

## Original Research

# A Comparison of Meal Replacements and Medication in Weight Maintenance after Weight Loss

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**Key words:** obesity, meal replacements, Orlistat, very low-energy diet, weight loss, weight maintenance

**Objective:** To compare the use of meal replacements or medication during weight maintenance subsequent to weight loss using a very low-energy diet (VLED) in overweight or obese adults.

**Design:** Participants followed a liquid VLED of 2177 kJ for 12 weeks followed by 4 weeks of re-orientation to solid foods. Participants were randomized at week 16 to receive either meal replacements or Orlistat both combined with a structured meal plan containing an energy value calculated to maintain weight loss.

**Subjects:** Sixty-four women (age =  $49.9 \pm 10$  y, weight =  $101.6 \pm 17.1$  kg, height =  $164.9 \pm 6.0$  cm, BMI =  $36.7 \pm 5.4$  kg/m<sup>2</sup>) and 28 men (age =  $53.7 \pm 9.6$  y, weight =  $121.8 \pm 16.0$  kg, height =  $178.7 \pm 5.6$  cm, BMI =  $37.8 \pm 4.9$  kg/m<sup>2</sup>) completed a 1 year weight management program. Behavioral weight management clinics included topics on lifestyle, physical activity (PA), and nutrition. Participants met for 90 min weekly for 26 weeks, and then biweekly for the remaining 26 weeks.

**Outcomes:** Minutes of PA, fruits and vegetables (FV), and pedometer steps were recorded on a daily basis and reported at each group meeting. Body weight was obtained at each group meeting.

**Results:** During VLED, the MR group decreased body weight by  $22.8 \pm 6.1$  kg and the Orlistat group decreased body weight by  $22.3 \pm 6.1$  kg. During weight maintenance, there was no significant group by time interaction for body weight, PA, FV consumption, or pedometer steps. At week 16, the meal replacement group had a body weight of  $85.4 \pm 14.3$  kg that increased to  $88.1 \pm 16.5$  kg at 52 weeks ( $p < 0.05$ ). At week 16, the Orlistat group had a body weight of  $85.7 \pm 17.9$  kg that increased to  $88.5 \pm 20.3$  kg at 52 weeks ( $p < 0.05$ ).

**Conclusions:** Subsequent to weight loss from a VLED, meal replacements and Orlistat treatments were both effective in maintaining weight significantly below baseline levels over a 52 week period of time. Meal replacements may be a viable alternative strategy to medications for weight maintenance.

## INTRODUCTION

Overweight and obesity continue to rise and present a serious public health risk in the United States [1,2]. Obesity is a risk factor for cardiovascular disease and is associated with a host of metabolic complications and co-morbidities [3,4]. Clinical studies have shown a significant reduction in obesity-related disorders with a moderate degree of weight loss [5]. However, many of the beneficial effects of weight loss disappear with weight regain [6,7]. Thus, a loss of 5–10% of initial

body weight, if maintained long-term, may be considered to be a successful treatment guideline [8].

Investigators have suggested that there are multiple strategies that may contribute to successful weight maintenance. McGuire et al. have identified three common elements among participants that have successfully maintained weight loss [9]. These include eating a diet low in fat, frequent self-weighing, and high levels of physical activity (PA). After a review of the literature, Jeffery et al. suggested 5 areas that may improve weight maintenance including: increasing the intensity of initial

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Abbreviations: VLED = very low-energy diet, FV = fruits and vegetables, PA = physical activity.

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treatment, extending the length of treatment, altering dietary and exercise prescriptions, enhancing motivation, and teaching maintenance behavioral skills [10]. Despite these advances, the difficulty of weight maintenance remains. In general, 50% of individuals who initially lose weight regain more than 45–75% of the weight within 12–30 month subsequent to treatment [11–13]. This provides rationale to further investigate strategies for prevention of weight regain.

Interventions that promote lifestyle changes and PA have shown better weight maintenance than interventions that do not have these components; however, weight generally increases with time [9]. To augment lifestyle changes and PA, medications have been used and have shown increased weight maintenance compared to behavioral interventions and placebo [14–16]. Unfortunately, medications are costly and have undesirable side effects. Recently, meal replacements have shown a greater weight loss compared to conventional meal plans and have shown less weight regain at 1 year [17,18]. Meal replacements do not have the side effects associated with medications and may be cost effective since they displace the costs normally associated with food purchases.

Our primary purpose was to determine if meal replacements were as effective as medications for enhancing weight maintenance in a weight management program that promoted lifestyle changes, nutrition, and PA. We specifically chose to compare meal replacements with the medication Orlistat which does not act centrally and may decrease the absorption of dietary fat thereby reducing total fat intake. Our secondary purpose was to determine treatment differences by gender since there are frequently differences in responses for women and men.

## **MATERIALS AND METHODS**

### **Participants**

To be eligible for participation, individuals had to be 19 to 70 years of age, overweight or obese ( $BMI \geq 28 \text{ kg/m}^2$ ), non-smokers, and able to exercise (i.e. walk). Individuals with any unstable medical condition (i.e. undiagnosed diabetes or hypertension), seeking treatment for depression or eating disorders, or a woman who was pregnant or lactating were excluded. Prior to entry into the study, each participant was required to complete a series of questionnaires regarding their health, diet, and exercise habits. In addition, each participant completed a physical examination performed by the study physician. All participants gave their consent to participate and the investigation was approved by the Human Subjects Committee at the University of Kansas.

### **Study Diet**

Weight loss was generated using a liquid very low-energy diet (VLED) for 12 weeks (Health Management Resources, Boston, MA). The VLED was a liquid formula taken primarily

as shakes consumed 4 to 5 times per day (2177 kJ per day) and was the only source of nutrition with the exception of non-caloric beverages that were consumed ad libitum. The VLED was followed by a 4 week re-introduction to solid foods. During these 4 weeks, participants were instructed to slowly incorporate solid foods, including fruits and vegetables (FV), into the diet following a progression designed to limit adverse events (i.e. nausea, diarrhea, etc.) and to achieve a weight maintenance level of energy intake by the end of week 4. At 16 weeks, participants were randomized to receive a structured meal plan combined with either meal replacements or Orlistat during the remaining 36 weeks of the study. The structured meal plan included a level of energy intake calculated to maintain weight and incorporated a diet low in fat (20–30% of total energy intake) and a FV consumption of at least 35 FV per week. The meal replacement group received 2 meal replacements per day that were incorporated into the structured meal plan. Meal replacements were in the form of entrees such as, vegetable stew, lasagna primavera, bean casserole, etc., and had an energy value from 628 to 1130 kJ per meal replacement. Along with the structured meal plan, the Orlistat group received medication that was prescribed twice daily at 120 mg per dose. The twice daily dosage was based on our previous clinical experience and participant feedback that most adults do not eat 3 meals per day. Both the meal replacement and Orlistat group reported the number of entrees or pills consumed at each meeting and those receiving the medication returned the unused portion before receiving additional medication. The meal replacements and medication were provided at no cost to the participants.

### **Treatment Clinics**

Clinics were conducted in a group format consisting of 15–20 individuals. Meetings included instruction in lifestyle modification, PA, and nutrition. Participants met weekly for the first 26 weeks and bi-weekly for the second 26 weeks of the program. Each meeting was approximately 90 min and began with a check-in where all participants were weighed and reported their weekly data that included minutes of PA, FV, and steps, as recorded by a step counter. Following check-in, a topic was presented for 30 to 45 min. Discussion followed and an assignment was given for the next meeting. All clinics used an identical protocol and were led by a trained staff of registered dietitians, exercise physiologists, and behavioral therapists. Complaints or adverse events associated with the treatments were recorded at every group meeting.

### **Laboratory Measurements**

Laboratory tests to determine body weight, body composition, and anthropometrics were performed at baseline, 26 weeks, and 52 weeks. To obtain body weight, participants were weighed in a hospital gown using a digital scale (Befour, Inc., Saukville, WI) accurate to  $\pm 0.1 \text{ kg}$ . To calculate BMI, height was measured using a stadiometer (Perspective Enterprises,

Portage, MI). BMI was calculated as kilograms divided by height in meters squared ( $\text{kg}/\text{m}^2$ ). Dual energy x-ray absorptiometry (DEXA) (Lunar Corp., Madison, WI) was used to determine fat-free mass, fat mass, and percent body fat. Female participants were required to receive a urinary pregnancy exam to ensure they were not pregnant prior to each DEXA testing. All participants were tested in a hospital gown to standardize clothing. In addition, waist and hip circumferences were assessed by obtaining 2 measurements per site each within 2 cm [19].

### Group Meeting Measurements

To promote protocol compliance and to enhance motivation, body weight was measured before each group meeting. Participants were weighed in light clothing without shoes using a digital scale accurate to  $\pm 0.1$  kg. Participants recorded their daily PA in minutes throughout the week and reported their weekly total at each group meeting. Although increased activities of daily living were encouraged, only leisure-time PA such as, brisk walking, cycling, and swimming were reported. The PA program designed for the participants was gradual, progressive, and at moderate intensity. The progression was intentionally slow as many of the participants reported being previously sedentary. Physical activity began with 15 min, three times per week and reached 5–6 times per week for 50–60 min at week 26. The overall goal was for participants to exercise at least 300 min per week and maintain that level after week 26. All participants were issued an activity pedometer (Accusplit<sup>®</sup>, San Jose, CA) and recorded their daily steps. Each participant totaled their daily steps throughout the week and reported their weekly total at each group meeting. Furthermore, participants recorded their FV consumption throughout the week and reported their weekly total at each group meeting.

### Statistical Analyses

This was an efficacy study; therefore, the primary analysis was for participants who completed all clinic and laboratory measures. The primary outcome was difference in body weight from week 16 to week 52 between the two treatment conditions. Descriptive statistics (mean, standard deviation, etc.) were calculated for each dependent variable. To determine differences in age, body weight, height and BMI between the meal replacement and Orlistat group at baseline and randomization, t-tests were utilized. To determine group differences during weight loss and during weight maintenance, data were analyzed for a significant interaction (group\*time) using a Mixed Effects Model. In the absence of a significant interaction term, main effects for group and time were examined. To accomplish the secondary purpose of this study, group differences were analyzed by gender and in the absence of a significant interaction were collapsed and reported by gender. In order to predict change in body weight during weight maintenance, a stepwise regression was performed using factors that

may affect change in weight such as, FV, PA, and steps. All statistical procedures were performed using PC-SAS (version 8.2, SAS Institute, Inc., Cary, NC). The level of significance was set at 0.05 for all statistical tests.

## RESULTS

### Participants

A total of 157 participants were enrolled in the study. At 16 weeks, 61 women and 25 men were randomized to receive meal replacements and 46 women and 15 men were randomized to receive medication (Fig. 1). A total of 92 participants completed all testing and clinic measures. Characteristics of the completers at 16 weeks are presented in Table 1. There were no baseline differences in age, body weight, height, or BMI between groups or when groups were analyzed by gender ( $p > 0.05$ ).

### Attrition and Adherence

Reasons for participant attrition included failure to comply with the study protocol, relocation, job-related conflicts, illness, and injury not related to the investigation. In general, adherence to the intervention was good for participants in both groups. However, the women averaged slightly below the prescribed number of meal replacements and medication. For women, the average number of meal replacements was 12.1 (86% of prescribed amount) per week and the average dose of Orlistat was 12.6 (90% of prescribed amount) pills per week. For men, the average number of meal replacements was 16.1 (>100% of prescribed amount) per week and the average dose of Orlistat was 13.4 (96% of prescribed amount) pills per week.

### Weight Loss

Participants achieved  $22.8 \pm 6.1$  and  $22.3 \pm 6.1$  kg weight loss during the initial 16 weeks for meal replacement and

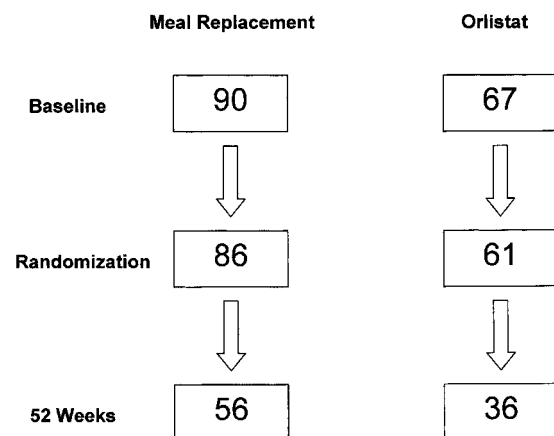


Fig. 1. Dropout by group and period.

**Table 1.** Group Characteristics for Women and Men at Randomization

	Women		Men	
	Meal Replacement (MR)	Orlistat	Meal Replacement (MR)	Orlistat
N	38	26	18	10
Age (y)	49.2 ± 8.7	52.9 ± 10.7	54.3 ± 8.4	55.2 ± 11.6
Weight (kg)	80.3 ± 13.3	81.0 ± 17.1	93.1 ± 12.5	99.5 ± 13.6
Height (cm)	164.9 ± 6.4	165.3 ± 5.8	177.5 ± 5.4	179.6 ± 5.5
BMI (kg/m <sup>2</sup> )	30.4 ± 5.6	29.9 ± 9.8	31.0 ± 4.4	32.5 ± 4.8

All values are means ± SD.

Randomization occurred at week 16. There were no significant differences for MR vs. Orlistat by gender.

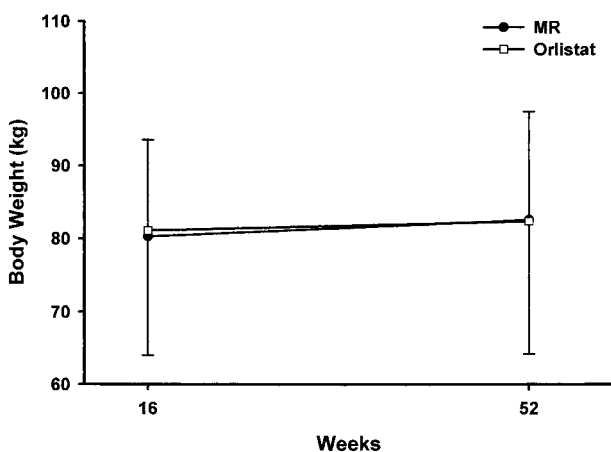
Orlistat groups, respectively. Between group differences for weight loss were not significant ( $p > 0.05$ ). During the first 16 weeks, women decreased their body weight from  $101.6 \pm 17.1$  kg to  $80.6 \pm 14.8$  kg ( $p < 0.05$ ) and men decreased their weight from  $121.8 \pm 16.0$  kg to  $95.4 \pm 13.0$  kg ( $p < 0.05$ ). This was equivalent to a 21% decrease in initial body weight for women and a 22% decrease in initial body weight for men.

### Weight Maintenance

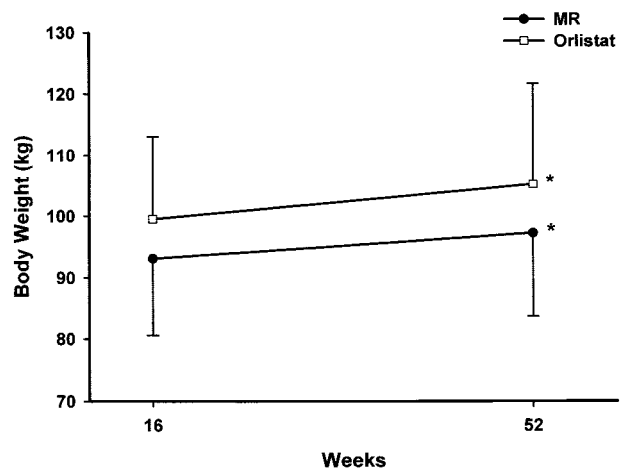
At randomization (week 16), there was no significant difference in body weight between the meal replacement and Orlistat groups. The meal replacement group had a body weight of  $85.4 \pm 14.3$  kg at week 16 that increased to  $88.1 \pm 16.5$  kg at 1 year ( $p < 0.05$ ). The Orlistat group had a body weight of  $85.7 \pm 17.9$  kg at week 16 that increased to  $88.5 \pm 20.3$  kg at 52 weeks ( $p < 0.05$ ). However, there was no significant group\*time interaction for body weight ( $p > 0.05$ ) indicating no difference in weight change between the two treatment groups during weight maintenance (weeks 16–52). Fig. 2 shows that in women body weight increased by 2.3 kg (2.9%) in the meal replacement group and by 1.3 kg (1.6%) in the Orlistat group during weight maintenance but these changes

were not statistically significant ( $p > 0.05$ ). For the women in the meal replacement group, body weight at week 52 was 18.9% below baseline body weight and for the Orlistat group 18.7% below baseline body weight. Fig. 3 shows that in men, body weight significantly increased by 4.1 kg (4.4%) in the meal replacement group ( $p < 0.05$ ) and 5.7 kg (5.7%) in the Orlistat group ( $p < 0.05$ ) during weight maintenance. For the men in the meal replacement group, body weight at week 52 was 18.0% below baseline body weight and for the Orlistat group 17.3% below baseline body weight. After collapsing the data across treatment groups and analyzing by gender, body weight during weight maintenance increased significantly in men ( $p < 0.05$ ) by 4.9% and increased by 2.4% in women though the increase was not significant.

There was no significant group\*time interaction for PA, FV, and steps during weight maintenance ( $p > 0.05$ ) indicating no differences between the meal replacement and Orlistat groups for these variables. Additionally, analysis of treatments by gender revealed no statistical difference in PA, FV, and steps for women or men of both groups across the duration of weight maintenance ( $p > 0.05$ ) (Table 2). Regression analysis showed that PA, FV, and steps did not significantly predict weight



**Fig. 2.** Body weight change in women during weight maintenance. There was no significant difference for MR vs. Orlistat between groups or across time. MR = meal replacement group.



**Fig. 3.** Body weight change in men during weight maintenance. There was no significant difference for MR vs. Orlistat. \*Indicates a significant difference across time ( $p < 0.05$ ). MR = meal replacement group.

**Table 2.** PA, FV, and Steps during the Weight Maintenance

	Women (64)			Men (28)		
	Week 16	Week 26	Week 52	Week 16	Week 26	Week 52
PA (min)	297 ± 158	274 ± 117	235 ± 135	256 ± 100	288 ± 122	312 ± 140
FV (serv)	32 ± 10	38 ± 9	36 ± 8	30 ± 12	43 ± 19	44 ± 19
Steps	64745 ± 26749	66301 ± 28464	58662 ± 26512	70476 ± 30410	64063 ± 28498	67303 ± 24040

All values are weekly means ± SD.

No superscripts indicate non-significance by gender.

PA = physical activity, serv = servings fruit and vegetables.

change during the weight maintenance period for either treatment group or by gender.

### Body Composition and Anthropometrics

Participants in both treatment conditions followed similar trends for body composition and anthropometrics. At 26 weeks, BMI, body fat percentage, fat-free mass, hip, and waist circumference decreased for both groups with no further change at 52 weeks. However, no between group differences were observed at baseline, 26 weeks, and 52 weeks ( $p > 0.05$ ). Table 3 shows that BMI, body fat percentage, fat-free mass, hip, and waist measurements followed similar trends for women and men. For each measurement, both women and men tended to increase from 26 weeks to 52 weeks; however, changes were not statistically significant.

### Adverse Events

Forty-one % of participants reported gastrointestinal problems related to the medication. Flatus was reported in 46% of those with adverse events, diarrhea 31%, oily spotting 23%, abdominal pain 15%, and unspecified 8%. No adverse events for the meal replacement group were reported.

## DISCUSSION

Although most individuals can lose weight, prevention of weight regain remains difficult. FDA approved medications

have shown increased weight maintenance compared to standard meal plans and behavioral therapy, but these medications may have undesirable side effects [14,20]. We used Orlistat in this study as it does not act centrally and is not associated with increases in blood pressure. Orlistat acts by blocking the absorption of approximately 30% of consumed dietary fat and has well known side effects [21]. In contrast, meal replacements have no known side effects and emerging data have shown they may be part of an effective strategy in weight loss compared to standardized meals plans.

It is well-documented that a VLED is effective in producing significant weight loss [22,23]. A VLED is motivating for many individuals due to the rapid weight loss experienced by a large proportion of individuals who use this diet. Unfortunately, benefits incurred from weight loss disappear with weight regain [7]. The main finding of this investigation was that subsequent to substantial weight loss by VLED, there was no difference in weight between participants receiving meal replacements and Orlistat at 52 weeks. However, we found that the women in both treatment groups maintained their weight whereas the men of both groups significantly increased their weight after 52 weeks indicating a potential gender difference in response to these treatments.

Five to ten percent weight loss or greater is believed to confer health benefits [24]. In the present study, the women maintained their weight loss, within  $2.3 \pm 5.8$  kg and  $1.4 \pm 4.3$  kg at week 52 for the meal replacement and Orlistat group, respectively. The men maintained their weight loss within  $4.0 \pm 5.3$  kg and  $5.7 \pm 7.1$  kg at week 52 for the meal replacement and Orlistat group, respectively. At week 52,

**Table 3.** Body Composition Measures across the Duration of the Study

	Women (64)			Men (28)		
	Baseline	Week 26	Week 52	Baseline	Week 26	Week 52
BMI (kg/m <sup>2</sup> )	36.7 ± 5.4 <sup>a</sup>	28.8 ± 4.9 <sup>b</sup>	30.2 ± 5.5 <sup>b</sup>	37.8 ± 4.9 <sup>a</sup>	30.1 ± 4.1 <sup>b</sup>	31.6 ± 4.5 <sup>b</sup>
Fat (%)	52.0 ± 4.6 <sup>a</sup>	41.5 ± 7.4 <sup>b</sup>	43.1 ± 7.9 <sup>b</sup>	40.0 ± 6.0 <sup>a</sup>	28.5 ± 8.9 <sup>b</sup>	32.0 ± 8.3 <sup>b</sup>
FFM (kg)	47.6 ± 6.5 <sup>a</sup>	44.9 ± 4.9 <sup>b</sup>	45.5 ± 5.3 <sup>b</sup>	69.9 ± 9.5 <sup>a</sup>	65.4 ± 5.7 <sup>b</sup>	65.4 ± 5.3 <sup>b</sup>
Waist (cm)	102.5 ± 12.8 <sup>a</sup>	87.8 ± 11.8 <sup>b</sup>	89.8 ± 12.6 <sup>b</sup>	120.1 ± 10.1 <sup>a</sup>	100.6 ± 12.6 <sup>b</sup>	103.6 ± 12.6 <sup>b</sup>
Hip (cm)	129.5 ± 12.1 <sup>a</sup>	111.1 ± 12.0 <sup>b</sup>	114.0 ± 13.0 <sup>b</sup>	124.6 ± 11.8 <sup>a</sup>	110.3 ± 10.3 <sup>b</sup>	113.8 ± 11.8 <sup>b</sup>

All values are means ± SD.

Different lettered superscripts indicate significant differences across time by gender ( $p < 0.05$ ).

FFM = fat-free mass.

women and men had an average weight 18.8% and 17.8% below baseline values, respectively. Thus, the women and men of both groups maintained a weight loss believed to be consistent with improved health.

Medication has been shown to be effective for prevention of weight regain compared to conventional diets [25]. Differences for weight gain between medication and conventional diets range from 3% to almost 30% [26]. The mechanism of action for the medication we chose (Orlistat) is well documented and includes inhibition of pancreatic lipase as well as possible alterations in behavior due to the potential side effects that may lead to social embarrassment [21]. In the present study, approximately 41% of participants reported gastrointestinal problems related to the medication whereas others have reported slightly higher frequency of adverse events [14,27]. Various studies have indicated that gastrointestinal adverse effects occur more frequently with Orlistat when compared to placebo [15,16]. As a result, the effect of Orlistat may be blunted by patients intending to limit adverse effects of the drug. Halsted et al. have suggested that participants taking Orlistat may attempt to avoid unwanted side-effects associated with consuming high amounts of fat while taking the medication by reducing fat intake or increasing the amount of carbohydrate intake [28]. Additionally, participants may avoid taking Orlistat if a fatty meal is consumed.

Meal replacements do not have documented side effects and may aid weight maintenance by reducing energy through diminished portion sizes and fat content. Heymsfield et al. [18] have suggested that the use of meal replacements may decrease the stress of ad libitum food selections associated with traditional food diets and they allow participants to learn and control appropriate portion sizes. In addition, they are relatively inexpensive, convenient, and palatable [18]. Wing and Jeffrey suggested that those using meal replacements may have improved behavioral compliance and increased nutritional knowledge [29]. In addition, meal replacements are easy to prepare, appear to be safe with no adverse events, and require minimal time for professional intervention [30].

A low fat diet and PA may contribute to successful weight maintenance [9,31]. In the present study FV intake was an important part of participants structured meal plan that incorporated a low fat diet. Likewise, moderate PA was an essential component of the study. Compliance to the study protocol for consumption of FV and PA was good and was similar for both groups. We recognize the potential influence of FV intake and PA for weight maintenance. However, in our study, there was little variation for FV and PA since these were mandatory components and this is likely why we found no relationship for weight maintenance.

Since this was an efficacy study, non-compliant participants, and those without complete laboratory data were terminated from the investigation and analysis. Of those that were randomized, approximately 33 percent did not complete the study after 52 weeks. The 1 year attrition rate of the present

study is similar to other investigations [32,33]. We recognize that this was not an effectiveness study and that application of the results to the general population will require help from behavioral scientists to encourage adherence to long-term interventions that become a part of an individual's lifestyle and can be maintained indefinitely.

## CONCLUSION

In combination with a behavioral weight management program, we found meal replacements to be as effective for weight maintenance when compared to Orlistat. Considering the potential for side effects and the additional expense with Orlistat, meal replacements appear to be a viable alternative for weight maintenance.

## ACKNOWLEDGMENT

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