, 24, and 52 weeks) and found that the weight losses were similar and not statistically different between those consistently taking medications and those not ($F=1.22$; $p=0.302$), but, as before, there was a main effect for weight loss over time ($F=258.5$; $p<0.001$). Table 3 presents weight change (kg) and percent change from baseline for 12, 24, and 52 weeks stratified by medication use status.

Similarly, we stratified the true completers by how consistent they were in using the supplement shakes (Table 3). Consistent supplement users were those individuals who reported consuming at least 2 shakes per day at all assessments ($n=73$; 22.8%) while inconsistent users were those who did not meet this criterion at all measurement points. Weight losses were similar and not statistically different between those consistently reporting consuming supplement and those not ($F=1.13$; $p=0.337$), but, as before, there was a main effect for weight loss over time ($F=214.3$; $p<0.001$).

Finally, we examined weight loss stratified by both consistent medication and supplement use combined. Among the sample of completers, 16.9% reported meeting the definition of consistent use of both medications and supplements (losing -9.8 ± 4.1 kg, -12.3 ± 7.1 kg, and -13.0 ± 7.9 kg at 12, 24, and 52 weeks, respectively) while 54.5% were consistent on one or the other (losing -9.6 ± 6.2 kg, -12.6 ± 8.4 kg, and -13.3 ± 9.8 kg at 12, 24, and 52 weeks, respectively), and 28.5% were not consistent on either (losing -8.7 ± 5.7 kg, -10.5 ± 7.9 kg, and -10.2 ± 8.2 kg at 12, 24, and 52 weeks, respectively). Figure 3 illustrates percent weight loss among these groups.

As before, there was an effect for weight loss over time ($F=229.7$; $p<0.001$), but the effect for group differences was not statistically significant ($F=1.52$; $p=0.169$); however, the study was not powered to detect this smaller difference. Nevertheless, it is notable that there were greater weight losses among those most consistently using both medications and shakes when compared to those not doing either.

DISCUSSION

Overall, the results of combining MMRS with obesity pharmacotherapy were extremely encouraging. First, it is notable that in a real world clinic providing treatment, half of the

TABLE 3
 Weight change for those consistently using medications and shakes compared to those who did not.

	Medication use		Supplement use	
	Consistent*	Less consistent	Consistent**	Less consistent
Weight change (kg)				
12 weeks	-9.5±5.8	-9.1±5.7	-10.7±7.1	-9.2±6.0
24 weeks	-12.4±8.1	-11.1±8.0	-12.7±7.2	-11.7±8.3
52 weeks	-13.0±9.3	-11.2±8.9	-13.7±8.4	-12.0±9.4
Weight change (% change from baseline)				
12 weeks	-9.9±5.2	-9.1±5.2	-10.6±4.1	-9.4±5.5
24 weeks	-12.8±7.0	-11.0±7.5	-13.2±6.7	-11.9±7.4
52 weeks	-13.4±8.0	-11.0±8.0	-14.2±7.6	-12.1±8.1

*Consistent medication use was defined as using medications at all assessments, regardless of medication type.

**Consistent supplement use was defined as reporting consumption of at least 2 shakes per day at all assessments.

patients remained in the program at 24 weeks and nearly 25% were still participating at one year. This is important because even in highly structured randomized trials involving medications and retention incentives, 50% attrition at one year is not uncommon (10) and case studies of very low calorie diets have evidenced >50% attrition in less than one year (2). Studies of weight loss in more naturalistic settings also demonstrate low long-term retention (11). For instance, Finley et al. (12) noted a 93.4% one-year attrition rate in a study of the Jenny Craig Platinum program. The relatively low drop out in this study may

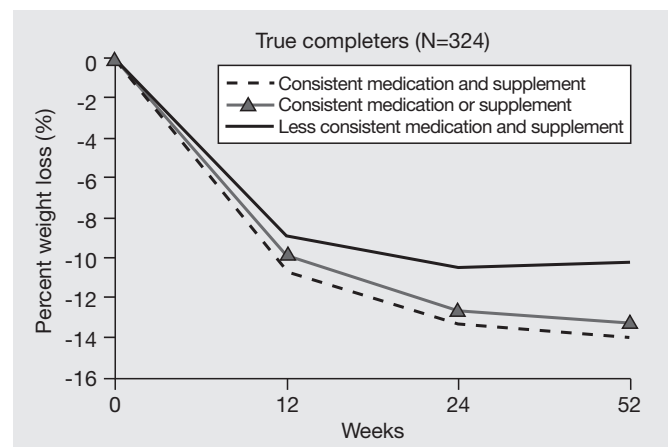


FIGURE 3
 Percent weight loss stratified by medication and supplement use combined.

be due to the fact that all participants were self-referred volunteers, were medically supervised, and made significant financial investment in the treatment program.

Weight loss results for completers, i.e., those participants who completed a full year of treatment, appear to have been very successful. The sustained weight losses demonstrated at each measurement point of 9%-12% change from baseline (i.e., up to 12 kg weight loss by week 52), were greater than those typically seen for most medications in both short- and long-term studies and also superior to those reported for partial meal replacement programs (10, 13, 14).

The results of combining both obesity pharmacotherapy and MMRS produced substantial and sustained weight losses that were superior to those typically reported in drug (10, 13) and meal replacement studies (14), particularly those lasting at least one year. Thus, the combining of obesity pharmacotherapy and MMRS appears to substantially enhance weight loss beyond that typically produced by either alone. In addition, our completers' data demonstrated that the majority of patients reporting using the medications and MMRS fairly consistently experienced the best average weight losses (although the difference was not statistically different from those who were less consistent) (Fig. 3). Because we excluded patient charts that did not have at least baseline and 12-week data, this study does not represent an examination of the outcomes of "all comers" who might use a MMRS and ASM program. Rather, we were more concerned about understanding the impact of the use of MMRS and ASM among patients who had received at least minimal treatment, which we defined as a minimum of 12 weeks.

Our study is limited in our ability to make comparisons to randomized trials because it represents that experience of patients who all received treatment at one clinic and there was no comparison group. In addition, our results do not represent outcomes that could be expected if we had included charts of any individual who enrolled in the program, but did not reasonably engage in the actual treatment program (e.g., someone who participated for few weeks and then dropped out). However, we believe the data that we analyzed are important because little is known about the effectiveness of weight loss interventions in real clinic settings where interventions cannot be provided with the same level of control as those typically evidenced in randomized trials. In addition, we believe these data are very useful in providing an estimate of the effectiveness

of combining MMRS with ASM in a real clinic setting for those patients who participate in the program for at least 12 weeks, which is a minimal amount of time to achieve reasonable weight loss.

ACKNOWLEDGEMENTS

This study was funded as a program evaluation by a Medifast Inc.

The conduct of archival study was funded by Medifast Inc. We would like to thank Ms. Diane Kallman and her clinic staff for their assistance with this study. In addition, we would like to acknowledge the pioneering clinical work of Dr. Arthur Kallman, who first started the weight loss program and treated many of the patients whose records were used in this study.

CONFLICT OF INTEREST STATEMENT

Medifast Inc. provided funds to Drs. Haddock, Poston, Foreyt, and Warner to conduct this retrospective evaluation study using archival records. Dr. DiBartolomeo is employed by the funder, Medifast Inc.

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