Research Article

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Efficacy of a Meal Replacement Diet Plan Compared to a Food-based Diet Plan after a Period of Weight loss: a Randomized Controlled Trial

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Background

Obesity is a chronic, complex, multifactorial disorder that has reached epidemic proportions in the United States [1]. Currently, an estimated 66% of the population is categorized as overweight or obese, and 32.2% obese [1,2]. Obesity is associated with an increased risk of morbidity and mortality secondary to complicating conditions that include heart disease, diabetes, cancer, asthma, sleep apnea, arthritis, reproductive complications, and psychological disturbances [3]. Moreover, obesity is associated with greater degrees of inflammation and oxidative stress, which have recently been shown to underlie many chronic conditions, from cardiovascular disease and cancer, to metabolic syndrome and nonalcoholic fatty liver disease, to neurodegenerative diseases, like Parkinson's disease [4,5-7]. Given the prevalence of obesity, its harmful consequences on human health, and the lack of effective treatment options, meal replacement diet plans represent a viable strategy for controlling weight and positively impacting health outcomes.

Results of previous research demonstrate the safety and efficacy of meal replacements for weight loss and weight maintenance among overweight and obese individuals [8]. Evidence has shown that dietary interventions utilizing meal replacements result in greater weight loss better compliance, are more likely to ensure adequate intake of essential nutrients, and demonstrate higher satisfaction and lower drop-out rates compared to other diets [8-12].

Previous studies have also found improvements in biochemical markers over both the short-term (3-months) and the long-term (≥ 27 months) when meal replacements were used as part of a hypocaloric diet. More recently, meal replacement diet plans have been shown to improve levels of C-reactive protein, a biomarker of systemic inflammation [13-17]. Increased body weight, percent body fat, and waist circumference have been positively correlated with levels of C-reactive protein [18]. Individuals categorized as overweight (BMI: 25-29 kg/m^2) have been shown to have higher levels of CRP compared to lean individuals BMI (<25 kg/m^2) [19]. Elevated levels of CRP are associated with an increased risk for insulin resistance, endothelial dysfunction, oxidative stress, and cardiovascular events [20-22]. Calorie-restricted weight loss has been shown to decrease CRP concentrations [16,17,22]. The loss of body weight, particularly around the abdomen, may lower the risk of chronic diseases like cardiovascular disease by dampening systemic inflammation and reducing levels of oxidative stress [4,5,23].

Thus, several lines of evidence suggest that hypocaloric meal replacement diet plans may be an effective strategy for fostering weight loss, ensuring compliance, and improving health outcomes in today's obesigenic environment. We therefore sought to evaluate the impact of a previously untested portion-controlled meal replacement diet plan on body weight and body composition compared to an isocaloric, food-based diet plan during a 12-week period of weight loss. Given the scarcity of existing research evaluating the impact of meal replacements on inflammation and oxidative stress, these biomarkers were also collected as secondary outcomes.

Methods

Data Collection Procedures

Participants were obese (BMI > 30.0 kg/m^2 ≤ 50.0 kg/m^2) men and women aged 18-65 who were interested in weight loss, but not actively involved in a weight loss program or losing weight. Some optifast meal replacements contain soy, wheat, gluten and nuts so we ensured participants had no known allergies to these ingredients. To avoid the potential effects on calorie intake and compliance, participants consumed ≤ 14 alcoholic beverages per week and agreed to avoid alcohol intake during the study. Participants were not currently using appetite-affecting medications [e.g selective serotonin reuptake inhibitors (SSRIs), steroids, Ritalin], and were not pregnant or lactating. Participants were required to have the permission of their primary care provider to enroll in the study.

Measurements of height, weight, waist circumference (WC), blood pressure, pulse, and body composition using bioelectrical impedance (BIA) were collected. Data on general demographics, medical history, weight history, alcohol and cigarette use, exercise, eating habits, and sources of stress were collected.

Intervention

Participants were randomly assigned to follow one of two hypocaloric (providing less than estimated calorie needs as determined by the Mifflin-St. Jeor equation) weight loss plans for a time period of 12-weeks: the optifast utilizing portion-controlled meal replacements

or an isocaloric food-based plan (FB) using guidelines from the USDA Food Guide Pyramid, both providing ~1000 kilocalories (kcal) per day. At the baseline visit, a registered dietitian reviewed the dietary intervention each participant was randomized to. Members of the study staff and study participants were not able be blinded to the type of diet, though participants received identical interventions and staff attention.

The intervention diet plan (optifast) included 3 meal replacements (120-150 kcal/each), 5oz lean protein, 2 cups of non-starchy vegetables, and up to 1 fat servings daily (providing 800-1000 kcal). The meal replacements used in this study were low fat, low glycemic index (GI), low sugar, provided a balanced ratio of carbohydrates to proteins, and were either soy and/or whey protein based. The FB plan included 3 ounces of grains, 1 cup of vegetables, 1 cup of fruit, 2 cups of milk, 5-7 ounces of lean protein, and 3 teaspoons of fat daily (providing ~1000 kcal/day). The FB group was also instructed to take a multivitamin and additional calcium to ensure micronutrient needs were met while following a low-calorie meal plan. Vitamin and mineral fortification of the Optifast meals precluded the need for additional supplementation in the OF group.

Physical activity above normal daily activities was not a requirement for participation in the study. 45 minutes of exercise per day above normal daily activities, is the recommended maximum. This same guideline was recommended to the FB group during the weight loss phase. Each participant met with a dietitian bi-weekly during the 12-week weight loss phase for dietary and behavioral counseling. Five different dietitians were used to counsel subjects. Each dietitian had subjects from both groups and reviewed identical information with each subject. Every effort was made to have the subjects see the same dietitian throughout the study; however, it was made clear at screening and throughout the study that an alternate dietitian could be requested for any reason until a suitable match was found. At each visit, all participants were provided a self-study module focusing on a behavioral component of weight loss (e.g. stress management).

Measurements

Baseline measures for weight, blood pressure, waist circumference (WC), and body composition [percent body fat, lean muscle mass (LMM) and visceral fat rating (VFR)] were obtained. Bioelectrical impedance (BIA) was used to determine body composition. VFR was determined by an algorithm based on BIA results that generates a rating - the amount of visceral fat itself is not measured. The range for the VFR is 0-59 with a healthy level of visceral fat receiving a rating of 0-12 and an excess level of visceral fat receiving a rating of 13-59. Weight and blood pressure were measured bi-weekly during the 12-week weight loss phase. WC and body composition were measured at weeks 4, 8 and 12.

Statistical Analysis

To have a 90 percent chance of detecting a 2% difference between the two diet groups in percentage of initial body weight lost at 12 weeks, with an assumed standard deviation of 5% and a noncompletion rate of 30%, 90 participants were required to be randomized (2 sided, $\alpha = .05$) to one of the two groups.

Between group differences in demographic, anthropometric and biochemical variables were investigated using χ^2 for categorical variables and non-parametric tests for continuous variables (e.g., Mann-Whitney U). Non-parametric tests were used due to the non-normal distribution of the sample's data for most outcome variables. To examine bivariate longitudinal changes, Wilcoxon signed-rank tests were employed. Random effects logistic regression models were used to examine the association between diet group and outcome variables (i.e., anthropometric and biochemical indices while controlling for confounding variables). Random effects regression allows for a subject-specific interpretation, and adjustment for excess between-individual heterogeneity. Where results did not differ between bivariate t-tests and random effects analyses, only t-test results are shown. Significance was defined as $p < 0.05$. Analyses were conducted using SPSS Version 15 and Stata Version 10 [24,25].

Results

Subjects

Of the 90 eligible participants (OF = 45, FB = 45) who began the diet, 48 (53%) completed the 12-week active weight loss phase. These included 28 of 45 (62.2%) randomized to the OF group and 20 of 45 (55.6%) randomized to the FB group ($\chi 2 = 2.857$, df = 1, $p = 0.091$). There were no significant adverse events in either group.

Weight

After the 12-week active weight loss phase, weight loss among completers averaged 12.3% (13.5 ± 5.9 kg) on the OF versus 6.7% (6.5 ± 6.8 kg) on the FB ($p = 0.001$). Twenty-six of 28 (92.9%) OF participants, lost ≥ 5% of their initial body weight at 12 weeks, versus 11 of 20 (55.0%) FB participants ($\chi^2 = 9.47$, df = 1, $p = 0.002$). 21 of 28 (75%) OF participants lost ≥ 10%, versus 5 of 20 (25%) FB participants ($\chi^2 = 11.75$, df = 1, $p = 0.001$). Over the12 weeks of active weight loss, BMI reduced from 38.5 to 33.8 kg/m^2, an average decrease of 12.3% for the OF, and from 37.8 to 34.7 kg/m^2, an average decrease of 6.7% for FB participants, representing a significant between group difference (Mann-Whitney U = 125, Z = -3.24, $p = 0.001$).

Body Fat Percentage and Lean Muscle Mass

During the 12-week weight loss phase, body fat % among the OF group decreased by a mean of 5.6%, representing a 13.6% reduction from baseline ($Z = -454$, $p < 0.0001$), whereas the FB group experienced a nonsignficant average decrease of 1.5%, representing a 2.7% reduction from baseline ($Z = -1.107$, $p = 0.27$). The between group difference for body fat % was statistically significant (Mann-Whitney U = 102.5, $Z = -3.605$, $p < 0.0001$). Lean Muscle Mass as a percent of total weight was significantly increased from baseline to Week 12 in the OF group (from 54.1% to 59.3%; $Z = -427$, $p < 0.0001$), whereas the FB group did not experience any significant change ($Z = -0.97$, $p = 0.332$). This difference was significant between groups ($p < 0.0001$).

Waist Circumference and Visceral Fat Rating

During the 12-week weight loss phase, WC decreased by a mean of 13.0 cm (11.2%) in the of group and 7.8 cm (6.8%) in the FB group ($p = 0.003$ and $p < 0.0001$, respectively). Visceral fat rating (VFR) was significantly reduced in the OF group, from a mean of 13.8 ± 3.8 at baseline to 10.6 ± 3.5 at 16 weeks, an average 25.4% reduction ($Z = 4.315$, $p < 0.0001$), while the FB group experienced an average marginal decrease of 3.7% ($Z = 1.743$, $p = 0.081$). This difference between group was significant (Mann Whitney U = 79, $Z = 3.948$, $p < 0.0001$).

Blood Pressure and Pulse

After the 12-week weight loss phase, both groups experienced

statistically significant declines in both systolic and diastolic blood pressure. The OF group lowered systolic blood pressure by a mean of 10.9 mmHg (8.5%) versus 9.2 mmHg (7.1%) for the FB group ($p < 0.0001$ and $p = 0.003$, respectively). For diastolic blood pressure, the OF group experienced a mean 6.5 mmHg (7.6%) decline, versus a 5.2 mmHg (5.7%) decline for the FB group ($p = 0.001$ and $p = 0.016$, respectively). Both groups had significant decreases in pulse; a 10.7% reduction in the OF group ($Z = -3.427$, $p = 0.001$) and a 5.7% reduction in the FB group ($Z = -2.538$, $p = 0.011$).

Discussion

Increasingly, meal replacement diet plans have been demonstrated to provide safe, effective, sustainable weight loss, and have also been shown to yield significant improvements in health outcomes [8,9,13-15]. Nutrient rich, portion-controlled meal replacements are a strategic tool that may assist dieters as they navigate the obesigenic environment by providing a convenient alternative to over-sized, high fat, empty calorie choices [23]. For these reasons, this study sought to evaluate the impact of a portion-controlled meal replacement diet plan on body weight and body composition compared to an isocaloric, food-based diet plan for a 12-week period of weight loss.

Following a low-energy diet consisting of 3 meal replacements daily and one self-prepared meal (OF group) led to twice the weight loss at the end of 12-weeks compared to a food group prescribed the same number of calories based on food selection guidelines of the USDA Food Guide Pyramid. Clinically significant weight loss, as defined by the Institute of Medicine (IOM), is a loss of at least 5% of starting body weight in one year; 93% of participants following the OF diet compared to only 55% of the FB group achieved this in a 10-month time period. Moreover, a robust mean weight loss of 12.3% was observed among the OF group after 12 weeks, a magnitude many drugs currently used for obesity pharmacotherapy do not achieve [26-28].

Significant improvements in body composition were also observed in the OF group compared to the FB group after 12 weeks of weight loss. OF participants lost five times more body fat and seven times more visceral fat, while maintaining more than twice the amount of lean muscle mass. Maintenance of lean muscle mass during weight loss on a hypocaloric diet is an important difference between the meal replacement diet plan under study and other weight loss plans [29]. Sustaining lean muscle mass is a crucial mechanism for maintaining weight loss, as muscle provides a higher contribution to resting metabolic rate (RMR) than does fat [30-32]. A likely explanation for the favorable body composition changes observed in the OF group is the macronutrient composition (low fat, low carbohydrate, higher protein) of the meal replacements, which is difficult to achieve without significant planning when dieters self-prepare meals.

A possible factor contributing to the greater overall effectiveness for initial weight loss on the meal replacement diet plan studied is ease of use for the end-user, leading to enhanced compliance with the diet plan. Better adherence to the diet using meal replacements has been shown over both the short-term and long-term] as well as among subgroups of individuals, such as those with type 2 diabetes, who are often challenging in terms of compliance and achievement of weight loss [8,9].

Conclusion

In conclusion, we found that a meal replacement diet plan of a fixed macronutrient composition yielded clinically significant weight loss for 93% of obese participants. This is roughly twice as much as the rate demonstrated in controlled clinical trials of currently approved pharmacologic agents for obesity treatment [28]. Also, the intervention with meal replacements yielded changes in body composition that favorably impacted many cardiovascular health outcomes. Our data suggest that the meal replacement diet plan evaluated is an effective strategy for producing robust initial weight loss and for achieving improvements in a number of health parameters during weight maintenance, including inflammation and oxidative stress, two key factors recently understood to underlie our most common chronic diseases.

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