Real-World Effectiveness of a Medically Supervised Weight Management Program in a Large Integrated Health Care Delivery System: Five-Year Outcomes

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ABSTRACT

Context: There are insufficient data on the long-term, nonsurgical, nonpharmacologic treatment of obesity.

Objective: To determine changes in weight over 5 years in participants enrolled between April 1, 2007, and December 31, 2014, in a medically supervised weight management program at Kaiser Permanente Northern California Medical Centers. The program consisted of 3 phases: Complete meal replacement for 16 weeks; transition phase, 17 to 29 weeks; and lifestyle maintenance phase, 30 to 82 weeks.

Design: Retrospective observational study of 10,693 participants (2777 available for analysis at 5 years); no comparator group.

Main Outcome Measures: Average change in weight from baseline to follow-up.

Results: Average age was 51.1 (standard deviation = 12.4) years, and 72.8% were women. Average baseline weight in the entire cohort was 112.9 kg (standard error [SE] = 0.23). Weight (kg) significantly changed over time: 4 months, -17.3 (SE = 0.12); 1 year, -14.2 (SE = 0.12); 2 years, -8.6 (SE = 0.14); 3 years, -6.9 (SE = 0.17); 4 years, -6.5 (SE = 0.16), and 5 years, -6.4 (SE = 0.29); $p < 0.0001$). In those with 5-year follow-up, weight loss between 5.0 and 9.9% below baseline occurred in 16.3% (SE = 0.004, 95% CI = 15.3% - 17.2%) and weight loss of 10.0% or more of baseline occurred in 35.2% (SE = 0.01, 95% CI = 33.6% - 36.7%).

Conclusion: The average weight change of obese adults who participated in a medically supervised weight management program, with available 5-year data, was a statistically and clinically significant 5.8% weight loss from baseline.

INTRODUCTION

Obesity increases the risk of type 2 diabetes mellitus, hypertension, hyperlipidemia, coronary artery disease, and other chronic diseases. It correspondingly raises the risk of all-cause mortality and cardiovascular mortality.[1] The 2009 US National Health and Nutrition Examination Survey demonstrated that approximately 80 million adults age 20 years or older were obese, with a slightly higher female preponderance (41% women vs 38% men),[2] making obesity a dominant contributor to the nation's public health decay. Moreover, the societal economic costs, in 2008 dollars, were an astounding $147 billion.[3] It is therefore imperative that accountable care organizations and others strive to meet the obesity epidemic using creative and thoughtful methods.

A US Congressional review in 1990 highlighted the need for formal evaluation of the effectiveness of weight management programs[4] because of rampant false advertising during that time. An appraisal of studies conducted during that period points to their limited scope and applicability to modern practice owing to small sample sizes and large losses to follow-up.[5-7] More recent, well-conducted systematic reviews have continued to yield a paucity of information supporting the long-term effectiveness of nonsurgical, nonpharmacologic, weight management programs affecting clinically significant weight loss[8,9] defined as 5% weight loss or greater from baseline.[1]

In January 2002, the Kaiser Permanente Care Management Institute in Oakland, CA, launched a weight management and obesity initiative to tackle pressing issues surrounding obesity care within the organization.[10,11] In response to this and other perceived needs,[12] several of the study authors (RA, MO, BK, WS, SP), along with contributions from the leadership team, initiated a medically supervised weight management program (MSWMP) across Kaiser Permanente Northern California (KPNC) Bay Area Medical Centers. The MSWMP was initially started at four medical centers (San Jose, CA; Sacramento, CA; Fremont, CA; and Oakland, CA) in 2007, with the primary aim of improving long-term weight management outcomes for KPNC members. The program was designed to include an initial period of complete meal replacement therapy along with a behaviorally based lifestyle modification curriculum that aimed to enhance weight loss, with the exclusion of pharmacologic agents.

The current report is an evaluation of the effectiveness of the MSWMP on weight loss and lipid changes in KPNC Medical Centers during a five-year period. We used a retrospective, cohort study design to determine the average short-term and long-term weight loss and lipid concentration changes of participants in this program.

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METHODS

Overview of Weight Management Program

The goal of the program was to offer a long-term behavior management program, on a fee-for-service basis, to treat obesity in KPNC members. At the start of the current study, there were 21 programs across the Northern California Bay Area, with all locations following the same protocol to ensure consistency. Prospective participants were self-referred or referred by KPNC physicians. To be considered for the program, participants had to be age 18 years or older and have a body mass index (BMI) of 30 kg/m^2 or higher or a BMI of 28 kg/m^2 or higher with 2 or more comorbid conditions. Exclusion criteria included severe medical or mental illness, current malignancy, pregnancy or lactation, type 1 diabetes, active substance abuse, and unwillingness to participate in group meetings and physical activity.

An initial one-hour information session was mandatory before the program start. Interested participants were then screened (using chart review, clinic visits, laboratory data, and electrocardiograms) to ensure they met program criteria. The final decision to admit screened participants was at the discretion of the supervising medical director. Participants were then enrolled in the program after patient agreements, and informed consents were obtained.

Program Phases

The 82-week program was composed of 3 phases: Complete meal replacement for 16 weeks; transition phase from 17 to 29 weeks; and lifestyle maintenance phase from 30 to 82 weeks. The duration of the program was based on a perceived need to extend behavioral treatment beyond the acute weight loss phase.[13,14] The active weight loss period consisted of complete meal replacement therapy, weekly closed-group behavior change sessions, and monthly medical and laboratory monitoring. The number of participants in the closed-group behavior change sessions was kept between 16 and 25. Most sessions were led by the same facilitator (educators trained to deliver guideline-based behavioral counseling), to ensure consistency.

The meal replacement phase was initiated in Week 2 of the program. The duration of the meal replacement phase was chosen on the basis of prior efficacy and safety data.[5,7,15,16] During this active weight loss phase (16 weeks), all participants were prescribed a minimum of 960 kcal/d (6 meal replacements per day). Most meal replacement products used were Optifast (Nestlé HealthCare Nutrition Inc, Florham Park, NJ) shakes (160 kcal) or soups (160 - 170 kcal). Robard bars (160 kcal, Robard Corp, Mount Laurel, NJ) were also used. Participants were expected to have a minimum of 4 Optifast meal replacement products with the option of the other 2 being Optifast products or Robard bars. Additional kilocalories were added for BMI above 40 kg/m^2 in a scaled manner.

Beginning Week 17, the transition to regular food was initiated. Meal replacement products were reduced by 1 every week until Week 20. By Week 21, all participants were expected to be off complete meal replacement or could continue using up to 3 partial meal replacements per day. The total caloric intake during this transition was gradually increased to approximately 1200 kcal/d. Additional kilocalories were added if BMI was 40 kg/m^2 or higher. Participants were expected to continue their attendance at weekly closed-group behavior change sessions during this period.

The maintenance (also called lifestyle) phase began at Week 31 and ended at Week 82. The focus at the weekly group behavior change sessions during this period was on attendance, accountability, and problem solving. During the maintenance phase, sessions were open to all participants who completed the initial 30 weeks. Furthermore, participants were strongly encouraged to participate in the weekly open-group sessions beyond 82 weeks.

Behavioral Intervention and Exercise Counseling

For the first 30 weeks, the group behavior change sessions were weekly, in-person, closed-group meetings conducted by trained facilitators with the specific purpose of aiding participants to change their eating and exercise behaviors. A closed group ensured that the same participants and facilitators stayed together for these first 30 weeks. Each session lasted between 60 and 90 minutes. From Weeks 31 to 82, meetings were open to all participants who had completed the first 30 weeks. These sessions were guided by the behavioral change framework originally described by Fisher and Fisher[17] in 1992, the information, motivation, behavioral skills model. The model, validated in other clinical scenarios,[18] was based on providing accurate information and motivation to initiate change, with the premise being that this will lead to acquisition of a self-management skill set that can lead to behavioral change over time. The topics of the behavioral sessions were focused on the appropriate caloric reduction needed for weight loss and the amount of physical activity needed for maintenance of weight loss. These were constantly reinforced along with strategies for long-term adherence. A set of SMART self-management skills (goal setting, self-monitoring, environmental control, social support, and reward/reinforcement) were also tailored to individual participants' unique situations.[19]

Participants were educated on targeted methods of physical activity, inclusion of exercise into daily routines, direct and indirect health effects of exercise, and exercise risk avoidance with strategies and techniques.[20] Exercise was defined as activity above the daily baseline activity. Participants were counseled on exercise methods and goals by the group facilitator, with a focus on increasing daily activity early in the program for the development of this behavior to become a long-term habit. Participants were also given the long-term goal of reaching 60 min/d to 90 min/d of exercise. The goal of 10,000 steps daily was reinforced during group sessions and quantified with use of a pedometer or equivalent means.[21-23]

Study Design and Population

This study was an observational, retrospective study of participants who were enrolled in the KPNC MSWMP between April 1, 2007, and December 31, 2014. Participants were followed up for five years or until they died. They were censored when they met any of the following criteria: End of the study follow-up period or disenrollment from the Health Plan (loss to follow-up). The study was approved by the Kaiser Foundation Research Institute's institutional review board. The requirement for informed consent was waived on the basis of the observational nature of the study because there was no contact with participants for study purposes.

The source population for the current study was made up of members of KPNC, a large prepaid integrated health care delivery system thought to be representative of the surrounding population.[24] The target population comprised of adults enrolled in the MSWMP who attended at least the first two weeks of the program.

Outcome Measures

The primary outcome was the average change in weight (in kilograms) from baseline to follow-up. The secondary outcome was the average change in lipid concentrations, specifically total cholesterol, triglycerides, and low-density lipoprotein (LDL)-cholesterol (all in milligrams per deciliter). Follow-up was obtained at four months and at one, two, three, four, and five years ± three months. Participant weights at baseline and follow-up were obtained using standard digital weighing equipment[25] and were captured using the KPNC electronic health records. Available lipid concentrations were captured using the KPNC electronic health records and the laboratory databases.

Primary Exposure and Baseline Covariates

The primary exposure was enrollment in the MSWMP. No control group was obtained for this study.

The baseline covariates collected were patient demographics, comorbidities (up to five years earlier), medications, and laboratory data (up to three months earlier). The baseline demographics collected for the current study included age at the time of enrollment, sex, race, BMI, and average neighborhood-level income. The baseline clinical comorbidities were obtained using International Classification of Diseases, Ninth Revision (ICD-9) codes. The comorbidities collected were the presence or absence of prediabetes, type 2 diabetes mellitus, hypertension, hyperlipidemia, liver disease, lung disease, myocardial infarction, congestive heart failure, ischemic stroke, hemorrhagic stroke, atrial fibrillation, sleep apnea, depression, and current tobacco use. Medication use was obtained electronically from KPNC pharmacy databases.

Statistical Analysis

Statistical analyses were performed using Stata Version 14 (StataCorp, College Station, TX). Descriptive statistics are presented using means and standard deviation [SD] for normally distributed continuous variables, median, and interquartile range for nonnormally distributed continuous variables, and proportions for dichotomous variables. For model-based estimations, we imputed missing data at baseline and follow-up using multiple imputation methods. We then used a linear mixed-effects model with unstructured covariance and a restricted maximum likelihood test option to assess the changes during the follow-up period. The model included a random intercept for each subject to address within-patient correlation of the repeated measures. Multivariable logistic regression analysis was then used to obtain the predictors of clinically significant weight loss at five years. We undertook several sensitivity analyses to assess whether any substantive variation was noted in effect sizes with and without the use of multiple imputation methods, as well as restricting analysis of five-year outcomes to only those participants who had both baseline and five-year weight data.

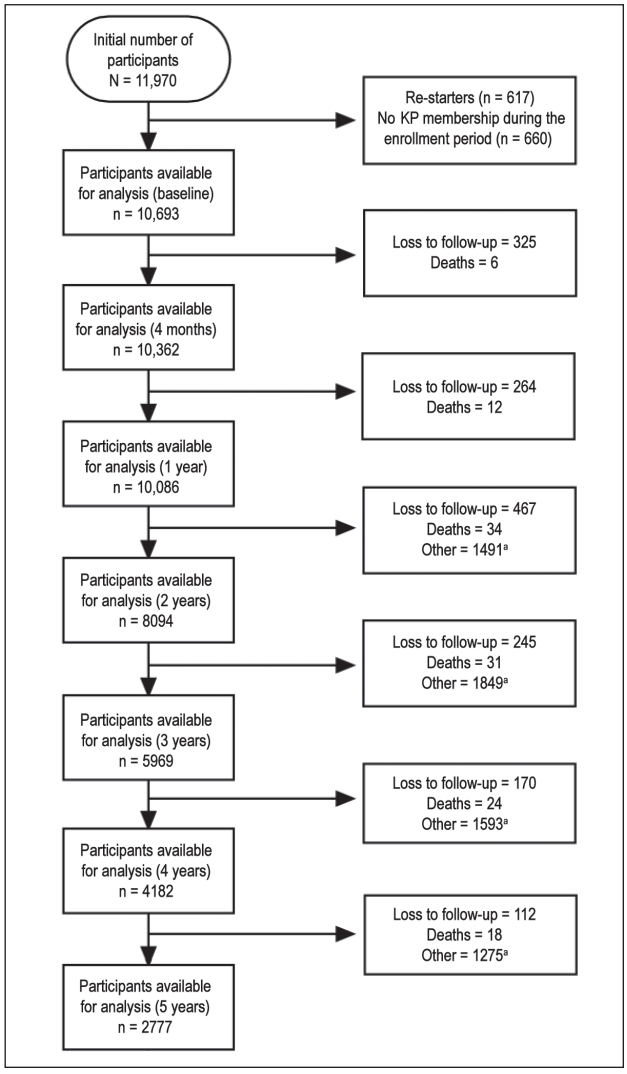

Figure 1. Flow diagram among participants of a weight management program across Kaiser Permanente (KP) Northern California Medical Centers.

[a] Other indicates participants who reached the end of the study before the specified period. For example, among 4182 participants who reached 4 years and who did not die or were not lost to follow-up between Years 4 and 5, the study ended before 1275 participants reached 5 years, and therefore they could not be counted at 5 years.

RESULTS

Patient Characteristics

An overview of patient entry into the study is shown in Figure 1. At baseline, the mean age was 51.1 [SD = 12.4] years, and the mean BMI was 39.7 [SD = 7.2] kg/m^2. White race (72.0%) and women (72.8%) represented most of the cohort. Approximately 42% had either prediabetes or diabetes mellitus, and 49.8% had a history of hypertension. Tobacco use was under 10% in the cohort. The median number of baseline comorbidities was 2, and the median number of baseline medications was 1 (Table 1). Baseline laboratory values of the weight management program participants are shown in Table 2.

Change in Weight

The average baseline weight in the entire cohort was 112.8 kg. The average weight change (in kilograms) at each point was clinically and statistically significant compared with baseline: 4 months (peak weight loss), -17.3 (standard error [SE] = 0.12); 1 year, -14.2 (SE = 0.12); 2 years, -8.6 (SE = 0.14); 3 years, -6.9 (SE = 0.17); 4 years, -6.5 (SE = 0.16); and 5 years, -6.4 (SE = 0.29; $p < 0.0001$]. The accompanying average percentage change from baseline is as shown: 4 months, -15.3%; 1 year, -12.4%; 2 years, -7.6%; 3 years, -6.2%; 4 years, -5.9%; and 5 years, -5.8% (Figure 2). Among participants with 5-year data, weight change between 5.0% weight loss from baseline to weight gain occurred in 48.5% (SE = 0.01, 95% confidence interval [CI] = 46.5% - 50.5%), weight loss 5.0 to 9.9% occurred in 16.3% (SE = 0.004, 95% CI = 15.3 - 17.2%), and weight loss 10.0% and greater occurred in 35.2% (SE = 0.01, 95% CI = 33.6% - 36.7%). The mean number of group behavior sessions attended was 35.1 ± 29.7, with a median of 29 (interquartile range = 29). The magnitude of short-term weight loss, number of group behavior sessions attended, and the number of baseline comorbidities were significantly associated with maintaining 5% or greater weight loss at 5 years (Table 3).

Table 1. Baseline demographics, comorbidities, and medication use among participants of a weight management program across Kaiser Permanente Northern California Medical Centers (N = 10,693)

Baseline variable	Value[a]
Demographics	
Age, mean (SD), years	51.1 (12.4)
Body mass index, mean (SD), kg/m^2	39.7 (7.2)
Average neighborhood income, mean (SD), dollars	66,683 (25,353)
Sex, %	
Women	72.8
Men	27.2
Race and ethnicity, %	
White	72.0
Black/African American	8.3
Latin American (Hispanic)	4.6
Asian/Pacific Islander	6.0
Other	9.1
Comorbidities, %	
Prediabetes	21.4
Diabetes mellitus	21.1
Hypertension	49.8
Hyperlipidemia	41.9
Liver disease	4.6
Lung disease	27.5
Myocardial infarction	1.0
Congestive heart failure	2.2
Ischemic stroke	0.7
Hemorrhagic stroke	0.2
Atrial fibrillation	3.0
Sleep apnea	13.9
Depression	10.7
Number of baseline comorbidities, median (IQR)	2 (2)
Tobacco use (current)	9.2
Medication use, %	
Angiotensin converting enzyme inhibitors	14.1
Angiotensin receptor blockers	9.9
β-blockers	19.8
Calcium channel blockers	10.3
Vasodilators	1.3
Statins	28.6
Diuretics	19.4
Warfarin	3.3
Oral antidiabetic medications	13.0
Insulin	6.1
Number of baseline medications, median (IQR)	1 (2)

[a] Missing values: age (1.0%), neighborhood-level income (15.0%), and baseline comorbidities (2.3%).
IQR = interquartile range; SD = standard deviation.

Sensitivity Analysis for Weight Changes

Sensitivity analyses were undertaken to assess the effect of multiple imputation, as well as limiting analyses to those with available baseline and 5-year weight data. There were no clinically substantive changes between the average weights at baseline and follow-up with or without the use of multiple imputation methods (data furnished on request). Restricting the analysis to only those who were not lost to follow-up, with available weight data at baseline and at 5 years (n = 2092) did not change the summary estimates substantially. The average weight loss at 5 years by this method was -6.7 kg compared with baseline ($p < 0.00001$). Last, we analyzed the differences in baseline characteristics between those with missing 5-year weight data and those without missing 5-year weight data. Participants with missing data were younger; less often white; and had no substantial clinical differences in baseline weight, blood pressure, or income. They represented a slightly healthier population as demonstrated by a lower prevalence of baseline comorbidities and medication use (data furnished on request).

Table 2. Baseline laboratory values among participants of a weight management program across Kaiser Permanente Northern California Medical Centers (N = 10,693)

Laboratory Test	Result[a]
Serum sodium, mg/dL	133.5 ± 28.8
Serum creatinine, mg/dL	0.8 ± 0.3
Glomerular filtration rate, mL/min	57.4 ± 11.7
Hemoglobin, g/dL	13.2 ± 2.8
Alanine transaminase, IU/L	24.5 ± 17.6
Aspartate transaminase, IU/L	20.6 ± 12.0
Total cholesterol, mg/dL	189.3 ± 38.3
Triglycerides, mg/dL	150.8 ± 94.3
HDL-cholesterol, mg/dL	49.6 ± 12.2
LDL-cholesterol, mg/dL	110.1 ± 32.9
Hemoglobin A_{1C}, %	6.3 ± 1.2

[a] Percentage with missing data: sodium, creatinine, glomerular filtration rate, hemoglobin, and alanine and aspartate transaminase (2.3%); total cholesterol (8.1%); triglycerides (8.3%); HDL-cholesterol (8.2%); LDL-cholesterol (8.2%); and hemoglobin A_{1C} (34.8%).
HDL = high-density lipoprotein; LDL = low-density lipoprotein.

Table 3. Predictors of weight loss of 5% or more from baseline at 5 years among participants of a weight management program across Kaiser Permanente Northern California Medical Centers

Variable	Odds ratio (95% CI), 5 years
Percentage difference in weight (baseline to 4 months)	1.04 (1.03-1.05)[a]
Weight management sessions (every 10 sessions)	1.03 (1.01-1.05)[a]
Number of comorbidities at baseline	1.06 (1.01-1.11)[a]
Women	1.02 (0.84-1.22)
Advancing age (every 5 years)	1.02 (0.99-1.05)
Median household income	0.98 (0.97-1.002)

[a] Indicates statistical significance ($p < 0.05$).
CI = confidence interval.

Change in Lipid Concentrations

Figure 3 demonstrates the model-based average percentage changes in lipids (total cholesterol, triglycerides, and LDL-cholesterol) and statin use during five-year follow-up.

DISCUSSION

This observational study of obese adults demonstrated the effectiveness of an 82-week, nonpharmacologic, nonsurgical, weight management program for short-term and long-term weight loss across 21 KPNC Medical Centers. We found that the average weight loss during the follow-up period was statistically and clinically significant. Most importantly, we found an average long-term weight loss of -5.8% from baseline at 5 years. In participants with 5-year data, the average weight loss in approximately half was -5.0% or greater weight loss with a third having, on average, -10% or greater weight loss compared with baseline. We found a significant association between the duration of participation in the program (every 10 weight management sessions attended was associated with a 3% increase in the odds of achieving clinically significant weight loss of -5% or greater at 5 years), along with the magnitude of 4-month weight loss, and the number of baseline comorbidities to long-term clinically significant weight loss of -5% or greater at 5 years. Last, significant lowering in all lipid concentrations was noted at 4 months, with triglyceride lowering seen throughout follow-up ($p < 0.0001$).

To our knowledge, there are no long-term studies of this scale evaluating the effectiveness of a real-world, nonsurgical, nonpharmacologic, behavior-based weight management program that included complete meal replacement at onset conducted either within or outside an integrated health care delivery system. Prior work has concentrated on the overall utility of weight management programs,[8] specific meal replacement programs such as Medifast (Medifast, Owings Mills, MD),[26] Optifast,[5,7] specific outcomes (weight, waist circumference, blood pressure),[26] and specific settings (routine clinical practice).[9] Despite this, our program participants were similar to other weight management cohorts described in the literature, consisting predominantly of middle-aged women with a low prevalence of baseline multimorbidity and medication use.

One meta-analysis of clinical trials performed in the context of usual care found that programs that offered meal replacements had a weight change of -6.8 kg at a follow-up of 1 to 2 years.[9] Another study of participants using liquid shakes and meal bars that replaced 2 meals and 2 snacks found that participants lost 7.1 kg in the first 3 months, and those who continued to replace 1 meal and 1 snack were noted to have a loss of 10.4 kg at 27 months.[20,27] Our program of an initial 16 weeks of complete meal replacement, using predominantly Optifast products, was relatively similar to a program described in 1997.[5] However, the overall sample size in the current study was larger (10,693 vs 621), with longer duration of the program (82 weeks vs 26 weeks), varied statistical analysis (current study using repeated-measure analysis and multiple imputation), and less loss to follow-up (14.8% loss to follow-up and 1.2% death vs 51.6% loss to follow-up). The overall short-term trends in weight outcomes were similar, but low sample sizes and substantial losses to follow-up rendered comparing long-term outcomes unfeasible.

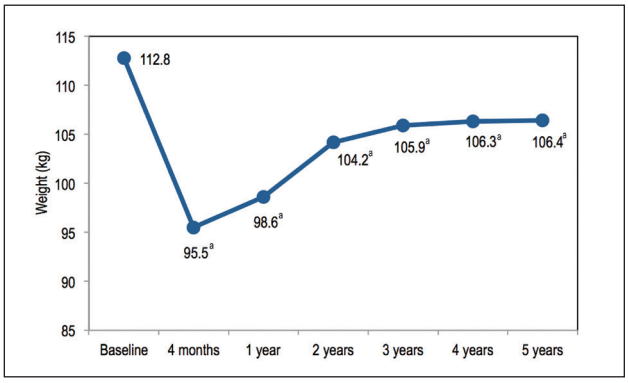

Figure 2. Average baseline and follow-up weights (kg) among participants of a weight management program across Kaiser Permanente Northern California Medical Centers.

[a] Statistically significant compared with baseline ($p < 0.05$). Graph shows the entire cohort after multiple imputation of baseline and follow-up weights and then fitting a linear mixed-effects model with unstructured covariance and a restricted maximum likelihood test option to assess the changes in weight during the follow-up period. The model included a random intercept for each subject to address within-patient correlation of the repeated measures. Standard errors of each estimate are shown and vary from 0.12 to 0.21 kg.

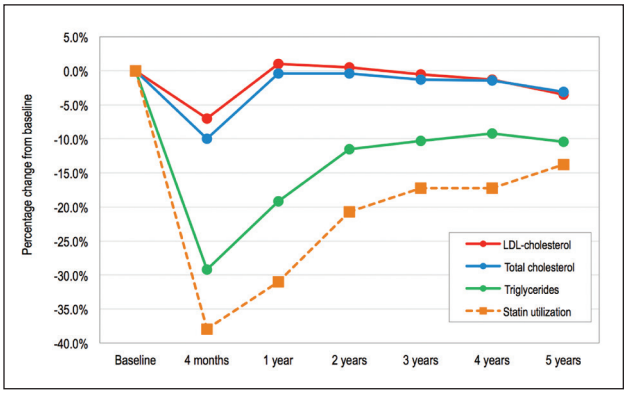

Figure 3. Average baseline and percentage change in lipid fractions and statin utilization during follow-up among participants of a weight management program across Kaiser Permanente Northern California Medical Centers.

LDL = low-density lipoprotein.

We noted in the current study that MSWMP participants lost an average of 17.3 kg at 4 months and 14.2 kg at 1 year. Although weight regain was noted after the initial 4 months, the average weight loss at 5 years continued to be clinically significant at -5.8%. We believe the reported 5-year weight loss was predominantly related to the magnitude of weight loss at 4 months because of initial complete meal replacement therapy, and because of the incremental number of group visits attended. We did not have data on the amount of participant meal replacement used to ascertain the role of long-term partial meal replacement.

The importance of behavior change in weight loss maintenance has been well documented in the literature. Traditionally, behavior modification sessions have been provided on-site and in groups of 10 to 20 participants. Group treatment has been reported to have a higher weight loss,[28] as well as providing social support and being cost-effective.[20,29] These groups are often led by registered dietitians or other health care professionals.[20,30] The length of treatment advocated has also varied, with longer-term support demonstrating a higher long-term weight loss. The results from our study are significant in that we demonstrated the strength of combining a long-term behavior change intervention with an initial meal replacement program in a large, well-developed, integrated health care delivery system. Behavioral interventions have adapted over time from solely in-person classes to the use of electronic media, social networks, and tracking applications. Our approach was in-person sessions provided by trained facilitators during the acute weight loss period and maintenance phases of the program.[1] Last, it is to be noted that our program captured most of the self-management and self-regulatory strategies that have recently been believed necessary for a comprehensive lifestyle modification program to achieve and maintain a -7% to -10% weight loss at 1 year or later.[20]

Prior studies of low calorie diet programs have usually had a comparator group and were often in the setting of a randomized clinical trial. They have described weight changes at 3 to 4 months and noted that the weight loss was between 4.8% and 22.1% favoring weight management programs. These studies were based on a sample size of approximately 300.[8] Our study demonstrated, on average, a 15.3% decrease in weight loss at 4 months. Furthermore, although the -5.8% weight loss at 5 years can be described as modest, this is one of the few studies that had the ability to describe a population of this size. A true nontrial-based control group, if present, we believe would have most likely shown no significant weight loss or perhaps weight gain,[9] because this is the basis of the obesity epidemic. Last, from a population health perspective, the average 5.8% decrease in weight that was achieved in our study is thought to be of sufficient magnitude to be epidemiologically associated with a decrease in mortality[31] and a decrease in the probability of the subsequent development of diabetes mellitus.[32] Future studies are needed to address whether medical weight management programs such as ours, if implemented on even larger scales, will affect population health and decelerate the rise in heart disease mortality attributed to obesity.[33]

The finding of weight loss and weight regain should not be a surprise. Our main analyses, using multiple imputation and repeated-measures regression, were comparable to findings from the intervention arm of the Look AHEAD (Action for Health in Diabetes) study, a large, well-run, randomized clinical trial.[34] Our sensitivity analyses further confirmed the findings, showing no substantive variation in the effect sizes. The rebound in lipid concentrations after acute weight loss also should not come as a surprise. Mehta et al,[35] in their systematic review of 27 trials, described changes in lipid concentrations during a 1-year period. They noted a 6-month change as follows: Total cholesterol, -0.8 to -12.3 mg/dL; LDL-cholesterol, -1.0 to -10.1 mg/dL; and triglycerides, +4.0 to -54.9 mg/dL. They reported a 1-year change of total cholesterol, +9.3 to -16.1 mg/dL; LDL-cholesterol, +13 to -14.9 mg/dL; and triglycerides, +1.0 to -60.0 mg/dL. Our study expanded on this and shows the changes in these 3 lipid concentrations during a 5-year period. We found that the maximum decrease in lipids occurred at 4 months, soon after the complete meal replacement phase. Peak decrease in total cholesterol was -19.0 mg/dL, triglycerides was -44.1 mg/dL:, and LDL-cholesterol was -7.7. mg/dL. The decrease during 5 years in the triglyceride fraction of the lipids was most noticeable. What others have not shown was the accompanying changes in utilization of medications such as statins.

A major strength of the current study is that the cohort is one of the largest followed in a behaviorally based MSWMP. We were able to collect long-term weight data on a reasonable proportion of the cohort. Because the study was carried out in an integrated health care delivery system, measurements of weights were done in a standardized fashion.

An inherent limitation of this study is the observational, retrospective study design. We also did not have access to the exact number of meal replacement products used by program participants during the active phase and beyond, data that could have aided in a further understanding of long-term predictors of clinically significant weight loss. We did not collect data on the incidence of adverse events such as constipation, cholelithiasis, or abnormalities of liver enzyme levels in the current study. Last, the generalizability of this study and this fee-for-service program may be limited to participants with insurance in an integrated health care delivery system.

CONCLUSION

Participation of obese adults in a behaviorally based, nonsurgical, nonpharmacologic, medically supervised weight management program in a large integrated health care delivery system resulted in a maximum weight loss at 4 months of 15.3% from baseline. At 5 years, the average weight change from baseline was -5.8%, with approximately 50% of participants achieving -5% or more, which is clinically significant weight loss. Future analyses will attempt to address the effects of the program on blood pressure and health care utilization. ❖

Disclosure Statement

This study was supported by a grant from Nestlé HealthCare Nutrition Inc, Florham Park, NJ. The sponsor did not have access to the primary data; did not participate in data collection, analysis, or interpretation; and did not have a decision to submit the manuscript for publication.

The author(s) have no conflicts of interest to disclose.

Authors' Contributions

Ashok Krishnaswami, MD, the study supervisor, had full access to the study dataset and takes responsibility for data integrity and analysis accuracy; primary responsibility for study concept and design and statistical analysis and interpretation; wrote the initial draft of the manuscript; and obtained funding. Rohini Ashok, MD; Michael Okimura, MD; Wayne Smith, MD; Sheri Pruitt, PhD; and Beth Kramer, MBA, helped conceptualize and design the study and helped analyze and interpret the data. Stephen Sidney, MD, MPH, and Michael Sorel, MPH, assisted with data acquisition from Kaiser Permanente databases and with analysis and interpretation of data. Lindsey Hogan, MHSA, helped analyze and interpret the data. All authors read and approved the final manuscript.

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