Study Summary: 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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Objective: To determine changes in weight over 5 years in adults participants enrolled in the Kaiser Permanente Northern California (KPNC) behavior based medically supervised weight management program (MSWMP).

Background: Obesity increases the risk of type 2 diabetes mellitus, hypertension, hyperlipidemia, coronary artery disease and other chronic diseases, correspondingly raising the risk of all-cause mortality and cardiovascular mortality (1). While the use of comprehensive lifestyle medically supervised programs including meal replacements for weight loss is an evidence-based intervention (2), long-term weight maintenance after non-surgical, non-pharmacological weight loss is still insufficiently characterized (3).

<u>Materials and Methods</u>: Observational, retrospective cohort study in adults (\geq 18 y) with obesity (BMI \geq 30 kg/m2) or overweight (BMI \geq 28 kg/m2) with at least 2 comorbid conditions. Subjects included were members of KPNC between April 1, 2007 and December 31, 2014. The KPNC-MSWMP is a long-term behavior management program (82 weeks) that includes initial 16 weeks of total meal replacement (960 kcal/day – mainly OPTIFAST®) with behavioral intervention and medical monitoring. The primary outcome was the average change in weight (in kilograms) from baseline to follow-up. Secondary outcomes were average change in lipids concentrations (total cholesterol, triglycerides, LDL-cholesterol). Descriptive statistics are presented (means and standard deviation) and a linear mixed-effects model with unstructured covariance to assess the changes during the follow-up. Multivariable logistic regression analysis was used to obtain predictors of clinically significant weight loss at 5 years.

Results: 10693 participants were available for analysis at baseline, mean age was 51.1 [SD 12.4] years and 72.8% were women. Mean BMI at baseline was 39.7 [SD 7.2] kg/m2. At baseline 49.8% of subjects presented with hypertension, 41.9% with hyperlipidemia, 21.1% with diabetes and 21.4% with prediabetes.

Weight loss and weight maintenance: The average baseline weight in the entire cohort was 112.8 kg. The average weight change (in kg.) at each point was clinically and statistically significant compared with baseline (Table 1). Among participants with 5-year data,48,5% sustained clinically significant weight loss of \geq 5%, and 35.2% of \geq 10%.

A statistically significant reduction in all blood lipids concentrations was observed at 4 months, with triglycerides lowering seen throughout follow-up (p<0.0001).

The magnitude of short-term weight loss (at 4 months), number of group behavior sessions attended and number of baseline comorbidities were significantly associated with maintaining \geq 5% weigh loss at 5 years (Table 2)

Table 1. Average baseline and follow-up weight changes among participants of the KPNC-MSWMP

	Average weight/ weight change, Kg [SE]	Percentage change from baseline,
Baseline	112.8	0
4 months	- 17.3 [0.12]ª	- 15.3%ª
1 year	- 14.2 [0.12]ª	- 12.4%ª
2 years	- 8.6 [0.14]ª	- 7.6%ª
3 years	- 6.9 [0.17]ª	- 6.2%ª
4 years	- 6.5 [0.16]ª	- 5.9%ª
5 years	- 6.4 [0.29]ª	- 5.8%ª

^a p<0.05

Table 2. Predictors of weight loss of \geq 5% from baseline at 5 years among participants of the KPNC-MSWMP

Variable	Odds ratio (95% Cl), 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 conditions 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.

Conclusion: An 82-week medically supervised weight management program utilizing initial 4 months of total meal replacements and weekly group behavior changes sessions resulted in significant early and long-term weight loss. Average percentage weight loss after 4 months was 15.3% and average weight loss at 5 years remained both clinically and statistically significant (-5.8%; p<0.05). At 5 years approximately 50% of the participants achieved -5% or more, which is clinically significant weight loss. Results from the study reinforce the strength of a standardized long-term behavior change intervention plus an meal replacement program in subjects with obesity and overweight.

(1) Jensen MD, et al. 2013 AHA/ ACC/ TOS guideline for the management of overweight and obesity in adults: A report of the American College of Cardiology/ American Heart Association Task Force on Practice Guidelines and The Obesity Society. J Am Coll Cardiol 2014 Jul 1;63(25 Pt B):2985-3023 (2) Heymsfield Sbet al. Weight management using a meal replacement strategy: meta and pooling analysis from six studies. Int J Obes Relat Metab Disord. 2003 May;27(5):537–49 (3) Dombrowski S U, et al. Long term maintenance of weight loss with non-surgical interventions in obese adults: systematic review and meta-analyses of randomised controlled trials BMJ 2014; 348 :g2646

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