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Original Article

Long-Term Weight-Loss Maintenance by a Meal Replacement Based Weight Management Program in Primary Care

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Key Words
Long-term weight loss maintenance · Primary care · Body composition · Meal replacement

Abstract
Objective: Structured obesity treatment programs at primary care level are becoming increasingly important. However, evidence from current treatment approaches in the long term is lacking. In view of this fact we evaluated a standardized, meal replacement-based weight loss program (myLINE®; AENGUS, Graz, Austria) according to the currently applicable guidelines. ***Methods:*** Data of overweight and obese individuals (n = 70) who participated at least 36 months in the program were analyzed. Data were collected at baseline (T0) as well as after 1, 3, 6, 12, 24, and 36 (T1–T36) months. Body composition was measured by conventional anthropometry and bioelectrical impedance analysis. ***Results:*** Compared to T0, a maximum weight, BMI, fat mass, absolute body cell mass (BCM) reduction and an increase of relative BCM could be seen at T6. Subsequently, the findings reveal a significant reduction of body weight and body fat and a satisfying development of body cell mass during the observation period of 36 months. ***Conclusion:*** The evaluated program complies with national and international guidelines for the therapy of obesity in adults and is efficient and meaningful for a long-term therapeutic use in primary care..

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Introduction

The latest Austrian Nutrition Report has shown a prevalence of overweight and obesity among adults of nearly 40%. Overweight is one of the most common health issues in Austria, as in many other European Countries [1, 2].

From a health care perspective, addressing overweight and obesity is an important strategy in the primary and secondary prevention as high body weight and body fat are associated with an increased risk of cardiovascular complications, certain cancers, diabetes mellitus type 2, Alzheimer's disease, gallbladder disease, sleep apnea, osteoarthritis, renal disease, and musculoskeletal disorders [2–5]. A modest weight loss of 5–10% has been shown to reduce the risk of developing diabetes by 58% in at-risk patients [6] and diminishes the overall risk of mortality by 20% [7–9]. Effective weight reduction can decrease disease risk, lower health service expenditure, and improve the quality of life of affected persons [10–12]. Studies have shown that structured treatment programs with regular follow-up are able to improve long-term weight loss and maintenance [13, 14]. Such programs, especially at primary care level, are becoming increasingly important to overcome the rising demand of treatment options in context with the constantly growing numbers of obese individuals. However, evidence in the long term (>24 months) from current treatment approaches is lacking. Many products and related plans are appearing on the market with little evidence of their tolerance and weight loss-promoting effectiveness [15].

Therefore, we hypothesized that participants of a standardized, meal replacement-based weight loss program can achieve clinically relevant weight loss and weight maintenance over a period of 36 months. For this purpose, we evaluated 36-month anthropometric data of a standardized, meal replacement-based weight loss program conducted in Austrian primary care units according to the currently applicable guidelines for the management of obesity in adults to provide additional information about realistic long-term outcomes for health professionals and patients.

The aim of this study was to prove our hypothesis that participants of a standardized, meal replacement-based weight loss program can achieve clinically relevant initial weight loss and weight maintenance over a period of 36 months.

Material and Methods

Subjects

Out of a random sample of 1,237 overweight and obese participants, those individuals who attended the program at least 36 months and have complete data at all evaluated time points (baseline (T0), 1, 3, 6, 12, 24 and 36 (T1–T36) month(s)), were analyzed, leaving a sample of 70 participants. Exclusion criteria were BMI < 25 kg/m^2, diabetes mellitus, being pregnant or lactating, cardiovascular disease, other medical conditions contraindicating weight loss, substance abuse, severe psychiatric illness, and eating disorders (anorexia nervosa, bulimia nervosa, binge eating disorder). The procedures used in this evaluation were in accordance with the Declaration of Helsinki in the currently valid version amended by the 64th WMA General Assembly, Fortaleza, Brazil, October 2013, and were approved and registered (No 2107/2013) by the Ethics Committee of the Medical University of Vienna. All participants gave their written informed consent prior to their inclusion into the program.

Program Design

The myLINE® program (AENGUS, Graz, Austria) (*www.myline.at*) is a standardized, meal replacement-based weight loss program with a duration of at least 24 weeks. The diet is in accordance with the latest nutritional recommendations of the German Nutrition Society (Deutsche Gesellschaft für Ernährung; DGE), the Austrian Nutrition Society (Österreichische Gesellschaft für Ernährung; ÖGE), the Swiss Nutrition Society

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Table 1. Age and body composition data from baseline to 36 months (n = 70)[a]

	T0[b]		T1		T0–T1[c]	T3		T0–T3[c]	T6		T0–T6[c]	T12		T0–T12[b]	T24		T0–T24[b]	T36		T0–T36[b]
	mean	SD	mean	SD	p	mean	SD	p	mean	SD	p	mean	SD	p	mean	SD	p	mean	SD	p
Weight, kg	92.8	18.3	89.2	17.7	<0.001	85.0	17.1	<0.001	82.3	16.3	<0.001	82.2	16.1	<0.001	82.9	16.8	<0.001	84.3	16.1	<0.001
BMI, kg/m^2	33.9	5.7	32.6	5.5	<0.001	31.0	5.2	<0.001	30.0	4.9	<0.001	29.9	4.6	<0.001	30.2	4.9	<0.001	30.8	4.9	<0.001
Weight loss,																				
kg	–	–	3.5	1.9	<0.001	7.7	3.8	<0.001	10.5	6.2	<0.001	10.5	7.7	<0.001	9.9	9.1	<0.001	8.4	9.4	<0.001
%	–	–	3.8	1.8	<0.001	8.3	3.8	<0.001	11.1	5.9	<0.001	11.0	7.0	<0.001	10.3	8.3	<0.001	8.6	8.4	<0.001
FM																				
kg	35.5	11.5	33.4	11.3	<0.001	30.4	10.7	<0.001	28.1	10.2	<0.001	28.1	9.6	<0.001	28.9	9.9	<0.001	29.9	9.8	0.001
%	37.8	7.4	36.8	7.5	0.02	35.1	7.6	<0.001	33.5	7.8	<0.001	33.6	7.2	<0.001	34.3	7.3	0.01	35.0	7.3	0.01
BCM																				
kg	28.2	6.1	27.8	5.8	0.001	27.0	5.7	<0.001	26.8	5.8	<0.001	26.8	5.9	<0.001	26.8	6.2	0.002	26.8	6.1	0.001
%	30.8	5.3	31.6	5.4	0.002	32.2	5.5	<0.001	33.0	5.7	<0.001	32.9	5.4	<0.001	32.7	5.6	0.001	32.1	5.3	n.s.

FM = Fat mass; BCM = body cell mass; n.s. = not significant.

[a] Data is represented as mean ± standard deviation (SD).

[b] Baseline.

[c] Comparison between baseline and following month(s) was calculated using analysis of variance.

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(Schweizerische Gesellschaft für Ernährung; SGE), and the Swiss Association for Nutrition (Schweizerische Vereinigung für Ernährung; SVE) which are called D-A-CH-recommendations [16].

The program consists of four phases [17] starting with a very low calorie diet (VLCD) for 2 days, followed by an energy-reduced diet consisting of meal replacements two times or once per day and one or two fat reduced meal(s) until the participant achieves two-thirds of the intended weight reduction, but at least for 10 weeks. Afterwards, the participants should maintain their weight without meal replacements. The regular follow-up intervals of the program are as follows: start, reduction, and transition phase – weekly or every 14 days; stabilization phase – once a month; afterwards – four times a year. During the whole program, the participants were measured at the regular visits by bioelectrical impedance analysis (BIA) and conventional anthropometry and received individual nutritional advice from a registered dietician. Within individual face-to-face consultations, aims and treatment plans, including improvement of the activity level in accordance with the actual recommendations, are defined. A nutrition and activity diary for self-reflection and a participant handbook for support and exercises at home are used as instruments of behavior therapy. After the weight reduction, there is the possibility to participate in a follow-up program for an unlimited period of time.

Meal Replacement

The declaration of all products took place at the Austrian Federal Ministry of Health as foods intended for use in energy-restricted diets for weight reduction. All products are in accordance to the directive 96/8/EG European dietetic food regulation. Furthermore, products undergo regular laboratory controls and are only available in primary care units in combination with regular follow-up examinations [18].

Body Composition

The measurement of body composition was performed by conventional anthropometry (weight, height, waist circumference) and BIA (AKERN BIA 101™ (SMT medical GmbH & Co. KG, Würzburg, Germany), BIACORPUS RX 4000™ (MEDI CAL HealthCare GmbH, Karlsruhe, Germany), Software BodyComposition V 8.4 Professional (MEDI CAL HealthCare GmbH)).

Statistics

Statistical analysis was performed by SPSS for Windows Version 20.0 (IBM Corporation, Armonk, New York, USA). All results are presented as mean and standard deviation (SD). Differences in the distribution of variables between time points as well as between men and women were tested by Student's t-test for two independent samples (in case of normally distributed variables) and by Mann-Whitney U-test (if variables were not normally distributed). We used repeated-measures analysis of variance (ANOVA), using random error (general linear model) to assess the effect of changes in anthropometric parameters between the sexes. Moreover, a post-hoc analysis with Bonferroni correction was applied. Linear regression was used to identify independent variables, e.g., age, gender, initial BMI, body cell mass (BCM), associated with differences in weight loss. Binary logistic regression was used to estimate the odds for influence of initial BMI on weight loss. P values < 0.05 were considered significant.

Results

Female individuals covered 81% of the population. The mean age was 54 ± 14 years. The baseline characteristics are presented in table 1. In comparison to their female counterparts, men showed higher weight, BMI, BCM (all $p < 0.001$) and lower fat mass (FM) ($p < 0.001$) at T0. These differences remained constant over the whole observation period, indicating that there are no significant differences in the development of weight, FM and BCM between the sexes over time (see fig. 2 as an example), but female participants showed lower weight and BCM and a higher FM compared to men.

The greatest mean reduction of absolute and relative weight (T0–T6: 10.5 ± 6.2 kg, $p < 0.001$; 11.1 ± 5.9%, $p < 0.001$), BMI, FM, and absolute BCM could be observed at T6 (fig. 1, table 1). Moreover, a maximum increase of relative BCM could be seen at T6 (table 1).

All evaluated parameters remained stable until T12. Out of the original sample (n = 1,237), those who attended the program at least 12 months (n = 1,167) showed a lower

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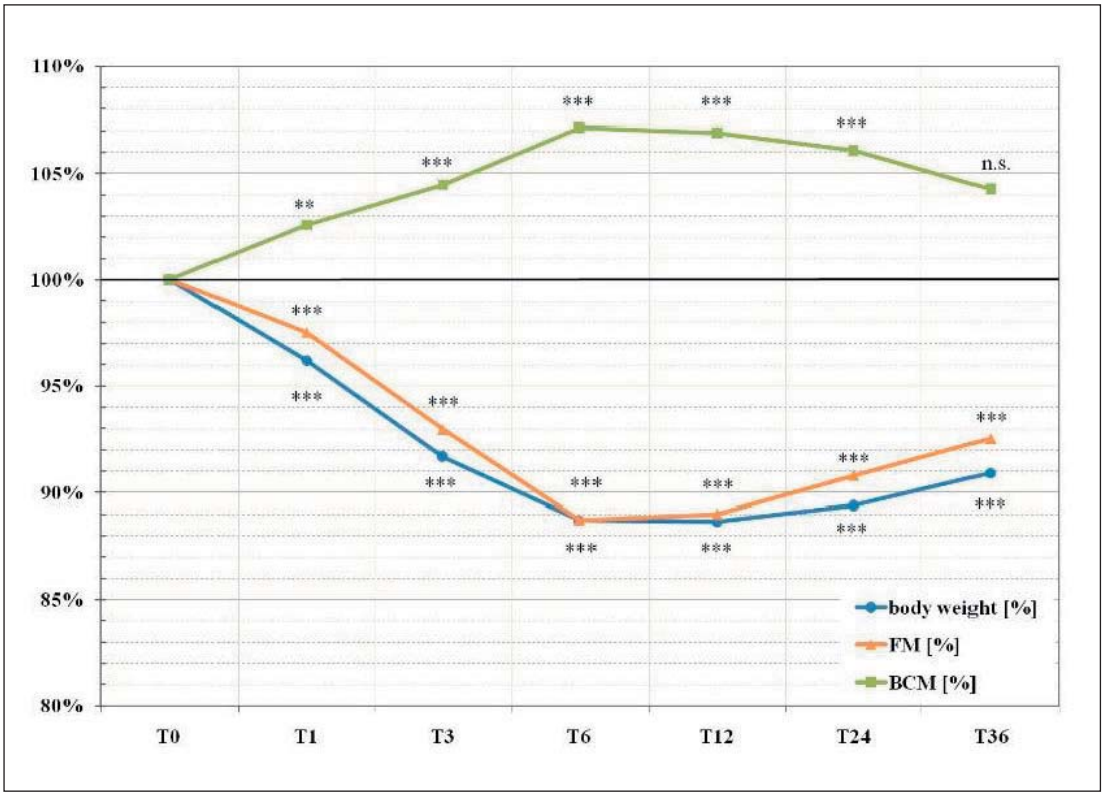

Fig. 1. Representing relative body weight, FM and BCM development from baseline (T0) (= 100%) to 36 months (mean ± SD). ***p < 0.001, n.s. = not significant.

weight loss at T12 in comparison with participants attending at least 36 months (n = 70) (8.6 ± 7.5 kg vs. 10.5 ± 7.7 kg, p < 0.05; 8.2 ± 7.8% vs.11.0 ± 7.0%, p = 0.01). At T12, 61% of all participants achieved a minimal weight loss of 5%, 36% of 10%, and 19% of more than 15% of their initial weight, which is comparable with the previously published data of the 12-month sample [17]. A slight weight and FM increase and a BCM decrease was seen at the subsequent 24- and 36-month follow-ups. Nevertheless, at T24 and T36, weight and FM were significantly lower and absolute BCM significantly higher compared to T0. At T36, relative BCM was not longer significantly higher compared to T0 (fig. 1).

By using a multivariate linear regression model with weight loss as independent variable (difference of weight in kg at T36 and at T0) and sex, age, initial BMI, and initial BCM as dependent variable, only initial BMI showed a significant negative association (β = –0.501; p < 0.001). Moreover, participants with an initial BMI ≤ 35 kg/m^2 had a higher chance of greater weight loss at T3 and T24 (T3: OR 1.70, 95%CI 1.09–2.67; p = 0.02; T24: OR 1.33; 95%CI 1.06–1.66; p = 0.02), but not at T12 (OR 0.56; 95%CI 0.38–0.82; p < 0.01).

Discussion

Successful weight maintenance after weight reduction is the greatest challenge in the therapy of obesity. Effective methods to achieve this ambitious goal, especially in primary care, are required [19, 20]. In this study, the long-term success of a meal replacement-based weight management program in adults with respect to changes in body weight and body

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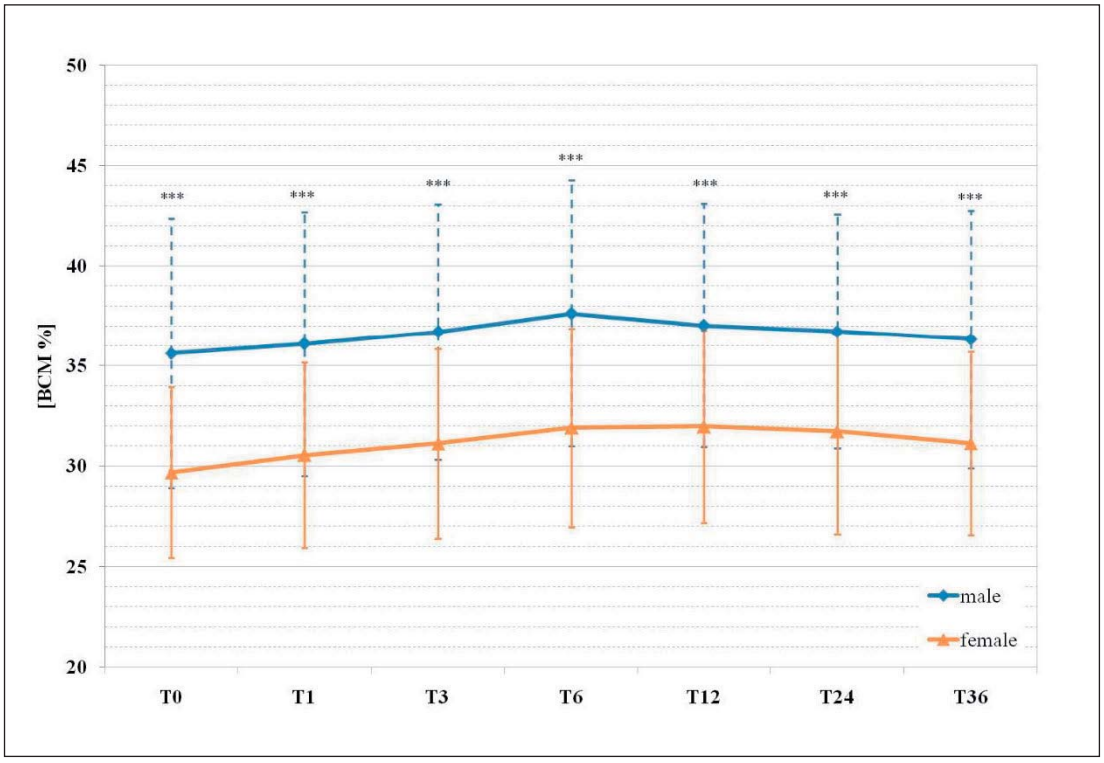

Fig. 2. Representing relative BCM development in males and females from baseline (T0) to 36 months (T36) (mean ± SD). ***p < 0.001.

composition was analyzed. As defined by the European guidelines, a weight reduction of 5–15% within 6 months or of 0.5–1.0 kg/week are realistic and desirable [2, 21]. International committees consider a weight reduction of 5–10% of the initial body weight as adequate to reduce the health risk in obese patients and, moreover, to prevent excess weight gain [19, 21]. Additionally, Hauner et al. [22] defined success for obesity therapy programs in primary care as follows: at least 50% of the participants have to lose 5% of their initial weight, and 20% should achieve a weight reduction of 10% from baseline. For the definition of long-term success, no uniform definition exists. The Institute of Medicine defined long-term success as an achieved body weight at least 5% below the initial weight or BMI at least one unit below the baseline BMI 1 year after weight reduction [23]. Furthermore, Wing and Hill [24] proposed that successful weight loss maintainers are defined as patients that initially have lost at least 10% of their body weight and stabilized at least for 1 year. Regarding weight maintenance, the Clinical Guidelines on Evaluation and Treatment of Overweight and Obesity in Adults have defined successful weight maintenance after weight loss as a weight regain of less than 3 kg in 2 years [25].

In regard to the evaluated program, the average weight reduction was 11 kg and 11% after 6 months. Compared to the data of Franz et al. [26], who systematically reviewed the long-term effect of 80 different weight loss interventions, the present data are within or even above the reported range, especially in comparison with trials using meal replacements. Franz et al. [26] concluded that weight loss tends to reach a plateau, ranging between 5.0 and 8.5 kg (5–9% of initial body weight) after 6 months of treatment, gradually decreasing to 3.0–5.0 kg (3–6% of initial body weight) after 48 months [26]. In the current study, more than 60% of the participants reached a weight reduction of minimum 5% and more than one-third

a reduction of minimum 10% of their initial body weight. Moreover, compared to BMI at the beginning of the program, BMI after 12 and 36 months was on average 4 and 3 units lower, respectively. These results are in accordance with the above referred criteria. Additionally, long-term weight loss was greater than observed in other primary care trials [27–30], with the exception of a study involving morbidly obese patients who were treated with intensive group lifestyle modification and weight loss medications [31]. Reduction in body fat and preservation of lean body mass is crucial for beneficial metabolic effects, prevention of weight regain, and sarcopenic obesity due to loss of BCM [19, 32]. White adipose tissue is recognized as an active endocrine tissue that secretes numerous immunomodulatory factors which play major roles in the regulation of human metabolic and vascular biology and is therefore significantly involved in the pathogenesis of the metabolic syndrome [33]. To significantly reduce the metabolic risk associated with endocrine active adipose tissue, it is necessary to reduce and maintain weight over a period of 3 years [34]. The collected data showed a body fat reduction of 11% at T6 and 8% at T36, which might suggest a metabolically effective weight reduction. In order to verify this effect, an additional analysis of laboratory parameters would be expedient. However, the measurement of body composition during weight reduction seems to be indisputable. In the present study, the routine measurement with the BIA appears as informative and beneficial. Results from dual energy X-ray absorptiometry would be more accurate but are not practicable and too expensive in primary care. During the observation period, the absolute BCM decreased although the relative BCM increased. This indicates a satisfactory overall development of muscle mass despite of weight reduction.

Interestingly, using a multivariate linear regression model and a logistic regression, we found that initial BMI influenced weight loss over the time period of 36 months. The other dependent variables, such as age, sex or initial BCM, showed no significant correlation with weight loss. Moreover, the results of the logistic regression strengthened the influence of initial BMI on weight loss as lower BMI at baseline showed a higher chance of greater weight loss in the short (T3) and in the long term (T24) but not in the medium term (T12). Possible explanations for the success of the examined weight management program might be the intensive patient contact, the individual dietary counseling, and the guidance for physical activity as well as the standardized optimal nutrient intake which are factors that were seen as preventive for weight regain [13, 14, 35, 36]. One essential component of the program is a long-term modification of dietary and physical activity habits. The program supports the participant during and after the weight reduction with behavioral interventions: i) a nutritional and physical activity diary for patient self-monitoring, ii) the participant handbook as basis for the therapeutic one-on-one counseling, iii) and the group meetings as a communication platform for participants and for increasing their nutritional knowledge. In further studies the quality of participant's contact and satisfaction in this program was evaluated [18, 37–39] and therefore the program corresponds also to the requirements of regular quality checks of obesity programs in primary care [22].

Limitations of the current report are the small sample size due to the restricted availability of complete 36-month data and the absence of an adequate control group. Nevertheless, this sample is well characterized and the anthropometric data are complete, which strengthens our study. Due to the analysis of complete 36-month data, the possibility of a selection bias exists and therefore the results may be biased towards an over-positive assessment of effectiveness. Nevertheless, the data are novel because to date and to our current knowledge no study has assessed 36-month anthropometric data of a meal replacement-based weight management program in primary care.

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Conclusion

This data shows clinical relevant initial weight loss and maintenance over a period of 36 months in participants of a standardized, meal replacement-based weight loss program. The evaluated program complies with national and international guidelines for the therapy of obesity in adults and is efficient and meaningful for a long-term therapeutic use in primary care. The results emphasize the importance of regular body composition measurements during weight reduction and weight maintenance. The findings reveal a significant reduction of body weight and body fat as well as a satisfying development of BCM during the observation period of 36 months. Nevertheless, during the observation period, a turning point was observed at T12 after 6 months stabilization. Accordingly, after 12 months, participants started slightly to regain weight and FM and to lose BCM. Based on these findings, we can assume that once the weight reduction has been terminated it is of great importance for patients and health professionals to stay motivated beyond the classical observation period of 12 months, especially in those patients with initial BMI > 35 kg/m^2. This means regular controls with conventional anthropometry, body composition measurements, dietary advice, and also behavior-therapeutic tools to support participants also after weight reduction. Further studies with an observation period of more than 24 months in consideration of metabolic parameters are needed to examine the long-term weight development and the metabolic effect of such weight management programs.

Disclosure Statement

Sandra Wallner-Liebmann and Bernhard Ludvik are members of the myLINE® scientific advisory board without remuneration. Maria Luger has no conflicts of interest and fundings to declare. Harald Lothaller and Renate Kruschitz have received funding from AENGUS for data processing. The authors do not have any commercial interest in the subject of the study.

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