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The MedWeight study: Design and preliminary results

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Abstract.
BAGKGROUND: Weight loss maintenance contributing behaviors have not been adequately studied in Mediterranean populations.
OBJECTIVE: The MedWeight study created a registry of weight loss maintainers and regainers, to assess and compare their features and lifestyle habits.
METHODS: Participants had intentionally lost ≥10% of their starting weight; maintainers were keeping the weight off for one year minimum, whereas regainers had regained the loss. Volunteers answered online questionnaires, regarding medical history, body weight, diet and exercise habits, social support, and personality traits. Two telephone 24-h dietary recalls per volunteer are conducted. Questionnaire follow-up will take place one year after study entrance.
RESULTS: Thus far, 169 maintainers and 57 regainers participated in the study, 43% men. Mean age was 32 years, with regainers being older than maintainers. Maintainers were sustaining a 21% loss, for over four years. Maximum weight and maximum Body Mass Index (BMI) did not differ between groups, but maintainers originally lost more weight than regainers. Maintainers lost weight mainly by themselves, whereas more regainers had consulted with a dietitian.
CONCLUSIONS: Preliminary data showed no differences between groups in maximum weight and BMI ever reached, but differences were found in weight loss methods employed and initial weight loss achieved.

Keywords: Weight loss maintenance, maintainers, regainers, obesity, overweight

Abbreviations

BMI = Body Mass Index
NWCR = National Weight Control Registry

1. Introduction

Maintenance of weight loss remains a challenge for individuals struggling to control their weight. According to a US telephone survey, only 21% of people who had reached a maximum Body Mass Index (BMI) of at least 27 kg/m^2, had maintained an intentional weight loss of ≥10% from their maximum weight for at least one year [1]. A similar telephone survey in Germany found that, 18% of those who have been overweight and 30% of those who have been

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obese, manage to intentionally maintain a weight loss at least 10% off their starting weight, for at least one year [2]. Weight loss clinical trials achieve even lower maintenance rates. According to the latest meta-analysis, at four years of follow-up, participants maintain a 3–6% weight loss [3].

Few studies, so far, have addressed the issue of maintenance related behaviors, most notably the National Weight Control Registry (NWCR), a US database of long-term weight loss maintainers [4]. Common behaviors among its members include high levels of physical activity, regular breakfast consumption, weight self-monitoring, a low-calorie low-fat diet and a consistent eating pattern. Additional studies show that maintainers, compared to other groups (i.e. regainers, persons not managing to lose weight, or overweight controls), are more likely to directly cope with lapses [5], avoid fast food restaurants [6], eat a low energy density diet [7], plan meals in advance and not use meal substitutes or diet pills [8].

To advance research in this area, many lifestyle parameters need to be more thoroughly studied. A detailed comparison between maintainers and regainers would provide valuable information on the behaviors characterizing these groups. Men and young adults should also be studied in detail, as preliminary data from the NWCR, which includes mostly middle-aged women, indicate differences between sexes and age groups [9, 10]. Correlations between obesity and parameters such as sleep habits, sleep quantity as well as quality [11–14], or personality traits, especially impulsivity [15–17], and even physiological parameters such as gut health [18], are present in the literature; however, these factors have not been extensively studied in relation to weight loss maintenance.

Furthermore, to improve generalizability of findings, the lifestyle habits contributing to weight loss maintenance should be examined in various populations. Mediterranean populations, in particular, have not been adequately studied relative to this perspective. Although the Mediterranean Diet has been associated with less weight gain prospectively and a lower probability of developing obesity [19–21], and can be effectively used for weight loss [22], there are no data concerning its effect on weight loss maintenance. Preliminary evidence from focus groups in a sample of Greek maintainers and regainers suggests that maintainers put emphasis on home-cooked meals, a finding prompting research into a potential role of the Mediterranean Diet for weight loss maintenance [23].

The MedWeight study aims to address the aforementioned issues by creating a Registry of maintainers and regainers, derived from a Mediterranean population and including adequate numbers of men and young adults. The main objective of the study is to investigate differences between the two groups, regarding their characteristics, behaviors and lifestyle habits, with an emphasis on detailed dietary assessment.

2. Methods

2.1. Participants

The MedWeight study comprises a Registry of people who lost weight and maintained it (maintainers), and people who lost weight but regained the loss (regainers). Eligible participants are men and women, aged 18–65 years, who have been at least overweight (maximum BMI $\geq$25 kg/m^2), and intentionally lost at least 10% of their starting weight. Volunteers maintaining the minimum 10% loss for at least one year at study entry are classified as maintainers. Those currently at a weight $\geq$95% of their maximum body weight are classified as regainers. Individuals with a current body weight between 90–95% of their maximum weight are excluded in order to avoid overlapping of groups. The inclusion criteria, i.e. intentionality of weight loss and the cut-off of a 10% loss maintained for a minimum of one year, were selected according to the definition of successful weight loss maintenance by Wing & Hill [24]. The maximum BMI criterion was applied so that results would be relevant to the overweight/obese population. The age limit serves to avoid implications due to unintentional weight losses over the age of 65 years [25]. Current pregnancy is an exclusion criterion.

Volunteer recruitment is accomplished by promoting the study in social media and local press. Before entering the study, volunteers are informed of its nature and purpose, through an electronic form displayed during the registration process. They are required to acknowledge reading the document in order to continue on in the study, thus providing their consent to participate. No compensation for participation is offered. The study protocol was approved by the Harokopio University Ethics Committee.

Volunteer inflow begun in December 2012 and is currently underway. To achieve statistical power of 80%, using energy intake as the calculating variable, we need to recruit 634 volunteers in total, 237 women and 397 men. The mean values and standard deviations of energy intake used in the calculations were drawn from NWCR data for the maintainers [26] and NHANES data for overweight/obese participants for the regainers [27], as relevant data for the Greek population are not available.

Potential volunteers use the MedWeight website (http://medweight.hua.gr) and are asked to answer a series of questions based on the study's inclusion criteria. Consequently, eligible participants proceed to complete the study questionnaires, available to them through the website.

2.2. Demographics

The demographic characteristics collected are marital status (single, married, divorced, widowed), employment status (private sector employee, public sector employee, freelancer, pensioner, unemployed, student, housekeeping), type of occupation, ranging on a scale from one (manual labor) to four (intellectual work), educational level (in years of education), and type of residence area (rural, suburban, urban). Additionally, participants are asked whether they have siblings and how many, as well as their own order of birth (e.g. first child, second child).

2.3. Medical history, including gastrointestinal function

Participants report any diagnosis of diabetes mellitus, hypertension, or hyperlipidemia, and whether they have a family history of either of these conditions. A list of major health events is provided, including heart attack, stroke, malignancy, clinically diagnosed depression etc., and participants indicate whether they had experienced any of the conditions listed. Use of medication is also recorded.

Women additionally complete a short menstrual and pregnancy history, indicating, among others, age of menarche, menopause status, and number of pregnancies and births. Finally, volunteers rate their perceived overall health status on a scale from one to ten, ten representing excellent health.

Gastrointestinal function is assessed using a questionnaire of gastrointestinal habits and symptoms, namely occurrence of abdominal pain, gastroesophageal reflux etc., before and after weight loss, as adjusted from Mitsou et al. [28].

2.4. Body weight history

Volunteers are asked to indicate the methods, and the primary method, they employed in order to lose weight. They are given a list of weight loss methods to choose from. Similarly, they indicate the motives, and the primary motive, prompting them to lose weight, from a list of options. Additionally, maintainers are asked in a similar fashion regarding motives in their current state of weight maintenance. The available answers for all aforementioned questions were developed based on findings from focus groups conducted by our research group (Table 1) [23].

Subsequently, participants are asked to complete a modified version of the Weight Cycling Questionnaire [29], with questions on the frequency of "watching their weight" and dieting, as well as weight recycling in a typical year and lifetime weight recycling. Finally, participants indicate how often they weigh themselves, ranging from *almost never* to *at least once daily*, and whether they perceive weighing as helpful or detrimental to their weight control efforts. History of overweight during childhood and adolescence is also recorded.

2.5. Lifestyle habits

This section includes questionnaires on various aspects of the volunteers' lifestyle habits. Physical activity levels are assessed using the short version of the International Physical Activity Questionnaire – IPAQ [30], translated and validated in the Greek population [31], which provides information on time spent walking, in vigorous- and moderate-intensity activities and in sedentary activities. Participants are instructed to recall the last seven days and refer to all domains of physical activity. Smoking status is also evaluated and participants are categorized as non-smokers, smokers or ex-smokers.

Table 1
List of weight loss methods, weight loss motives, and maintenance motives, as presented to volunteers

Weight loss methods	Weight loss motives	Maintenance motives *(maintainers only)*
I lost weight by myself	To improve my appearance, I didn't like the way I looked, my clothes didn't fit me, I couldn't find clothes to suit me	My appearance has improved, I like the way I look now, I find clothes to suit me
I consulted with a dietitian	My weight was negatively affecting my self-esteem	My self-esteem has improved
I consulted with a doctor (excluding surgery)	To improve my social relationships, I was feeling socially "excluded"	My social relationships have improved
Bariatric surgery	I had to lose weight for health reasons, I had elevated levels of blood sugar/cholesterol, my doctor advised me to lose weight	My health has improved, blood test results have improved
I referred to another "specialist" (excluding dietitian, doctor)	I could not move easily, my stamina was low and I was getting tired easily, I had back and/or knee pains	I am able to move more easily, I have improved stamina, I feel an overall "wellness" and "euphoria"
I followed a diet from a book, a magazine, or friends and family	To improve my performance in a sport/activity	My performance in sports/activities has improved
I used meal substitutes and/or diet pills	Professional reasons	Professional reasons
Fasting, detox diet, other fad diet	My friends and/or family prompted me to lose weight	I can be a positive example for and give hope to others trying to lose weight
Other: *(please specify)*	Other: *(please specify)*	Other: *(please specify)*

Sleeping patterns are assessed through two questions, on the number of hours of sleep during the night, or during the day (midday naps). Moreover, sleep quality is assessed by the Athens Insomnia Scale – AIS [32], which examines the frequency of sleep disturbances such as difficulty falling asleep and mid-sleep awakenings. Participants are asked to provide information regarding frequency of leisure time activities and socializing, such as visiting friends, going out to a restaurant, going to the movies, attending church, reading books, gardening, using an adjusted version of previous questionnaires [33, 34]. Finally, volunteers record how many hours a day, on average, they spend using a computer, using the internet, using virtual social media and watching television.

2.6. Social support

Participants indicate how many close friends they have, and how many of them are overweight. To assess social support, the relevant scales developed by Kiernan et al. are used [35]. These scales examine the frequency of supporting or sabotaging behaviors, from family and friends, regarding eating and exercise; examples of such behaviors include a person eating something unhealthy in front of the participant (sabotage) or a person complimenting the participant on his/her exercise habits (support).

2.7. Psychological assessment

This section comprises three questionnaires focusing on personality aspects. First, we assess personality traits using the Ten Item Personality Inventory - TIPI [36], a brief scale based on the Big-Five personality domains, providing scores on extraversion, agreeableness, conscientiousness, emotional stability, and openness to experience. Then, we assess the trait of impulsivity, using the previously validated Greek version of the Barratt Impulsiveness Scale - BIS [37, 38], a set of 30 questions assessing attentional, motor and non-planning impulsiveness. Third, the extent to which the participant perceives he/she is in control of his/her weight status and fluctuations is evaluated through the Multidimensional Health Locus of Control - MHLC scales [39]. Volunteers are also asked whether they had experienced any stressful events (e.g. parents' divorce, abuse) during childhood or adolescence.

2.8. Dietary assessment

Dietary intake is evaluated using the 24-h recall method [40]. In the 24-h dietary recall the participant is asked to report in detail all foods and beverages consumed during the previous day, defined in our study as the timeframe between waking up in the morning and going to bed at night. The multiple-pass approach is used, which accurately estimates dietary intake in normal weight and obese men and women [41, 42]. The 24-h recall provides an estimate of the absolute energy and macronutrient intakes, while the open-ended questions allow for flexibility in future analysis, as for example those regarding meal patterns and environmental aspects of the meal.

Each volunteer reports on two 24-h dietary recalls, administered over the phone. Telephone interviews limit participant burden and also have the advantage of an unannounced "surprise" recall, which does not allow the volunteers to tamper their diet in anticipation of the recall. Telephone administered recalls have been shown to adequately replace a face-to-face recall [43]. Because a single day is unlikely to be representative of usual dietary intake, we opted to conduct two recalls per volunteer, as when the intent is to generate a population distribution of nutrients, two days of recall in a sample are adequate [40]. The two recalls are conducted 10 days apart, with weekdays and weekends proportionately represented among volunteers. To minimize variation between researchers, dietary intake is recorded by the same dietitian for a given volunteer, and the dietitian is blind regarding the volunteer's weight maintenance status (maintainer vs. regainer).

All dietitians are specifically trained for the MedWeight study's protocol. In specific, for the dietary recall, the dietitians are trained to ask open ended questions, probe for additional foods, additional detail, such as food preparation methods, and quantity estimates, as needed, remaining neutral and non-judgmental, without directing the answers. To help quantify the amount of food eaten the interviewers refer to common volume measures, such as cups, tablespoons, teaspoons, the palm of the hand. If possible, the brand of the product eaten is recorded to facilitate future analysis. Participants are also asked on their water intake (including tap water), whether they took any vitamin/mineral supplements, and whether they are on a diet to lose weight. In addition to food consumption, time, location, parallel activities and fellow diners are recorded for each eating episode. Recall data are analyzed using the dietary analysis software Nutritionist Pro™ (2007, Axxya Systems, Texas, USA).

Additionally, as part of the online questionnaires, dietary patterns are assessed with questions on frequency of eating outside the house, frequency of eating with company, breakfast consumption, number of meals per day, use of dietary supplements, self-assessed eating rate, ranging from *very slow* to *very fast* [44], and involvement in meal preparation.

2.9. Follow-up

The one year follow-up consists of five questionnaires, completed through the study's website. Questionnaires mirror the baseline questionnaires, adjusted as necessary to investigate changes during the previous year. They cover the themes of demographic information, medical history, weight self-monitoring habits (part of the baseline questionnaire on body weight history), lifestyle habits including diet and exercise, and social support. In addition, questions regarding financial/occupational stress during the previous year were added.

2.10. Statistical analysis

Analyses are carried using IBM SPSS Statistics v. 19.0. Students' *t*-test is used to check for differences between groups regarding normally distributed, as checked with Q-Q plots, quantitative variables. For non-normally distributed quantitative variables the Mann-Whitney test is performed. For nominal variables Pearsons' chi-squared test is used to check for differences between groups. Level of statistical significance is set at 0.05.

3. Results

Results presented in this paper are preliminary and refer to the participants' characteristics at study enrolment only, as no follow-up data have been collected yet. So far, 226 volunteers have participated in the study, 169 maintainers

Table 2
Sample characteristics

	Total sample ($n = 226$)	Maintainers ($n = 169$)	Regainers ($n = 57$)	p
Sex (male)	42.5%	43.9%	38.2%	0.456
Age (years)	31.5 ± 10.0	30.7 ± 9.5	33.8 ± 11.3	**0.049**
Weight (kg)	77.8 ± 16.2	74.1 ± 14.2	88.9 ± 16.7	**<0.001**
BMI (kg/m^2)	26.3 ± 4.7	25.0 ± 4.1	30.3 ± 4.0	**<0.001**
Max weight (kg)	94.8 ± 22.9	95.7 ± 24.5	92.1 ± 17.2	0.304
Max BMI (kg/m^2)	32.0 ± 6.7	32.3 ± 7.4	31.3 ± 4.2	0.243
Initial weight loss achieved (kg)	22.8 ± 14.6	25.6 ± 15.8	14.5 ± 4.5	**<0.001**
Maintaining weight loss %	–	21.3 ± 8.5	–	–
Maintenance duration (years)	–	4.6 ± 4.3	–	–
Years of school	15.9 ± 3.4	15.7 ± 3.6	16.5 ± 2.8	0.128
Married	24.8%	20.4%	36.4%	**0.018**
Employed	55.1%	52.2%	63.6%	0.143
Overall health (score 1 – 10, 10 = excellent)	8.2 ± 1.3	8.3 ± 1.2	7.8 ± 1.5	**0.009**
Hypertension	6.3%	3.9%	12.7%	**0.021**
Hyperlipidemia	9.7%	7.2%	16.4%	0.050
Depression (clinically diagnosed)	5.8%	3.9%	10.9%	0.058
On medication	23.7%	23.0%	25.5%	0.717
Other chronic disease	17.4%	16.4%	20.0%	0.551
Polycystic ovary syndrome (women only)	20.2%	18.8%	23.5%	0.563

Values are presented as mean ± standard deviation for quantitative variables and relative frequencies for qualitative variables.

and 57 regainers. Men constitute 43% of the sample. Mean age is 31.5 ± 10.0 years for the total sample, with regainers being approximately 3 years older than maintainers. Current weight and BMI differ between groups, with regainers being heavier, as expected. However, maximum weight and maximum BMI are similar for the two groups. Maintainers lost approximately 11 kg more weight than regainers. Upon entry into the registry, maintainers were at a weight 21% lower than their starting weight, and maintaining this loss for over four years. Mean education level for the total sample, as indicated by school years, was at the university degree level. Approximately one fourth of the volunteers were married, and a little more than half were actively employed. Regainers scored lower on the overall health scale, indicating feeling less healthy than maintainers. Sample characteristics are presented in Table 2.

When participants were asked to indicate the primary method they used in order to lose weight, 47.1% of maintainers stated losing weight by themselves, vs. only 26.8% of the regainers, whereas the most prevalent method among regainers (44.6%) was consulting with a dietitian ($p = 0.091$). Next, participants were asked to indicate all methods they had occasionally employed to lose weight; more maintainers had tried to lose weight by themselves or had undergone bariatric surgery, but all other methods were more frequently employed by regainers (Fig. 1). Among maintainers, most cited motivators for weight loss maintenance were improved appearance, improved self-esteem and easier movement, whereas health reasons were only cited by 20% of maintainers (Fig. 2).

4. Discussion

The MedWeight is one of few studies to create a Registry of weight loss maintainers as well as regainers, and assess in detail their diet, sociodemographic characteristics and lifestyle habits. The Registry allows to cross-sectionally evaluate differences between maintainers and regainers, and to prospectively identify behaviors contributing to maintenance of weight loss. Preliminary data showed no differences between groups in maximum weight and BMI ever reached, but differences were found in weight loss methods employed and initial weight loss achieved.

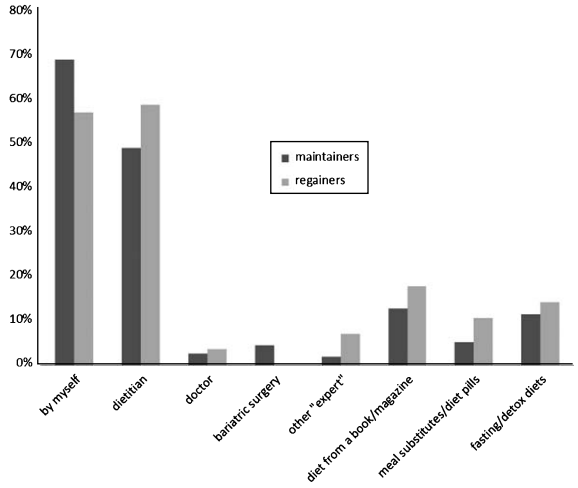

Fig. 1. Weight loss methods. No statistical differences between groups.

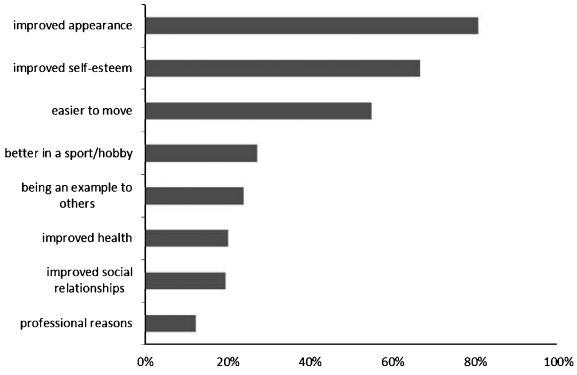

Fig. 2. Maintenance motives.

Average maximum BMI was 32 kg/m^2 for the total sample, with no differences between maintainers and regainers. Hence, having been obese does not appear related to success or failure in maintaining weight loss. Initial weight and BMI predict greater absolute weight loss [45], but there are no data relative to whether they affect maintenance outcomes.

Initial weight loss differed between groups, with maintainers originally losing 11 kg more than regainers. Thus, our data indicate that losing more weight could be a positive predictor of successful maintenance. In contrast, a systematic review of weight loss during intervention and weight maintenance after at least one year, showed no association between weight loss during the intervention and percentage of maintenance [46]. We speculate that this discrepancy reflects differences in weight loss methods: almost half of the maintainers lost weight by themselves, whereas regainers appeared more prone to trying out multiple weight loss methods and seeking external help. Losing weight mainly by oneself is a common pattern among NWCR participants as well [47]. Due to the nature of our data, cross-sectional so far, causal relationships cannot be established. As depicted in Fig. 1, regainers were less prone to even attempt to lose weight by themselves. However, because of the gap between regainers who attempted to lose weight by themselves (57.1%) and those who reported this method as the primary slimming method (26.8%), it may be speculated that regainers either did not manage to lose enough weight by themselves or they did not manage to maintain the weight lost, so they had to refer to a dietitian or try alternative methods.

Among maintainers, the most prevalent reasons motivating them to maintain their new body weight were improvements in appearance, self-esteem and movement. Only 20% of maintainers stated health reasons as motives during maintenance. In the NWCR a comparable 23% of participants stated that their reason for pursuing weight loss was a medical trigger [48]. However, that was the most prevalent reason cited in the NWCR, and it was associated with greater initial weight loss and less weight regain. Young adults in the NWCR though, aged less than 36 years, were more likely to be motivated by appearance rather than health [10]. Our population is perhaps more similar to the young adult sub-sample of the NWCR, as mean age in the NWCR is 45 years [47] and in the MedWeight study 32 years.

Strengths of the MedWeight study include the Mediterranean population sample, a population that has not as yet been studied relative to weight loss maintenance, and the young age of our volunteers, as in most relevant studies participants were middle-aged [6, 47, 49, 50]. Moreover, in the existing literature, men are also underrepresented, contrary to the MedWeight study. Cluster analysis of NWCR data shows that men perhaps follow different patterns than women to achieve weight loss and maintenance [9]. Men constitute 42.5% of our sample, allowing for analyses stratified by sex. Regarding assessment tools, the 24-h recall method will allow for a detailed diet assessment and flexibility in analysis. Furthermore, the sleep, personality, and social support questionnaires will provide novel information in the field of weight loss maintenance. The use of web-based technology is an additional advantage, given that it allows us to recruit participants across Greece.

Self-selection of participation may be a study limitation, as it could possibly lead to recruiting participants who are more health-conscious, especially as it regards to weight control. This is apparent in recruitment, where enrolling regainers in the study has proven more challenging. However, this methodology mimics real-life conditions, where the choice to lose weight and the decision on how to achieve this goal is a personal matter, possibly affected by individual's characteristics. Moreover, self-selection provides the opportunity to study people who attempt weight control by themselves. These individuals cannot be studied in controlled intervention trials.

In conclusion, the MedWeight study is designed to enhance research in the field of weight loss maintenance, by emphasizing understudied populations (e.g. a Mediterranean sample, men and young adults), and by including regainers and studying lifestyle parameters that may emerge as influential in the field of obesity.

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