



## Improving maintenance of lost weight following a commercial liquid meal replacement program: A preliminary study



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### ABSTRACT

Clinic-based liquid meal replacement (800 kcals/day) programs produce substantial weight loss. Nevertheless, long-term maintenance remains a challenge. A limitation of maintenance programs is that they continue to promote large behavior changes that are initially required to induce weight loss which may be unsustainable long-term. The study aims were to conduct a preliminary assessment of the feasibility, acceptability, and effectiveness of a small changes maintenance intervention (SCM) for 30 patients who completed liquid meal replacement program (LMR). The 20-session SCM delivered over 52 weeks offered no preset goals for maintenance behaviors and all changes in behavior were self-selected. Participants had a median BMI of 40.9 kg/m<sup>2</sup> and weight of 111 kg at the start of LMR. At LMR completion, they lost 18% (21 kg) of body weight. The SCM was completed by 22 patients (73%); 19 completers (86%) attended  $\geq 17$  of 20 sessions with a median satisfaction rating of 9 (on a scale of 1 to 9). Completers were asked to record self-selected maintenance behaviors daily (median 351 days recorded). The most commonly reported daily behaviors were self-weighing, use of meal replacements and step counting. Median percent regain at week 52 was 14% (2.8 kg) of lost weight (range, –42 to 74%), significantly less than a median of 56% (11 kg) percent regain of lost weight (range, –78 to 110%) in a demographically similar historical control group with no maintenance intervention after LMR completion ( $P < 0.001$ ). Thus, SCM holds promise for improving weight maintenance. Future research should compare SCM to standard maintenance programs that promote large program-directed changes.

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### 1. Introduction

For patients with medically complicated obesity who lack access or the desire to have bariatric surgery, a commercial liquid meal replacement program (800 kcals/day) is a safe and effective method of promoting substantial weight loss (Hemmingsson et al., 2012; Saris, 2001; Tsai & Wadden, 2006). At minimum, a liquid meal replacement program (LMR) should provide medical monitoring, lifestyle education with a particular focus on the risk of weight regain without substantial effort to maintain lost weight, and a maintenance program (Hemmingsson et al., 2012; Wadden, Van Itallie, & Blackburn, 1990). In the short-term, LMR programs provide a significant advantage with regard to weight loss (15–25% of body weight) (Tsai & Wadden, 2005) over low-calorie diets that produce moderate weight loss of 5–10% of body weight (Hemmingsson et al., 2012; Saris, 2001; Tsai & Wadden, 2006). Moreover, research has shown that rapid initial weight loss with greater

calorie restriction is not associated with poorer long-term outcome (Casazza et al., 2013).

Nevertheless, long-term maintenance of lost weight remains a significant problem and more research is needed to determine the effectiveness of commercial weight loss programs in real-world setting (Hemmingsson et al., 2012). In the year following treatment, patients who do not participate in ongoing follow-up care are likely to regain 40–50% of lost weight (Anderson et al., 1994). Systematic reviews of long-term weight maintenance following LMR programs have shown a sustained reduction in body weight of 5–6% at 4 and 5 year follow-up (Anderson, Konz, Frederich, & Wood, 2001; Tsai & Wadden, 2006) (Turk et al., 2009). Overall, adding a maintenance program such as promotion of high level of physical activity appears to slow but not prevent weight regain (Borg, Kukkonen-Harjula, Fogelholm, & Pasanen, 2002).

Thus far, a limitation of maintenance programs is that they continue promoting the behavior changes initially required to induce large weight loss which may be unsustainable long-term for many patients. A recent study randomized patients to 1000 vs. 1500 kcals per day during a 12-month weight loss treatment program (Nackers et al., 2013). Participants who had the largest energy reductions (>50%) from their baseline eating patterns struggled to adhere to the 1000 kcal per day

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diet and regained more weight during the extended care condition than participants in the 1500 kcal per day condition. Thus, there is a need for the development of innovative behavioral maintenance programs that promote sustained adherence to weight maintenance behaviors for individuals who have lost a large amount of weight (Saris, 2001; Wing, Tate, Gorin, Raynor, & Fava, 2006).

The primary aim of this study was to obtain a preliminary assessment of the feasibility and acceptability of delivering a novel 52 week small changes maintenance intervention (SCM) in a real-world clinical setting for patients who completed a medically supervised LMR program. In contrast to traditional weight maintenance programs, SCM offered no prescribed changes or preset goals for maintenance behaviors and all changes in behavior were self-selected. We hypothesized SCM would be feasible to implement as evidenced by recruitment and retention of participants and acceptable to participants as evidenced by self-reported ratings of satisfaction with the program and adoption of weight maintenance behaviors. A secondary aim was to obtain a preliminary assessment of the effectiveness of SCM compared to a historical control group of LMR program patients who did not participate in follow-up care.

## 2. Methods

### 2.1. Study participants and historical controls

#### 2.1.1. Small Changes Maintenance (SCM)

A total of 39 patients who completed our clinic-based liquid meal replacement (LMR) program were eligible to participate in SCM. These 39 patients completed the program consecutively during the 12-month recruitment period between October 2010 and October 2011. The LMR program offers rolling entry 52 weeks per year. Inclusion criteria were: lost  $\geq 10\%$  of body weight during LMR program, could participate in all aspects of the intervention, and refrain from participating in other weight loss interventions. Nine patients were excluded: could not participate in all aspects of the intervention ( $n = 6$ ) and lost less than 10% of body weight ( $n = 3$ ). The 30 remaining patients agreed to participate in SCM. The study was approved by the medical center institutional review board.

#### 2.1.2. Historical controls (HC)

All patients who completed our clinic-based LMR program prior to the start of the SCM (May 2008 and October 2010) were considered for inclusion in the HC ( $n = 82$ ). A total of five patients lost less than 10% of body weight during the LMR program and were excluded from further analyses. Of the remaining 77 patients, follow-up weights were available within 9–12 months after the final LMR program medical visit for 64 patients (Hemmingsson et al., 2012). Weights were extracted from patients' electronic medical records from in-clinic visits at the medical center. Weights were unavailable for 13 patients: no in-clinic weight between 9 and 15 months after the final LMR medical visit ( $n = 4$ ), no follow-up care at the medical center ( $n = 7$ ), and underwent bariatric surgery ( $n = 2$ ).

### 2.2. Design

This study employed a pre-post treatment design consisting of 30 consecutive patients who completed 21–28 weeks of a clinic-based LMR program using the OPTIFAST 800® product (800 kcals/day). Baseline assessments included body weight, height, BMI, resting metabolic rate, and a three day food diary. Caloric needs for maintenance of lost weight were determined for each patient individually using resting metabolic rate (Medgem™ by Microlife©) combined with an activity factor (e.g., sedentary to high active) (Tudor-Locke, Hatano, Pangrazi, & Kang, 2008). SCM included 20 sessions offered biweekly for the first 26 weeks and once every 4 weeks (monthly) thereafter for a total of 52 weeks. Participant entry was rolling in an open-group format. They

were provided with one box of product (7 meal replacements) per week free of charge as incentive for study participation. At week 52, baseline assessments were repeated.

### 2.3. Intervention

SCM sessions were based on the theoretically driven ASPIRE weight loss program that promotes self-selected changes in caloric intake and physical activity (Lutes et al., 2008, 2013). SCM was led by our LMR program staff, a registered dietitian and a licensed psychologist with extensive experience in conducting weight management groups. Traditional weight maintenance interventions continue promoting preset goals that include large decreases in intake and large increases in physical activity that are initially required to induce large weight loss. In contrast, SCM offered no prescribed changes or preset goals for maintenance behaviors and all changes in behavior were self-selected. For example, participants were not given any preset goals with regard to calorie intake, but rather they were provided with strategies for maintaining calories within a personal calorie range derived at baseline using resting metabolic rate and an activity factor. Furthermore, participants were encouraged to consider maintenance calories as a balance between over-eating before starting the LMR program versus restrictive dieting during the LMR program.

Other maintenance behaviors promoted during the intervention included self-weighing, use of food diaries, use of meal replacements, and physical activity. For example, patients were given guidelines about self-weighing and were encouraged to weigh themselves frequently (Wing et al., 2006). To create a small change, participants self-selected goals and altered the quality, quantity, and/or frequency of a behavior in response to weight change during the previous weeks (Lutes et al., 2013). No foods were specified as off limits but were considered negotiable with regard to quality, quantity, and frequency of consumption. Participants were encouraged to eat all foods in moderation in an effort to avoid feelings of deprivation that may be associated with weight regain (Nackers et al., 2013).

### 2.4. Measures

#### 2.4.1. Body weight

Participants were weighed in kilograms in light clothing with shoes off using a Scale-Tronix 6002 scale at each treatment visit by clinic staff.

#### 2.4.2. Weight maintenance behaviors

The 20-item Weight Management Skills Evaluation was designed for this study to measure adoption of weight maintenance behaviors. Responses were measured on a 9 point Likert scale (1 = strongly disagree to 9 = strongly agree). Item 20 of the measure asked participants to rate satisfaction with SCM on a Likert scale (1 = not at all satisfied to 9 = extremely satisfied). A modified version of the timeline follow-back method (Sobell, Sobell, Leo, & Cancilla, 1988) was used in this study where participants recorded maintenance behaviors on a calendar for each day of the month. Participants were provided with a calendar for each month of the intervention and checked off use of self-selected maintenance behaviors including food diaries, self-weighing, meal replacements, pedometer steps, and planned exercise  $\geq 30$  min. Calendars were collected at each intervention session. Three day food diaries (kcals) at baseline and week 52 were analyzed using FoodWorks® nutrient analysis software (The Nutrition Company). Step counts were measured by Omron HJ-112 digital pocket pedometer.

### 2.5. Statistical analyses

The proportion of participants who attended the intervention sessions was estimated to measure feasibility; the SCM was to be considered feasible if  $>50\%$  of participants attended a minimum of 17 of the 20 sessions. SCM acceptability was evaluated by the sample median

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