ADHERENCE TO MEDITERRANEAN DIET OR PHYSICAL ACTIVITY AFTER BARIATRIC SURGERY AND ITS EFFECTS ON WEIGHT LOSS, QUALITY OF LIFE, AND FOOD TOLERANCE.

Anna Gils Contreras,[1,2] Anna Bonada Sanjaume,[1,2] Nerea Becerra-Tomás,[2,3] Jordi Salas-Salvadó[1,2,3]

[1] Nutrition Unit, Department of Internal Medicine, University Hospital Sant Joan. Reus, Spain.

[2] Human Nutrition Unit, Department of Biochemistry & Biotechnology, Pere i Virgili Institute of Health, Rovira i Virgili University, Reus, Spain.

[3] Consorcio CIBER, M.P., Physiopathology of Obesity and Nutrition (CIBERobn), Instituto de Salud Carlos III (ISCIII), Madrid 28029, Spain.

Corresponding author: Jordi Salas-Salvadó, MD, PhD, and Nerea Becerra-Tomás, RD, PhD, Human Nutrition Unit, Faculty of Medicine and Health Sciences, Universitat Rovira i Virgili, C/Sant Llorenç 21, 43201 Reus, Spain (Email: jordi.salas@urv.cat and nerea.becerra@urv.cat).

ABSTRACT

Objective: To assess whether a healthy dietary pattern or physical activity after bariatric surgery mediates the effects of surgery on weight loss, the quality of life or food tolerance.

Methods: A prospective observational study conducted in the context of a randomized controlled trial. We assessed the extent to which increasing or decreasing adherence to the Mediterranean diet (MedDiet)– assessed by MEDAS (Mediterranean Diet Adherence Screener)– and of increasing or decreasing physical activity (PA) –assessed with the short questionnaire of international PA (IPAQ-short q)– after bariatric surgery affected changes in weight, body mass index (BMI), quality of life (Moorehead-Arlet-questionnarie) and food tolerance (Suter test). Assessments were recorded at baseline and quarterly up to 12 months of surgery.

Results: Seventy-eight morbidly obese participants undergoing bariatric surgery were assessed up to 1 year after surgery. Those individuals who increased adherence to MedDiet showed a significantly higher mean of total weight loss percentage than those who decreased or maintained their adherence during follow-up:37.6% (35.5-39.8) vs. 34.1% (31.8-36.5);P=0.036. No significant differences were observed in changes in weight or BMI comparing individuals who increased their PA versus those who maintained or decreased PA, nor in quality of life or food tolerance between those individuals who increased versus those who decreased adherence to MedDiet or PA during the follow-up.

Conclusions: After bariatric surgery, morbidly obese subjects present greater weight loss if they adhere to the MedDiet. PA after surgery is not associated with the magnitude of weight loss nor the quality of life and tolerance to diet.

Key words: Mediterranean diet, physical activity, weight loss, bariatric surgery, obesity.

INTRODUCTION

Obesity is one of the main health problems in society today. In Spain, 21.6% of the adult population suffers from obesity, which is known to increase the risk of comorbidities and, therefore, alter the quality of life of these subjects and increase mortality (1). A high BMI increases the risk of mortality and has been associated to a 8-10 year reduction in life expectancy, especially in those individuals with a BMI between 40-45kg /m^2 (2).

Bariatric surgery is recognized as an effective treatment for weight loss in subjects with severe obesity (BMI ≥ 40 kg / m^2 or ≥ 35 kg/m^2 who have comorbidities) for whom conventional treatment has failed. Bariatric surgery can improve comorbidities and, consequently, increase the quality of life and longevity. However, sometimes the weight loss achieved is lower than expected and/or the associated comorbidities do not improve or even reverse. Post-surgical complications or poor dietary tolerance may influence weight loss. Nevertheless, the lifestyle (i.e. diet, physical activity, sedentary behaviors and smoking) adopted after surgery has been implicated as a possible determinant not only of the weight loss achieved but also of the ability to maintain it in the medium and long term. Consequently, it may affect the quality of life.

Various methodologies have been developed to evaluate changes in quality of life, metabolic effects and complications after bariatric surgery: for example, the Bariatric Analysis and Reporting Outcome System (BAROS), developed in 1998 (3) and modified in 2003 (4). It is one of the most recognized systems of evaluation that takes into account the magnitude of weight loss and uses the Moorehead-Ardelt Quality of Life Questionnaire II (self-esteem, physical activity, work activity, social relationship and sexual satisfaction) to evaluate the quality of life. It also evaluates the evolution of comorbidities and surgical complications after surgery.

However, this questionnaire does not take into account the quality of the diet, its tolerance, physical activity (PA) or other lifestyle behaviors. In this regard, in 2007 a questionnaire was developed by Suter et al., to assess the quality of food consumed through the self-reported satisfaction with dietary intake, tolerance to specific foods and the frequency of vomiting or regurgitation in patients undergoing bariatric surgery (5) (6). However, food quality encompasses more than the items contained in the Suter test. Dietary quality is determined by the food pattern and the amount of macro and micronutrients consumed through diet. One of the most recognized healthy dietary patterns is the Mediterranean diet (MedDiet), which is characterized by a high intake of fruit, vegetables, legumes, nuts, whole grains and extra virgin olive oil, a moderate consumption of fish and poultry and a low intake of red and processed meat, sugar-sweetened beverages and processed foods. It is largely recognized that high adherence to the MedDiet has cardiometabolic benefits and reduces cardiovascular disease and mortality (7)(8)(9). Another factor that should be taken into account in the evaluation of lifestyle is the level of physical activity, because PA and exercise are also important determinants of weight loss and maintenance (10)(11).

Unfortunately, few studies have evaluated lifestyle changes after bariatric surgery and its impact on weight loss and BMI, food tolerance and comorbidities. Therefore, the aim of the present study was to evaluate changes in weight, BMI, quality of life and food tolerance and how these changes are related to changes in the dietary food pattern, PA and food tolerance after bariatric surgery.

MATERIALS AND METHODS

The present study is a prospective observational design in the context of a randomized controlled trial carried out at the University Hospital Sant Joan de Reus, Spain, which evaluated the effect before undergo bariatric surgery of two dietary interventions of 21 days (a very low calorie diet versus a low calorie diet) on weight loss and liver volume.

Participants

We recruited men and women with morbid obesity pending laparoscopic bariatric surgery: Roux-en-Y gastric bypass (LRYGB) and laparoscopic sleeve gastrectomy (LSG) bariatric surgery. The inclusion criteria were: men and women between 18 and 66 years old, with: (a) a BMI ≥35 kg/m^2 and associated comorbidities such as type 2 diabetes mellitus, hypertension, dyslipidemia, sleep apnea, and obstructive sleep apnea-hypopnea syndrome; or (b) a BMI ≥40 kg/m^2 and for whom conservative treatment had failed. The exclusion criteria were as follows: (a) a BMI < 35; (b) pregnant or breast-feeding women; (c) severe systemic or organic pathology (severe respiratory pathology or renal insufficiency, active neoplastic disease, advanced liver disease, myocardial infarction or stroke in the past 6 month); (d) individuals being treated with insulin; (e) individuals with coagulation problems; and (f) individuals with unresolved eating disorders or severe psychiatric pathology.

After surgery, we provide leaflets to the patients with general dietary recommendations following a general protocol (progressive diet during the first month). After the first month of surgery periodically in each visit, we provide general recommendations to adhere to a healthy diet by providing personalized advice.

All the subjects provided written informed consent for their participation. The study was approved by the Ethical Committee of the University Hospital Sant Joan de Reus. All procedures performed were in accordance with the 1964 Helsinki declaration and its later amendments. The study was registered at ISRCTN: (http://www.isrctn.com/ISRCTN16967604).

Exposure

Adherence to MedDiet and PA was measured at baseline (3 weeks before bariatric surgery), and quarterly thereafter until 12 months after surgery.

To estimate adherence to MedDiet, a validated 14-point method called Mediterranean Diet Adherence Screener (MEDAS) (12) was administered. This questionnaire contains 14 short questions which provide information on adherence to the MedDiet. Each of the 14 items is scored with 1 point if the answer adheres to the MedDiet or with 0 if it does not. The final score ranges from 0 to 14 and subdivided in four categories : very low adherence (0-4 points), low (5-7 points), medium (8-11 points) and high adherence (12-14 points).

For our study, adherence to MedDiet was dichotomized into: 1) an increase, or 2) a decrease or maintenance of adherence 12 months after surgery in relation to the baseline situation.

PA was assessed using the International Physical Activity Questionnaire-Short Form (IPAQ-SF). This questionnaire was validated for the Spanish population and evaluates the sedentary lifestyle and the activity during the previous 7 days taking into account the frequency (days per week), intensity (mild, moderate or vigorous) and duration (minutes per session). Depending on the type of activity and its intensity, specific metabolic

equivalents (METs) are assigned and then the weekly PA is calculated and expressed in METs-min-week (13)(14).

Participants were grouped in the following levels of PA: 1) low, when the level of PA does not meet the criteria for high or moderate PA; 2) moderate: ≥ 3 or more days of vigorous activity for at least 20 minutes or ≥ 5 days of moderate PA and/or walking ≥ 30 min/day, or ≥ 5 days of some combination of walking, moderate PA and vigorous PA, obtaining ≥ 600 MET-min/week., and 3) high: ≥ 3 days of vigorous PA (≥ 1,500 MET-min/week); 7 days/week of some combination of walking, moderate PA or vigorous PA, accumulating ≥ 3,000 MET-min/week.

For the present study individuals were categorized as increasing or decreasing PA 12 months after surgery.

Outcomes

At baseline, 3, 6, 9 and 12 months after surgery, weight, quality of life and food tolerance were recorded. We used the 12-month changes from baseline as outcomes.

Height was measured at baseline using a wall stadiometer (Seca 223, 2010). Body weight was measured by bioelectrical impedance (TANITA TBF-420; 2014) with the patient under controlled fasting, with light clothes and without shoes. All measurements were made twice and the average of the two measurements was used for the study. Total weight loss (TWL), total percentage of weight loss (%TWL), percentage of excess weight loss (%EWL) and percentage of excess BMI loss (%EBMIL) were determined.

Quality of life was determined by the Moorehead-Ardelt Quality of Life Questionnaire II (4). This questionnaire consists of 6 questions on mood, physical activity, social relationships, work capacity, sexual satisfaction and dependence on food. The questions are scored from -0.5 (worst rating) to 0.5 (best rating) with ten intervals of

0.1 between them, with total scores ranging from -3.0 to 3.0. The quality of life is reflected in the score obtained: Very poor: -3.0 to -2.1; Poor: -2.0 to -1.1; Reasonable: -1.0 to 1.0; Good: 1.1 to 2.0; Very good: 2.1 to 3.0. The total score of this questionnaire is the sum of each item.

Food tolerance was measured 3, 6, 9 and 12 months after surgery using the Spanish version of the Suter test (5)(15). The questionnaire contains 4 sections although section 2 is not included in the total points score: 1) Patient satisfaction with food quality; the subjects rate their satisfaction with values from 1 (very poor) to 5 points (excellent); 2) Questions about the timing of meals and the intake of food between meals (not scored); 3) Tolerance of eight different types of food (red meats, white meats, salads, vegetables, bread, rice, pasta and fish) whose individual score per food is the following: if the patient tolerates food intake with no difficulty (2 points), if the patient has some difficulty with intake (1 point) and if the patient cannot tolerate the food (0 points); 4) Evaluation of the frequency of vomiting and/or regurgitation; the score ranges from 0 to 6: 0 points, when the symptoms are present daily; 2 points, when symptoms are present more than twice a week; 4 points, when symptoms are rare; and 6 points, when symptoms are never present. Thus, with the sum of section 1, 3 and 4, the score ranges from 1 (low food tolerance) to 27 (excellent food tolerance).

Statistical analysis

The continuous variables are expressed as means ± standard deviation and medians (interquartile range: percentile 25–75), as appropriate, and the categorical variables as numbers and percentages.

The normality of distribution of the continuous variables was assessed by the Kolmogorov-Smirnov test. The paired Student's t-test was used to evaluate within-group differences. To determine differences between groups, an analysis of covariance

(ANCOVA) was applied. The ANCOVA model included: a) sex, age, baseline weight, type of intervention (Roux-en-Y gastric bypass or sleeve gastrectomy), smoking (yes or not) and diabetes prevalence; b) The same covariates and their corresponding basal value.

We also explored the joint effect of combining MedDiet adherence and PA on mean changes in total weight loss expressed as a percentage. Categories were cross-analyzed: decreased adherence to MedDiet & increased PA; increased adherence to MedDiet & decreased PA; increased adherence to MedDiet & increased PA; and decreased adherence to MedDiet and decreased PA. An ANCOVA test with the same aforementioned variables was used.

The level of significance was established at $p \leq 0.05$ for all analyses, which were carried out with the package SPSS 20.0 (SPSS Statistics IBM®, Chicago, IL).

RESULTS

Patient's baseline characteristics

A total of 311 individuals were assessed to determine whether they were eligible to be included in the RTC. Of these, 46 were excluded because they did not meet the inclusion criteria, 3 did not want to participate and 178 were excluded because the surgery was programmed at short notice. Therefore, 84 participants were randomized into the trial. A total of 6 participants were lost during the follow-up. Thus, 78 participants remained for the present analysis. Figure 1 shows the details of the flow-chart.

Table 1 shows the baseline characteristics of the participants. A total of 75.6% of the participants were women with a mean age of 45.3 years and a BMI of 47.2kg/m^2. A total of 59.2% of the participants had low or very low adherence to the MedDiet, and 50% had a low level of physical activity. Only 23.6% of the individuals reported having a good or very good quality of life.

Impact of adherence to the Mediterranean diet and physical activity on weight loss and BMI

Table 2 shows the baseline and the changes in adherence to the MedDiet, PA, weight and BMI in those participants who increased MedDiet adherence versus those who decreased adherence after a 12-month follow-up. Compared to those who decreased or maintained adherence to the MedDiet, individuals who increased adherence had a significantly higher weight loss: -48.7kg (-45.8, -51. 6) vs. -43.9kg (-40.7, -47.1), P = 0.035; percentage of excess weight lost (%EWL): -71.2% (-66.8, -75.6) vs. -63.1% (-58.3, -67.9), P=0.018; and a non-significant decrease in BMI: -17.7kg/m^2 (-16.6, -18.8) vs. -16.1kg/m^2 (-15.0, -17.2), P = 0.061; and percentage of excess BMI lost (%EBMIL):

-81.8% (-77.2, -86.3) vs. -75.1% (-70.1, 80.0), P=0.057. At 9 and 12 months of follow-up, individuals who increased adherence to the MedDiet reported a higher percentage of weight loss than those who did not (Figure 2).

Table 3 shows the baseline and the changes in MedDiet adherence, PA, weight and BMI in those participants who increased PA versus those who decreased during the follow-up. No significant differences were observed for none of the parameters of weight loss or BMI between those participants increasing or maintaining and decreasing PA during the follow-up.

Figure 3 shows the joint effect of combining adherence to the MedDiet and PA on changes in total weight loss. No significant differences were observed between categories in mean changes of total weight loss expressed as a percentage (P=0.083).

Impact of adherence to the Mediterranean diet and physical activity on quality of life

Figure 4 shows the changes after a 12-month follow-up in the Moorehead-Ardelt quality of life questionnaire total score and each of its items depending on whether adherence to the MedDiet increased or decreased during the follow-up. Although the mean score of each item increased significantly in comparison to baseline in both categories, no significant between-group differences were observed. Similarly, no differences between groups in terms of changes in total score were observed after 12 months of follow-up.

Figure 5 shows the changes after 12-months in the quality of life questionnaire (total score and individual item scores) depending on whether PA increased or decreased during the follow-up. An increase in all the items was observed for those participants who increased PA during the follow-up, whereas an increase was observed only in the self-

esteem, PA and approach to food items for those who decreased PA. Significant differences between-categories of PA were observed in the item approach to food.

Impact of adherence to the Mediterranean diet and physical activity on food tolerance

The type of surgery (LRYGB vs LSG) led to no differences in food tolerance at 3, 6, 9 and 12 months (data not shown). Neither were there any differences in the 3 sub-sections of the test (food satisfaction, food tolerance and frequency of vomiting or regurgitation) in the total score of food tolerance between those individuals who increased or decreased their adherence to the MedDiet (23.4 vs 23.4, p=0.921) or their level of PA (23.3 vs 23.8, p=0.533).

DISCUSSION

Although several studies have demonstrated the efficacy in adhering to the Mediterranean diet and physical activity in terms of weight loss in populations with overweight or obesity, no study had ever analyzed this in morbidly obese patients undergoing bariatric surgery.

The present study shows that those individuals who increased adherence to the MedDiet after bariatric surgery presented a greater weight loss than those who maintained or decreased adherence. However, an increase in PA was not associated with changes in weight or BMI. Similarly, the joint effect of adherence to the MedDiet and PA showed no differences between categories in mean changes of total weight loss. No differences were observed between categories of adherence to the MedDiet or levels of PA after surgery in terms of quality of life and food tolerance.

Bariatric surgery is an effective method for weight loss, though the results obtained are not always as expected. It has been seen that both food tolerance and lifestyle after surgery can have a considerable effect on weight changes and quality of life.

Several studies have analyzed the influence of adherence to the MedDiet and/or PA on weight loss (16). Unfortunately, most were conducted in subjects with a BMI <40 kg/m^2. Moreover, to the best of our knowledge, no previous study has evaluated the mediation effect of a healthy diet (such as MedDiet) and/or PA on weight and BMI changes, quality of life or food tolerance in bariatric surgery. One of the most important studies that assesses the effect of a lifestyle intervention program with an energy restricted MedDiet and PA promotion on weight loss and cardiovascular risk is the PREDIMED-PLUS study, 2018 (8). In the pilot study of this randomized clinical trial, carried out in 626 overweight and obese subjects (BMI ≥27 and <40 kg/m^2) with metabolic syndrome, subjects who adhere to an energy restricted MedDiet and PA had lost more weight than

the control group (following recommendations to adhere to a non-energy restricted MedDiet).

The fact that in our study subjects who increased adherence to MedDiet after surgery lost significantly more weight than those who decreased it has also been observed by Ruiz-Tovar et al. (2014) in subjects who have undergone vertical gastrectomy. They showed a positive correlation between the increase in adherence to the MedDiet and weight loss achieved after surgery (9).

In terms of PA, the present study observed that individuals who increased their levels of PA tended to lose more weight than those who maintained or decreased their PA, although no significant differences were observed between groups. Similarly, in the study by Boan et al. (2004), PA was not shown to be a predictor of weight loss even if PA was significantly increased after the intervention (17). However, our results are not in line with those reported in a prospective study (2019) with a 6-month follow-up (n = 52), which reported a significant association between an increase in PA and weight loss (10). Furthermore, in a retrospective study, a low level of physical activity, high BMI, low educational level, prevalent diabetes and poor adherence to post-surgery follow-up visits were determinants of a reduced body weight response after bariatric surgery (18). These results are in line with a systematic literature review and meta-analysis (2018) that reported that exercise training programs after bariatric surgery were effective at increasing weight loss and loss of fat mass (19).

A meta-analysis of clinical trials has demonstrated that the combination diet (in this case the MedDiet) and PA loses weight more effectively at 12 months than programs that focus only on diet recommendations or physical activity alone (20). Another meta-analysis of randomized controlled trials in 3,436 participants with overweight or obesity showed that an increase in adherence to the MedDiet is particularly effective for losing

weight if the diet is energy restricted and is accompanied by increased PA for at least 6 months (11). Although our study did not show a significant effect of a combination of adherence to the MedDiet and PA on changes in total weight loss, those individuals who increased adherence to the MedDiet and their levels of PA did tend to lose more weight. This is in line with the two aforementioned meta-analyses.

It is worth to mention that regarding the effectiveness of the surgery in terms of weight loss, mean weight loss in our study may be considered as excellent when expressed in terms of %EBMIL (>65%), and good expressed as %EWL (50-74%) according to the 2018 Spanish Consensus Document in Bariatric Endoscopy (21) for the four groups analyzed (increase and decrease in adherence to MedDiet and PA).

Several studies have associated an increase in quality of life with weight loss after bariatric surgery (22)(23). However, there is also evidence of an improvement in the quality of life just after bariatric surgery even when weight loss is only modest, suggesting that it may also be influenced by other psychological, social and physical factors (24). In the present study, we tried to determine how adhering to the MedDiet and PA after surgery influences the quality of life. No differences were observed in either the total quality of life score or the scores for the individual components between those subjects who increased versus those who decreased adherence to the MedDiet. Similarly, regarding PA, there were no differences between groups in terms of total score, although significant differences were observed in the individual item of "approach to food". Therefore, it seems that participants who decreased PA were significantly less hungry than those who increased it.

In the literature there is some controversy about the relation of LRYGB and LSG with food tolerance (25). In the present study, there were no significant differences between the type of intervention and its effect on food tolerance. Some studies have

shown that individuals are less tolerant to food during the first years after surgery, and that this intolerance can influence the quality of the diet. Some of the least tolerated foods during the first year after surgery are pasta, rice and red meat (26). Other studies have observed a direct association between dietary tolerance and the quality of the diet (27). We evaluated if increased or decreased MedDiet adherence or PA after one year was related to food tolerance, but found no significant differences between groups.

One limitation of our study is that we have not used biomarkers to assess adherence to the MedDiet or any technology to objectively record PA, even using validated questionnaires, data cannot accurately show compliance with the diet or the actual PA carried out. The limited number of subjects r and the short follow-up without taking into account long-term weight regain usually observed after 12 month, can be considered other limitations of the present study.

However, as strengths, validated recording methods were used, and the periodic appointments with medical staff were very thorough, so the results can be assumed to be reliable. In addition, our study presents a homogeneous population in terms of age and degree of obesity. And the main strength we should mention is that our study has evaluated for the first time the effect of a combination of adherence to the MedDiet and PA on weight loss, quality of life and food tolerance in morbidly obese patients undergoing bariatric surgery.

CONCLUSIONS

Our study showed that an increase in adherence to the MedDiet after bariatric surgery is associated with greater weight loss in morbidly obese participants after bariatric surgery. However, an increase in PA is not associated with weight loss or BMI. The Mediterranean diet and physical activity after surgery do not seem to have a direct influence on the quality of life and food tolerance. More studies with larger samples are needed to confirm these findings.

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COMPLIANCE WITH ETHICAL STANDARDS

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Conflict of Interest

Author 4 reports receiving a grant from Nestlé thorough his institution. The other authors declare that they have no conflict of interest.

Informed Consent

Informed consent was obtained from all individual participants who took part in the study.

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Table 1. Descriptive baseline characteristics of the study participants

Parameters	**Group** **n=78†**
Sex, female; n (%)	59 (75.6)
Age (years)	45.3±10.1
Weight (kg)	129.1±20.3
Height (cm)	165.1±8.1
Body mass index (kg/m^2)	47.2±5.2
Adherence to Mediterranean diet[a]	**n=76**
Very low adherence (<5); n (%)	7 (9.2)
Low adherence (5-7); n (%)	38 (50.0)
Moderate adherence (8-11); n (%)	31 (40.8)
High adherence (≥12); n (%)	0 (0)
Level physical activity[b]	**n=78**
Low level of physical activity; n (%)	39 (50.0)
Moderate level of physical activity; n (%)	25 (32.1)
High level of physical activity; n (%)	14 (17.9)
Quality of life[c]	**n=68**
Very poor (-3 to -2.1); n (%)	1 (1.5)
Poor (-2 to -1.1); n (%)	2 (2.9)
Reasonable (-1 to 1); n (%)	49 (72.1)
Good (1.1 to 2); n (%)	11 (16.2)

Very good (2.1 to 3); n (%)	5 (7.4)

Abbreviations: SD, Standard deviation;

Results are expressed as mean ± standard deviation or number (percentage) of individuals.

† Of the 78 subjects, 53 (67.9%) underwent Laparoscopy Roux-en-Y gastric bypass and 25 (32.1%) laparoscopic sleeve gastrectomy.

[a]Adherence to Mediterranean diet measured by the MEDAS score. [b]Physical activity measured by the international physical activity short questionnaire (IPAQ-short q). [c]Quality of life was assessed by the Moorehead-Ardelt Quality of Life Questionnaire.

Table 2. Baseline and changes in Mediterranean diet adherence, physical activity, weight and BMI, in those participants who increase Mediterranean diet adherence versus those who decrease adherence after a 12-month follow-up

	Adherence to the Mediterranean diet			
	Increase (n=41)†	Decrease (n=35)††	Differences between groups	Adjusted P-value
Adherence to MedDiet score at baseline	5.9 (5.4, 6.4)	8.1 (7.5, 8.6)	2.1 (1.3, 2.9)	<0.001[a]
Change in adherence to MedDiet at 12 months	1.9 (2.1, 1.6)*	-0.4 (-0.04, -0.7)*	2.3 (1.8, 2.8)	<0.001[b]
METs per week at baseline	1819.5 (1097.2, 2541.8)	1546.3 (761.5, 2331.0)	-273.2 (-1364.9, 818.6)	0.619[a]
Change in METs per week at 12 months	1163.8 (2104.4, 223.2)*	2365.4 (3387.4, 1343,3)*	-1201.6 (2624.7, 221.5)	0.097[b]
Weight at baseline (Kg)	129.3 (123.8, 134.9)	129.0 (123.0, 135.1)	-0.3 (-8.6, 8.1)	0.948[a]
Change in weight at 12 months (Kg)	-48.7 (-45.8, -51.6)*	-43.9 (-40.7, -47.1)*	-4.8 (-9.2, -0.3)	0.035[b]
Total weight loss at 12 months (%)	-37.6 (-35.5, -39.8)	-34.1 (-31.8, -36.5)	-3.5 (-6.8, -0.2)	0.036[b]
Excess weight loss at 12 months (%)	-71.2 (-66.8, -75.6)	-63.1 (-58.3, -67.9)	-8.1 (-14.7, -1.4)	0.018[b]
BMI (kg/m^2) at baseline	47.0 (45.4, 48.5)	47.4 (45.7, 49.2)	0.5 (-1.9, 2.9)	0.683[a]
Change in BMI at 12 months (kg/m^2)	-17.7 (-16.6, -18.8)*	-16.1 (-15.0, -17.2)*	-1.5 (-3.2, 0.1)	0.061[b]

Excess BMI loss at 12 months (%)	-81.8 (-77.2, -86.3)	-75.1 (-70.1, -80.0)	-6.7 (-13.6, 0.2)	0.057[b]

Abbreviations: MedDiet, Mediterranean diet; METs, Metabolic equivalents; BMI, body mass index; NS, not significant.

†Of the 41 subjects, 30 (73.2%) underwent Laparoscopy Roux-en-Y gastric bypass and 11 (26.8%) Laparoscopic sleeve gastrectomy. †† Of the 35 subjects, 23 (65.7%) underwent Laparoscopy Roux-en-Y gastric bypass and 12 (34.3%) Laparoscopic sleeve gastrectomy.

*Results are expressed as means and 95% confidence intervals (CI) in brackets. To determine differences in the same group, we applied a paired analysis (Student's t-test). To determine differences between groups, we applied an analysis of covariance (ANCOVA). The ANCOVA model included: [a] sex, age, baseline weight, type of intervention (Roux-en-Y gastric bypass or sleeve gastrectomy) smoking (yes or not) and baseline diabetes; [b] The same covariates in addition to their corresponding basal value. *: p value <0.05 versus baseline values.*

Table 3. Baseline and changes in Mediterranean diet adherence, physical activity, weight and BMI, in those participants that increase physical activity versus those that decrease at 12-month of follow-up.

	Physical activity			
	Increase (n=62)†	Decrease (n=16)††	Differences between groups	Adjusted P-value
Adherence to MedDiet score at baseline	7.0 (6.5, 7.5)	6.7 (5.7, 7.7)	-0.3 (-1.4, 0.8)	0.614[a]
Change in adherence to MedDiet score at 12 months	0.8 (1.1, 0.4)	1.1 (1.8, 0.4)*	-0.3 (-1.1, 0.4)	0.407[b]
METs per week at baseline	1097 (604, 1590)	3825 (2837, 4813)	2728 (1613, 3842)	<0.001[a]
Change in METs per week at 12 months	2569 (3248, 1891)*	-1599 (-116, -3081)*	4169(2453, 5884)	<0.001[b]
Weight at baseline (Kg)	130.2 (125.9, 134.5)	124.3 (115.7, 132.9)	-5.9 (-15,6, 3.7)	0.225[a]
Change in weight at 12 months (Kg)	-46.5 (-44.1, -48.9)*	-44.7 (-39.9, -49.5)*	-1.8 (-7.2, 3.6)	0.502[b]
Total weight loss at 12 months (%)	-36.1 (-34.3, -37.9)	-34.6 (-31.0, -38.1)	-1.5 (-5.5, 2.5)	0.456[b]
Excess weight loss at 12 months (%)	-67.2 (-63.6, -70.9)	-66.4 (-59.1, -73.7)	-0.9 (-9.1, 7.4)	0.835[b]
BMI (kg/m^2) at baseline	47.7 (46.5, 48.9)	45.0 (42.6, 47.4)	-2.7 (-5.5,0.01)	0.049[a]
Change in BMI at 12 months (kg/m^2)	-16.9 (-16.1, -17.8)*	-16.5 (-14.8, -18.2)*	-0.4 (-2.4, 1.6)	0.670[b]
Excess BMI loss at 12 months (%)	-78.6 (-74.8, -82.3)	-76.5 (-69.0, -84.0)	-2.1 (-10.6, 6.4)	0.631[b]

Abbreviations: MedDiet, Mediterranean diet; METs, Metabolic equivalents; BMI, body mass index; NS, not significant.

†Of the 62 subjects, 44 (71.0%) underwent Laparoscopy Roux-en-Y gastric bypass and 18 (29.0%) Laparoscopic sleeve gastrectomy. †† Of the 16 subjects, 9 (56.3%) underwent Laparoscopy Roux-en-Y gastric bypass and 7 (43.8%) Laparoscopic sleeve gastrectomy.

*Results are expressed as mean and 95% confidence intervals (CI) in brackets. To determine differences in the same group, we applied a paired analysis (Student's t-test). To determine differences between groups, we applied an analysis of covariance (ANCOVA). The ANCOVA model included: [a] sex, age, baseline weight, type of intervention (Roux-en-Y gastric bypass and sleeve gastrectomy), smoking (yes or no) and baseline diabetes; [b] The same covariates in addition to their corresponding basal variable. *: p value <0.05 versus baseline values.*

Figure 1. Diagram of the study progress

Abbreviations: n=number.

Figure 2. Changes in the percentage of total weight lost per quarters in those participants who increase adherence to the Mediterranean diet versus those who decrease adherence after bariatric surgery

Abbreviations: %TWL: total weight loss expressed as a percentage; MedDiet: Mediterranean diet.

*ANCOVA test adjusted for sex, age, baseline weight, type of intervention, smoking and diabetes. *a: p-value < 0.05 between groups.*

Figure 3. Comparison of changes in total weight loss in subjects who decrease adherence to the Mediterranean diet and physical activity versus those who increase one or both variables after bariatric surgery

Abbreviations: TWL: total weight loss (%); MedDiet: Mediterranean diet.

Results are expressed as mean and maximum values. To determine differences between groups we applied Student's t test and an analysis of covariance (ANCOVA). The statistical analysis was conducted by using ANCOVA. The model was adjusted for sex, age, baseline weight, type of intervention, smoking and diabetes. There were no significant differences between groups.

Figure 4. Changes in quality of life after a 12-month follow-up in those participants who increase adherence to the Mediterranean diet versus those who decrease adherence after bariatric surgery

Abbreviations: Q: question; MedDiet: Mediterranean diet.

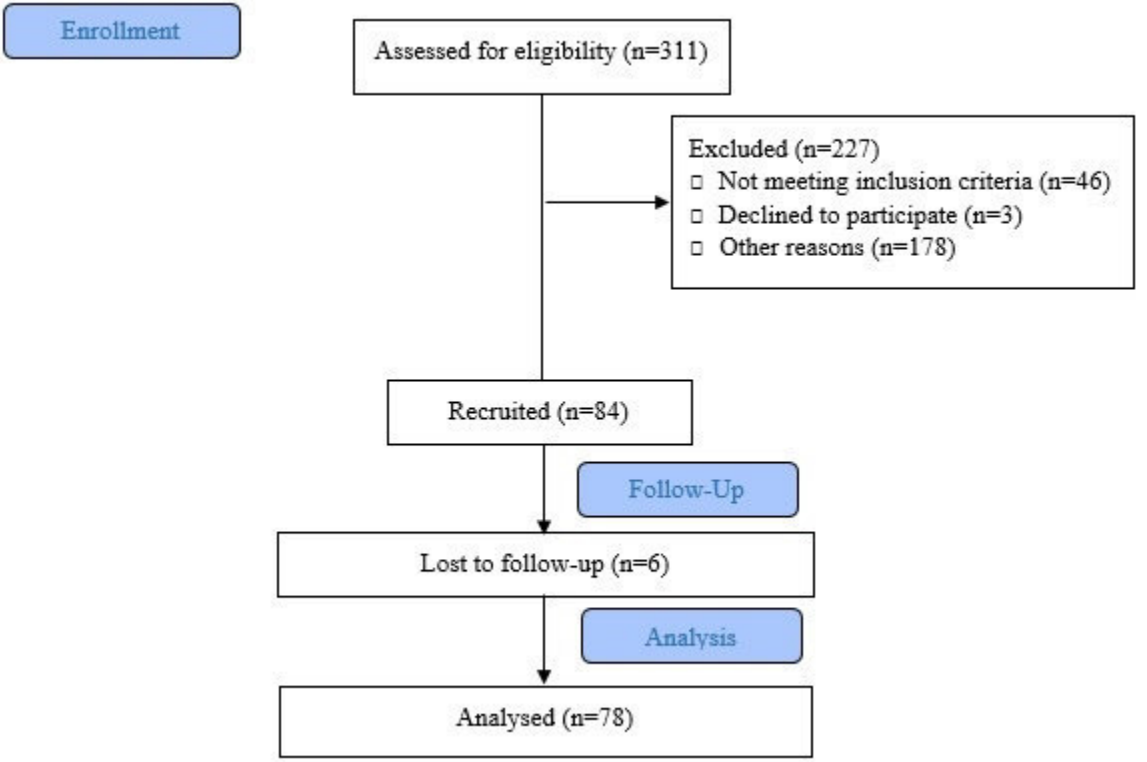
Results are expressed as means and 95% confidence intervals (CI) in brackets. To determine differences between groups, we applied Student's t test and an analysis of covariance (ANCOVA) adjusted for sex, age, baseline weight, type of intervention, smoking status and diabetes in addition to their corresponding

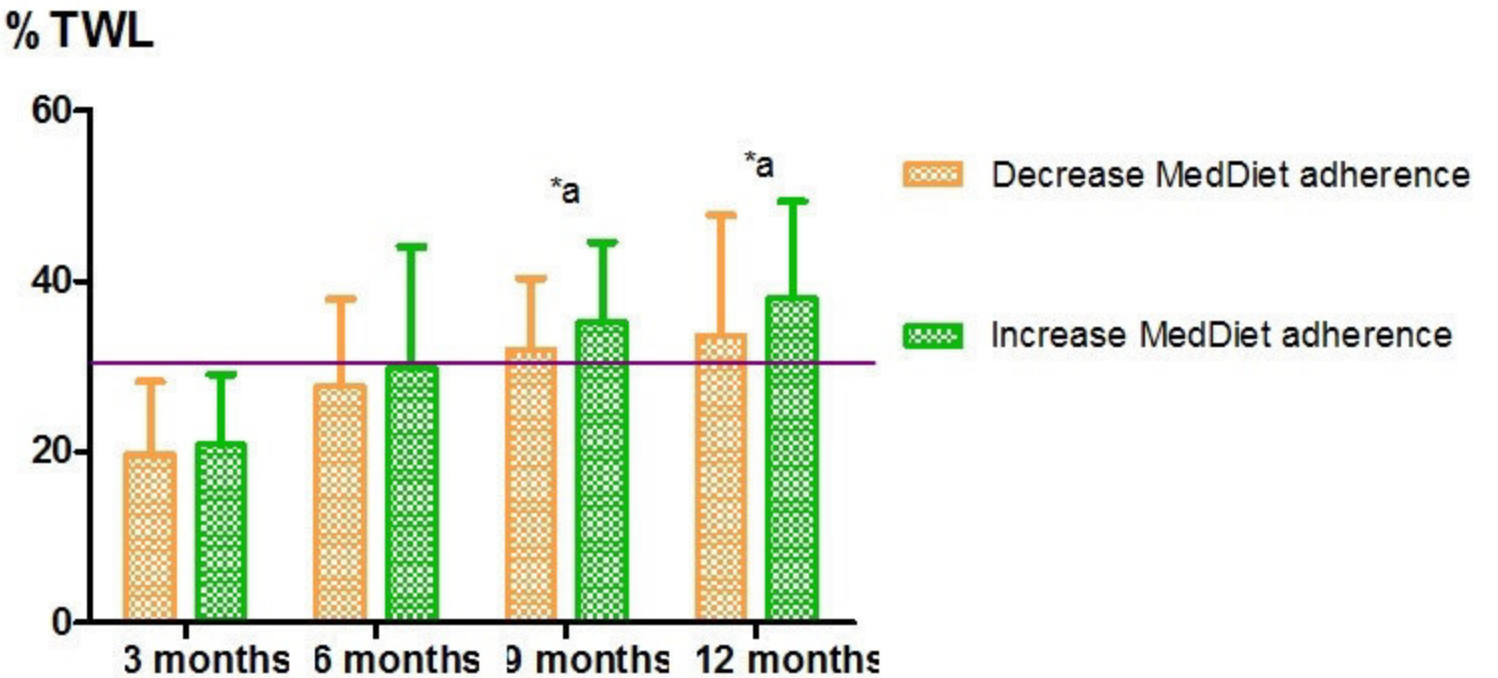
*basal variable. *: p value <0.05 versus baseline values. There were no significant differences between groups.*

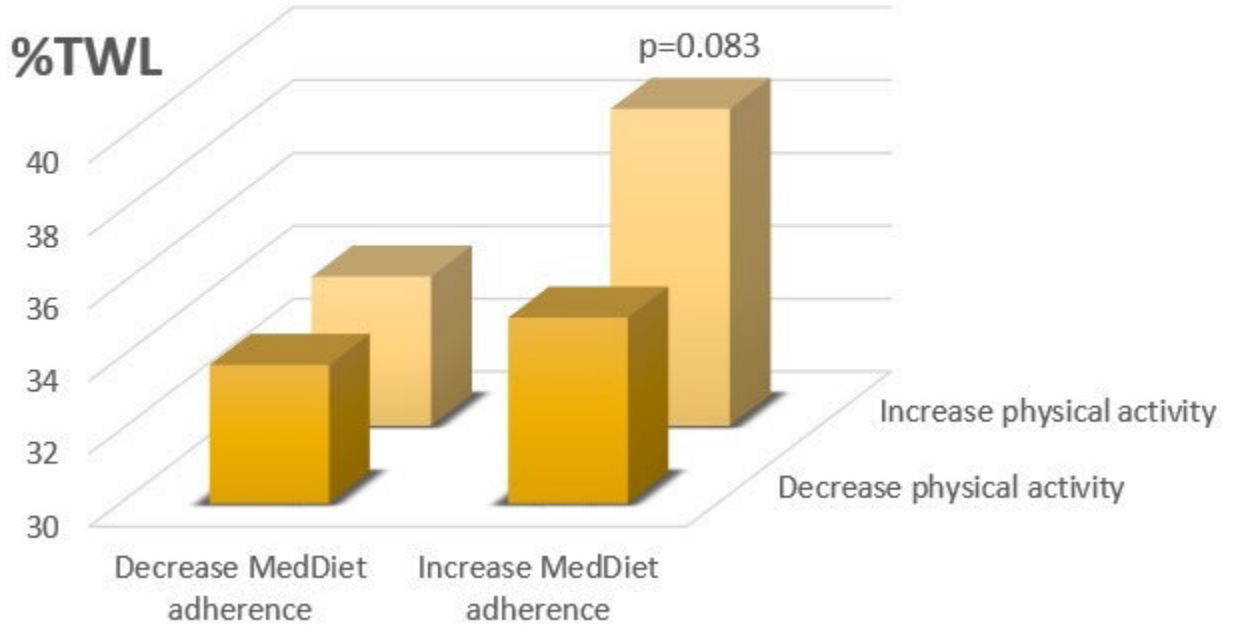
Figure 5. Changes in quality of life after a 12-month follow-up in those participants who increase physical activity versus those who decrease it after bariatric surgery

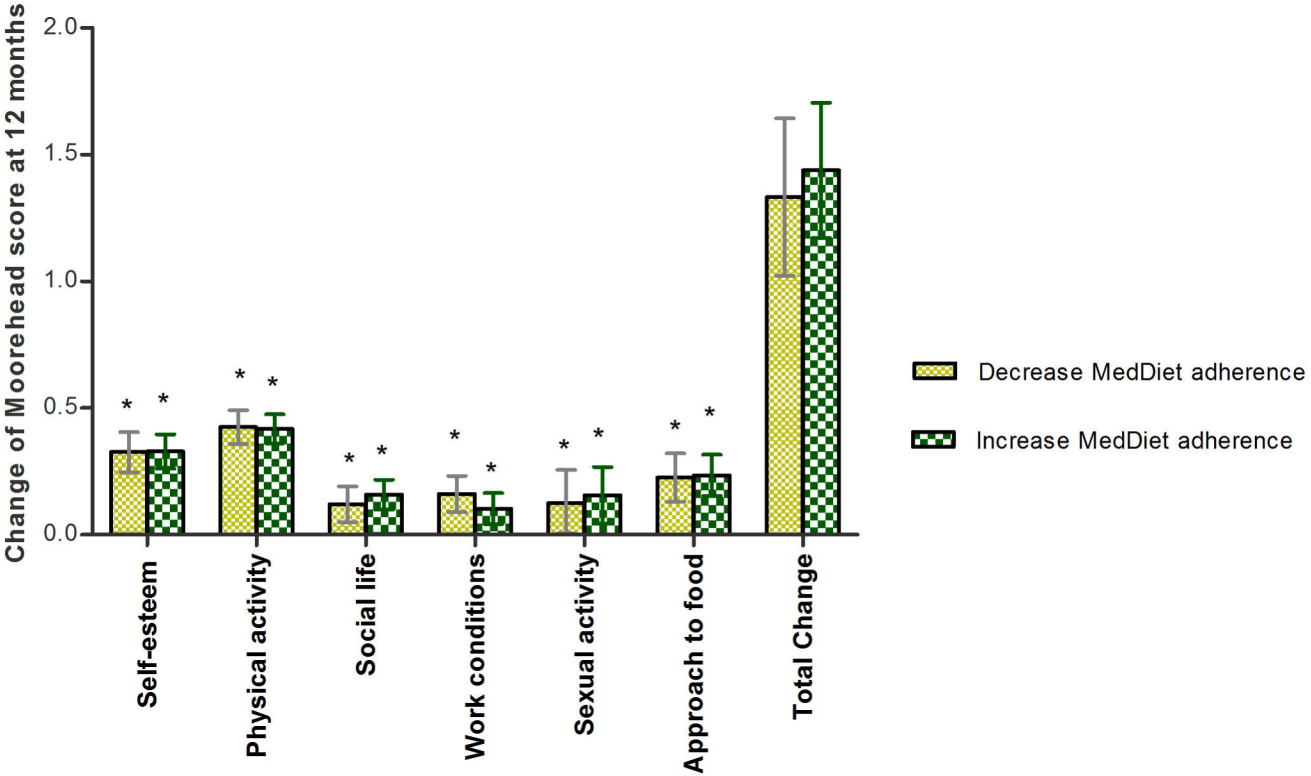
Abbreviations: Q: question.

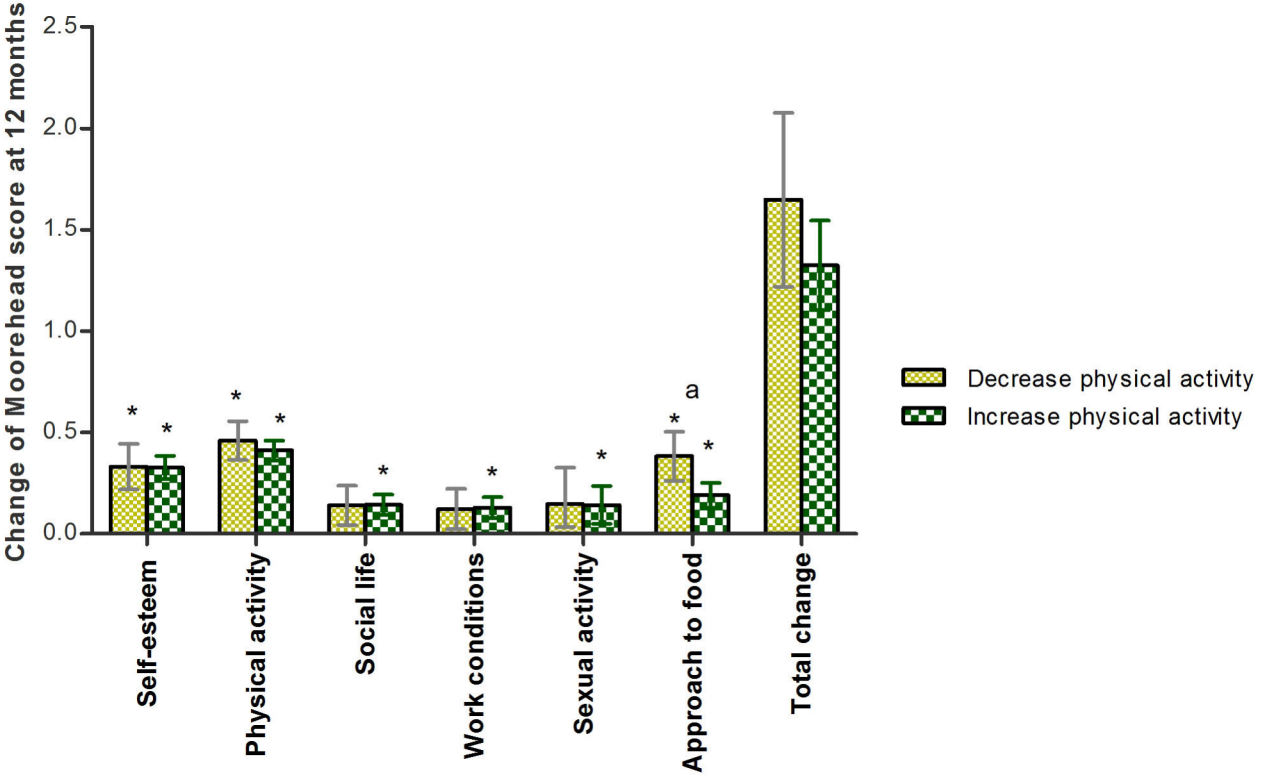
*Results are expressed as means and 95% confidence intervals (CI) in brackets. To determine differences between groups, we applied the Student's t test and an analysis of covariance (ANCOVA) adjusted for sex, age, baseline weight, type of intervention, smoking status and diabetes in addition to their corresponding basal variable. *: p value <0.05 versus baseline values. *a: p value <0.05 between groups.*


Enrollment
Assessed for eligibility (n=311)
Excluded (n=227)
Not meeting inclusion criteria (n=46)
Declined to participate (n=3)
Other reasons (n=178)
Recruited (n=84)
Follow-Up
Lost to follow-up (n=6)
Analysis
Analysed (n=78)


% TWL
60
40
20
0
*a
*a
3 months
6 months
9 months
12 months
Decrease MedDiet adherence
Increase MedDiet adherence


%TWL
p=0.083
40
38
36
34
32
30
Increase physical activity
Decrease physical activity
Decrease MedDiet adherence
Increase MedDiet adherence


Change of Moorehead score at 12 months
2.0
1.5
1.0
0.5
0.0
Self-esteem
Physical activity
Social life
Work conditions
Sexual activity
Approach to food
Total Change
Decrease MedDiet adherence
Increase MedDiet adherence


Change of Moorehead score at 12 months
2.5
2.0
1.5
1.0
0.5
0.0
*
*
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*
*
*
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*
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a
*
Self-esteem
Physical activity
Social life
Work conditions
Sexual activity
Approach to food
Total change
Decrease physical activity
Increase physical activity