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Body weight of individuals with obesity decreases after a 6-month high pasta or low pasta Mediterranean diet weight-loss intervention

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KEYWORDS
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Quality of life

Abstract *Background & aims:* The effect of pasta consumption within a low-energy Mediterranean diet on body weight regulation has been scarcely explored. This paper investigates the effect of two Mediterranean diets, which differed for lower or higher pasta intake, on body weight change in individuals with obesity.
Methods & Results: Forty-nine volunteers finished a quasi-experimental 6-month two–parallel group dietary intervention. Participants were assigned to a low-energy high pasta (HP) or to a low-energy low Pasta (LP) group on the basis of their pasta intake (HP $\geq$ 5 or LP $\leq$ 3 times/week). Anthropometrics, blood pressure and heart rate were measured every month. Weight maintenance was checked at month 12. Body composition (bioelectrical impedance analysis, BIA), food intake (24-h recall plus a 7-day carbohydrate record) and the perceived quality of life (36-item short-form health survey, SF-36) were assessed at baseline, 3 and 6 months. Blood samples were collected at baseline and month 6 to assess glucose and lipid metabolism. After 6-month intervention, body weight reduction was $-10 \pm 8\%$ and $-7 \pm 4\%$ in HP and LP diet, respectively, and it remained similar at month 12. Both dietary interventions improved anthropometric parameters, body composition, glucose and lipid metabolism, but no significant differences were observed between treatment groups. No differences were observed for blood pressure and heart rate between treatments and among times. HP diet significantly improved perception of quality of life for the physical component.
Conclusions: Independent of pasta consumption frequency, low-energy Mediterranean diets were successful in improving anthropometrics, physiological parameters and dietary habits after a 6-month weight-loss intervention.
This trial was registered at clinicaltrials.gov as NCT03341650.

List of abbreviations: SF-36, 36-item short-form health survey; BIA, bioelectrical impedance analysis; BP, bodily pain; BW, body weight; CVD, cardio-vascular disease; RE, emotional problems; FM, fat mass; FFM, fat-free mass; GH, general health; GI, glycemic index; HC, hip circumference; HP, low-energy High Pasta group; LP, low-energy Low Pasta group; MCS, mental component summary; MH, mental health; OGTT, oral glucose tolerance test; PCS, physical component summary; PF, physical function; RP, physical problems; SF, social function; TBW, total body water; TC, total cholesterol; VT, vitality; WC, waist circumference.

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Introduction

The worldwide prevalence of obesity nearly tripled between 1975 and 2016 [1]. The common health consequences of an excessive body weight are mainly cardiovascular disease (CVD), the most common cause of death in industrialized countries [2]; type 2 diabetes, one of the most significant global health issues of the 21st century [3]; musculoskeletal disorders [4]; and various cancers [5]. The etiology of obesity is complex and includes genetic, environmental, physiological, social and economic factors [6]. However, the leading cause of obesity and overweight is the energy imbalance between consumed and expended energy over time [6]. Thus, an energy-restricted diet results in clinically meaningful weight reduction as a result of a negative energy balance [7], more than of a change in the proportions of the macronutrient intake. However, many factors contribute to the success or failure of weight-loss and weight-management interventions. Among them, a common limitation is a poor long-term adherence to a dietary prescription, while a key factor to successful weight management is sustained adherence to a diet [8]. Indeed, weight regain could be due to the fact that changing an individual's behavior is not necessarily successful in changing an individual's habits [9].

In Italy, pasta is one of the most consumed staple foods [10] and it is a traditional component of the Mediterranean diet, which has been recognized as a healthy eating model and associated with several health benefits [11–16]. Recently, pasta consumption has been negatively associated with BMI, waist circumference (WC) and waist-to-hip ratio in two large Italian cohorts [17]. Therefore, an energy-restricted Mediterranean diet adjusted to local food availability and individuals' habits could be successful in terms of treatment compliance, weight loss and maintenance.

To the best of our knowledge, this is the first study aimed at investigating if the frequency of pasta consumption could influence the success of an energy-restricted Mediterranean dietary intervention. In particular, the effects of a low-energy high pasta (HP) intake and a low-energy low pasta (LP) intake on weight loss were compared, with a main target of 10% reduction of initial body weight, as indicated by the US Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults [18]. Body composition, blood glucose and lipid metabolism, and quality-of-life perception have also been monitored.

Methods

Participants

Participants were recruited among the patients attending the local hospital, where they entered voluntarily to follow a dietary treatment between January 2016 and March 2017. Volunteers who declared intentions to decrease body weight and to participate in the study were screened for eligibility during their first visit at the clinic. Eligible volunteers were adults with obesity (BMI between 30 and 45 kg/m^2). Other inclusion criteria were regular meal consumption (not skipping lunch and dinner), no recognized eating disorders, no celiac disease, no food allergies, low level of physical activity and, for women, not being pregnant and/or lactating during the last 12 months and not being in menopause. Volunteers were not eligible if they were less than 18 years old, with a BMI <30 or >45 kg/m^2, if they had diabetes, hepatic or kidney diseases, anemia, thyroid disease and any other chronic disease, or with a current diagnosis of an eating disorder.

Study design and dietary intervention

This study was a two–parallel group, quasi-experimental (without random assignment, for the reason explained below), 6-month weight-loss dietary intervention with 1-year follow up (Fig. 1). During the first admission to the

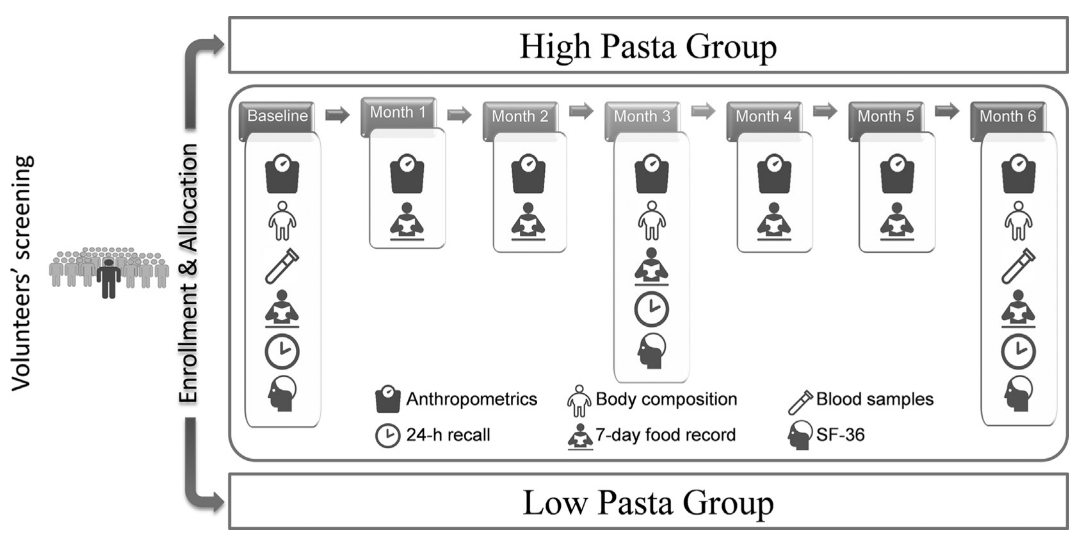

Figure 1 Study design and procedure.

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clinic, participants underwent a detailed visit with a nutritionist and a psychologist. Inclusion/exclusion criteria were checked by the nutritionist for anthropometric and clinical variables and by the psychologist to ascertain the absence of eating disorder. The eligible patients were enrolled in the study, after obtaining their written informed consent. Participants completed a dietary interview on their habitual food habits and were allocated in one of the two groups based on their habitual pasta consumption (balanced in terms of sex, age and BMI). The ones that usually consumed pasta at least five times/week were assigned to the low-energy HP group, while the volunteers habitually consuming pasta less than three times/week were allocated in the low-energy LP group. This approach prevented a proper randomization, but was thought to drastically increase the adherence to the treatment. The cut-off of the frequency of pasta consumption was set on the basis of the mean daily pasta consumption of the Italian adult population [19]. All participants received a personalized low-energy dietary plan, considering also food preferences and eating behavior. The dietary intervention was designed to be a personalized weight-loss program based on the national recommendations in accordance with the principles of the Mediterranean diet [20,21]. Participants enrolled in the HP group were asked to consume five or more portions of pasta (1 portion = 80 g [21]) every week, while participants in the LP group were asked to not eat more than three portions of pasta per week. In addition, participants were provided with a recipe book with dishes promoting the consumption of legumes, vegetables and fruits but differed for the use of pasta or other cereal-based products as main carbohydrate-based food.

The trial was performed in compliance with the Helsinki declaration, approved by the Hospital of Parma Ethical Committee (n.37,171–13/10/15) and registered at clinicaltrials.gov as NCT03341650.

Anthropometric measurements and body composition

Anthropometric measurements were assessed at baseline and monthly until month 6 and body weight was also measured during the follow-up visit at month 12 (6 months after the end of the intervention).

Body weight (BW) was measured to the nearest 0.01 kg using a calibrated mechanical weight scale SECA711 (220 kg, III class, 103,835) using a stadiometer and height was measured to the nearest 0.1 cm. BMI was calculated as weight in kilograms divided by the square of height in meters. WC and hip circumference (HC) were measured to the nearest 0.1 cm at the midpoint between the lower rib and the upper margin of the iliac crest, and at the level of the greater trochanters, respectively, using a non-stretchable tape measure with participants in standing position.

Body composition was evaluated at baseline and at month 3 and month 6 by a nutritionist through the bioelectrical impedance measure using a single-frequency bioelectrical impedance analyzer (BIA) (AKERN bioresearch, Firenze, Italy), according to the manufacturer's instructions. Subjects were in fasting conditions with voided bladder, wore underwear and laid in a prone position on a non-conductive table. Total body water (TBW), fat mass (FM) and fat-free mass (FFM) were obtained as derived measures using the BIA manufacturer's software (Bodygram Plus 1.1.4.13, 2016).

In addition, systolic and diastolic blood pressure and heart rate were measured at baseline and at every monthly visit, with subjects laying in a prone position on a table in resting condition.

Biochemical analyses

A 75 g oral glucose tolerance test (OGTT) was performed before the enrollment, to check for diabetic volunteers to be excluded, and to measure glucose levels at baseline (after 12 h fast) and at 60, 120 and 180 min.

Blood samples were collected at baseline and after 6 months to assess fasting glucose, insulin, total cholesterol (TC), high-density lipoprotein (HDL), low-density lipoprotein (LDL), triglycerides and uric acid. Blood was obtained from an intravenous catheter and was collected into tubes containing EDTA, heparin or nothing depending on the analysis. Analyses were performed blind by the personnel of the Laboratory of Clinical Chemistry and Haematology, University Hospital of Parma (Italy). The hospital central laboratory analyzed fasting plasma glucose, insulin, TC, HDL, triglycerides and uric acid using standard methods, while LDL was calculated using the Friedewald formula. In addition, the homeostatic model assessment for insulin resistant (HOMA-IR) index was calculated as the product of glucose in mg/dL and insulin in μIU/mL divided by 405.

Dietary assessment

Dietary information was collected at baseline and after 3 and 6 months. A nutritionist interviewed participants about the food they consumed the day before the visit and recorded the answers using the Automated Self-Administered 24-h dietary assessment tool (ASA24, U.S. National 154 Cancer Institute Bethesda, MD) [22]. In addition, participants registered their weekly frequency of consumption of pasta (compliance to the intervention), rice, other cereals, bread, pizza, potatoes and tubers, breakfast cereals, biscuits and desserts, legumes, fruit and vegetables, in a self-completed qualitative 7-day carbohydrate record completed the week before each visit at the clinic.

Subjective health-related quality of life

The perceived health-related quality of life was assessed using the 36-item short-form health survey (SF-36) [23] and considering the eight dimensions of health status: physical function (PF), role limitations due to physical problems (RP), bodily pain (BP), general health (GH), vitality (VT), social function (SF), role limitation due to emotional problems (RE) and mental health (MH). Each of these

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components was scored through a scale from 0 (lowest health status) to 100 (highest health status). PF, RP, BP and GH were summed to calculate the physical component summary (PCS); VT, SF, RE and MH to obtain the mental component summary (MCS), and the Total Quality of Life was obtained by summing all components.

Statistical analysis

The primary analyses were performed considering the *per-protocol* (PP, n = 49) group, defined as participants with no protocol violation (inclusion/exclusion criteria not met) and with completed data. To confirm the PP analysis, an intention-to-treat (ITT, n = 73) analysis was also carried out on anthropometric measurements, body composition data and blood parameters considering all volunteers initially enrolled in the study.

Continuous variables were expressed as mean ± standard deviation (SD). Normality of data distribution was verified through the Kolmogorov–Smirnov tests and not normally distributed variables were transformed using the natural logarithm (ln). The effect of time, treatment, time x treatment and time within each treatment group on BW and on BMI was assessed using a repeated-measure ANOVA model, testing the sphericity through the Mauchly test and, when violated, using the corrected value with Greenhouse–Geisser if epsilon was <0.75, or Huynh–Feldt if epsilon was >0.75. Bonferroni *post-hoc* tests were used for multiple comparisons if there was a main effect of time. The same repeated-measure ANOVA model was used to assess the effect of time within each treatment group for all other variables, using Bonferroni *post hoc* pairwise comparisons. Between-group differences were explored, after checking for the homogeneity of the variance through Levene's test, using an independent-sample T-student test at each time point. To check whether body weight changed during the follow-up, a paired-sample T-student test was performed between month 6 and month 12.

Qualitative variables (frequencies of food group consumption and quality-of-life scores) were expressed as median (interquartile range) and analyzed using Friedman's ANOVA for related-sample non-parametric tests with Dunn–Bonferroni *post hoc* pairwise comparisons to explore within-group differences among time points, and Wilcoxon non-parametric tests for between-groups comparison.

A p-value < 0.05 was considered statistically significant. All statistical analyses were performed with IBM SPSS 25.0 Statistics (IBM SPSS, Inc., Chicago, IL, USA).

Results

Baseline characteristics

Of the 85 volunteers assessed for eligibility, 73 were enrolled in the study and assigned to the HP (n = 37) or LP (n = 36) group. Of these, a total of 49 (n = 25 in the HP and n = 24 in the LP group) completed the 6-month dietary intervention (Supplemental Fig. 1). One volunteer diagnosed with a metabolic disease at the beginning of the study and another volunteer who became pregnant were excluded, while all other volunteers dropped out because they decided to be no longer on diet. Participants were mostly female, aged 23–61 years, with obesity (mean BMI = 37.3 ± 4.5 kg/m^2), and presented normal OGTT values (between 60 and 100 mg/dL under fasting condition, less than 200 mg/dL at 1 h and less than 140 mg/dL at 2 h). At baseline, the two groups were balanced in terms of age, sex and BMI, received a prescribed diet similar in terms of energy and nutrient composition but differed for their habitual intake of pasta (Table 1 and Supplementary Table 1).

Intention-to-treat analysis

Over-time differences within and between groups obtained for the ITT analysis were similar to the ones from the PP analysis for body weight, BMI, body circumferences, BIA-derived measures of adiposity and blood parameters related to both glucose and lipid metabolism (Supplementary Table 2). Since no differences were found between ITT and PP analyses, only results from the PP analysis are presented below.

Anthropometric measurements and body composition

Anthropometric and body composition data are presented in Table 2.

Body weight decreased in both groups from baseline to month 6, but no significant differences between HP and LP groups were observed. The mean changes in body weight at the end of the 6-month intervention were −10 ± 8% and −7 ± 4% in the HP and LP groups, respectively (Fig. 2), without significant differences between groups. A main effect of time ($p<0.001$) and of time within treatments ($p<0.001$ for both groups) was observed for body weight, while no effect of time x treatment was found. The body weight significantly decreased from baseline to month 3 in the LP group ($p<0.001$), while it was significantly lower also at month 4 compared to previous values in the HP group ($p < 0.001$). A trend of body weight loss was observed in both groups also in the last months of assessment but values remain similar to month 3 and month 4 in the LP and HP groups, respectively.

At the follow-up visit (month 12), participants' body weight was similar to month 6 in both HP and LP groups, and no differences were found between treatments.

According to body weight loss, participants' BMI significantly decreased from baseline to month 6, with a main effect of time ($p < 0.001$) and of time within treatments ($p < 0.001$ for both groups), but no differences were found between treatment groups. Irrespective of the dietary treatment, patients moved from class II obesity at baseline to class I obesity at the end of the intervention.

Similarly, a main effect of time ($p < 0.001$) and of time within treatments ($p < 0.001$ for both groups) was found for waist and hip circumferences. Body circumferences were significantly lower at 6 months ($p < 0.001$ for both

Table 1 Baseline characteristics and nutritional composition of the dietary prescriptions for the total population and for each treatment group (PP analysis).

Anthropometrics	Total (n = 49)	High Pasta (n = 25)	Low Pasta (n = 24)	*p* value
Sex (n F/M)	38/11	19/6	19/5	0.791§
Age (years)	47.9 ± 9.1	48.1 ± 9.3	47.6 ± 9.1	0.863
BMI (kg/m^2)	37.3 ± 4.5	37.7 ± 4.8	37.0 ± 4.3	0.592
OGTT t0 Glucose (mg/dL)	97.4 ± 11.1	95.1 ± 10.7	99.8 ± 11.3	0.144
OGTT t60 Glucose (mg/dL)	163.1 ± 41.3	158.8 ± 43.8	167.5 ± 39.0	0.463
OGTT t120 Glucose (mg/dL)	123.9 ± 36.0	126.0 ± 38.6	121.8 ± 33.9	0.687
OGTT t180 Glucose (mg/dL)	90.0 ± 24.4	93.6 ± 22.5	85.7 ± 26.3	0.279
Pasta intake (times/week)	4 (3–6)	6 (5–7)	3 (2–3)	<**0.001***
Dietary prescription				
Energy (kJ/day) (kcal/day)	6660.8 ± 648.4 (1591.2 ± 154.9)	6778.0 ± 670.2 (1619.2 ± 160.1)	6538.5 ± 614.9 (1562.0 ± 146.9)	0.200
Carbohydrates (%)	47.3 ± 5.6	48.8 ± 4.2	45.8 ± 6.5	0.061
Fats (%)	32.5 ± 2.8	32.5 ± 2.7	32.5 ± 3.0	0.976
Proteins (%)	21.4 ± 4.6	20.9 ± 2.5	22.0 ± 6.1	0.439

Data are expressed as number, means ± SD or median (IR). *P*-values refer to between-group comparisons (§χ^2 for categorical variables,
* Mann–Whitney non-parametric test, and *t*-tests for all continuous variables).
Numbers in bold are significant p values.

CV and CF) compared to baseline but were similar between treatments at each time point.

BIA derived measures of adiposity were all similar between treatments at baseline, month 3 and month 6. A main effect of time was found for FFM ($p = 0.021$) and FM ($p < 0.001$), while no effect of time x treatment was observed. When the two treatment groups were considered separately, a similar main effect of time on FFM ($p = 0.031$) and FM ($p < 0.001$) was found in the LP groups, while a main effect of time was only observed on the FM ($p < 0.001$) in the HP group. In both groups, the FM significantly decreased from baseline to month 3 ($p = 0.002$ and $p < 0.001$ in HP and LP, respectively) and month 6 ($p < 0.001$, in both groups), but not between 3 and 6 months.

Regarding blood pressure and heart rate measurements, participants presented normal values throughout the 6-month intervention (Table 2). No main effect of time, time x treatment and time within treatment groups was found and no differences were registered between groups at every time point.

Blood parameters

Blood values related to glucose and lipid metabolism are presented in Table 2.

Fasting blood glucose, insulin and HOMA-IR index values were similar between the two treatment groups at baseline and at month 6. In both groups, all parameters significantly decreased after the 6-month dietary intervention ($p < 0.001$ for all parameters in the LP group, $p = 0.001$ for glucose and HOMA-IR index and $p = 0.009$ for insulin in the HP group).

Likewise, no significant differences were found for TC, HDL-C, LDL-C and triglycerides between HP and LP groups at both time points. A similar trend of decrease over the time was observed in both groups for TC, LDL-C and triglycerides, but the reduction was significant only for TC in the HP group ($p = 0.048$) and for triglycerides in the LP group ($p = 0.044$). On the contrary, HDL-C values slightly increased from baseline to month 6 in both groups but only significantly in the HP group ($p = 0.045$).

Dietary intake and compliance to the dietary prescription

Self-reported dietary intake was similar between HP and LP groups in terms of daily energy and macronutrient intakes, at baseline, and at 3 and 6 months (Table 3). There was a main effect of time, independent of treatment, on energy ($p = 0.008$), fat ($p = 0.027$), carbohydrate ($p = 0.002$) and sugar intakes ($p = 0.003$), which decreased over time, while a main effect of treatments and treatments x time was not observed. When the two groups were considered separately, mean energy intakes decreased over time in both treatment groups, but a main effect of time on energy intakes was found only in the HP group ($p = 0.006$). There was a main effect of time on carbohydrate intakes ($p = 0.011$) only within the LP group, while time significantly affect fat ($p = 0.020$), and sugar intakes ($p = 0.010$) in the HP group.

Regarding weekly frequencies of consumption of carbohydrate-based foods (Table 3), only pasta consumption was different between treatment groups at each time point from baseline to month 6 ($p < 0.001$ for all), in line with the dietary prescription. Participants in the LP group had higher frequencies of consumption of cereals other than pasta and rice at baseline ($p = 0.044$) and at month 1 ($p = 0.010$), pizza at baseline ($p = 0.030$) and potatoes at baseline ($p = 0.048$). In contrast, participants in the HP group had a higher frequency of consumption of legumes at month 2 ($p = 0.005$) and month 4 ($p = 0.024$).

The weekly consumptions of fruit and vegetables were found to be significantly different among time points within each treatment group ($p < 0.001$ for all). In the HP group, fruit and vegetable frequencies of consumption were significantly increased at each time point compared to baseline ($p = 0.025$ and < 0.001 for month 1, $p = 0.011$

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Table 2 Anthropometrics, body composition, blood pressure, heart rate and blood parameters for each treatment group during the 6-month intervention (PP analysis).

Anthropometrics	Time	High Pasta (n = 25)	Low Pasta (n = 24)	*p* value
Body weight (kg)	Baseline	99.3 ± 12.5[a]	99.7 ± 14.2[a]	0.924
	Month 1	95.3 ± 11.6[b]	96.6 ± 13.9[b]	0.710
	Month 2	93.2 ± 11.8[c]	95.2 ± 14.1[c]	0.594
	Month 3	91.5 ± 12.0[d]	93.8 ± 14.0[d]	0.525
	Month 4	90.2 ± 12.4[e]	93.4 ± 13.8[d]	0.397
	Month 5	89.5 ± 12.6[e]	92.9 ± 13.6[d]	0.369
	Month 6	89.2 ± 13.3[e]	92.6 ± 13.5[d]	0.380
BMI (kg/m^2)	Baseline	37.7 ± 4.8[a]	37.0 ± 4.3[a]	0.592
	Month 1	36.2 ± 4.8[b]	35.8 ± 4.2[b]	0.800
	Month 2	35.4 ± 5.0[c]	35.3 ± 4.4[c]	0.930
	Month 3	34.8 ± 5.2[d]	34.8 ± 4.4[d]	0.981
	Month 4	34.2 ± 5.2[e]	34.6 ± 4.3[d]	0.757
	Month 5	34.0 ± 5.4[e]	34.5 ± 4.3[d]	0.746
	Month 6	33.9 ± 5.6[e]	34.4 ± 4.3[d]	0.746
Waist Circumference (cm)	Baseline	106.6 ± 10.2[a]	105.6 ± 10.5[a]	0.733
	Month 1	103.2 ± 8.9[b]	102.5 ± 10.5[b]	0.814
	Month 2	101.2 ± 10.1[bc]	101.3 ± 10.9[bc]	0.965
	Month 3	99.5 ± 9.6[cd]	100.2 ± 10.7[c]	0.803
	Month 4	98.9 ± 10.2[cd]	99.8 ± 10.5[c]	0.749
	Month 5	98.1 ± 10.3[d]	99.5 ± 10.0[c]	0.627
	Month 6	97.6 ± 11.3[d]	99.0 ± 9.7[c]	0.634
Hip Circumference (cm)	Baseline	118.1 ± 9.4[a]	118.3 ± 8.5	0.934
	Month 1	116.1 ± 8.8[b]	117.0 ± 7.8	0.727
	Month 2	114.5 ± 9.4[bc]	116.5 ± 8.1	0.435
	Month 3	113.0 ± 9.9[c]	115.6 ± 8.5	0.331
	Month 4	112.5 ± 9.6[c]	115.6 ± 8.2	0.231
	Month 5	111.8 ± 9.9[c]	115.0 ± 8.1	0.223
	Month 6	111.5 ± 11.0[c]	114.8 ± 8.0	0.241
Body composition				
Free Fat Mass (kg)	Baseline	61.6 ± 10.5	61.0 ± 12.0[ab]	0.787
	Month 3	60.4 ± 9.9	61.7 ± 12.0[a]	0.753
	Month 6	60.1 ± 10.7	59.6 ± 10.9[b]	0.840
Fat Mass (kg)	Baseline	37.7 ± 9.4[a]	38.7 ± 9.2[a]	0.706
	Month 3	31.1 ± 11.5[b]	32.2 ± 9.8[b]	0.571
	Month 6	29.1 ± 11.2[b]	33.0 ± 8.7[b]	0.120
Total Body Water (kg)	Baseline	45.5 ± 7.8	45.6 ± 9.5	0.948
	Month 3	45.1 ± 7.9	45.9 ± 9.4	0.811
	Month 6	44.9 ± 8.7	44.6 ± 8.8	0.869
Blood pressure & heart rate				
Systolic blood pressure (mmHg)	Baseline	123.2 ± 11.1	122.1 ± 14.4	0.762
	Month 1	124.4 ± 11.9	123.8 ± 12.8	0.855
	Month 2	124.2 ± 15.6	129.2 ± 13.9	0.246
	Month 3	125.6 ± 11.7	124.4 ± 12.4	0.724
	Month 4	125.0 ± 9.2	116.7 ± 18.2	0.053
	Month 5	119.0 ± 18.8	114.8 ± 22.8	0.483
	Month 6	122.0 ± 11.8	121.0 ± 11.2	0.772
Diastolic blood pressure (mmHg)	Baseline	75.2 ± 8.8	74.0 ± 8.6	0.621
	Month 1	74.2 ± 9.1	75.6 ± 9.6	0.596
	Month 2	74.8 ± 8.5	78.3 ± 7.9	0.138
	Month 3	75.8 ± 6.9	77.1 ± 5.1	0.463
	Month 4	77.2 ± 5.6	75.0 ± 13.8	0.466
	Month 5	76.8 ± 6.6	74.6 ± 5.7	0.215
	Month 6	74.2 ± 7.6	73.8 ± 6.6	0.826
Heart rate (bpm)	Baseline	69.1 ± 8.6	71.8 ± 9.3	0.301
	Month 1	71.0 ± 7.9	71.7 ± 9.7	0.805
	Month 2	71.0 ± 5.9	70.7 ± 7.6	0.881
	Month 3	72.1 ± 8.1	69.4 ± 6.9	0.215
	Month 4	73.8 ± 8.4	68.9 ± 7.1	0.103
	Month 5	72.7 ± 7.6	68.9 ± 7.1	0.077
	Month 6	73.1 ± 6.9	70.8 ± 7.2	0.248
Glucose metabolism				
Fasting glucose (mg/dL)	Baseline	95.1 ± 10.7[a]	99.8 ± 11.3[a]	0.139
	Month 6	87.6 ± 10.3[b]	87.9 ± 9.8[b]	0.894
Fasting insulin (μU/mL)	Baseline	18.4 ± 12.3[a]	20.7 ± 11.5[a]	0.289
	Month 6	13.6 ± 5.8[b]	14.0 ± 6.5[b]	0.874
HOMA-IR index	Baseline	4.5 ± 3.5[a]	5.1 ± 3.0[a]	0.189
	Month 6	3.0 ± 1.4[b]	3.1 ± 1.6[b]	0.863
Lipid metabolism				
TC (mg/dL)	Baseline	205.0 ± 45.1[a]	200.1 ± 32.4	0.815
	Month 6	192.6 ± 35.5[b]	194.2 ± 32.0	0.828
HDL-C (mg/dL)	Baseline	54.2 ± 17.4	50.8 ± 10.1	0.566
	Month 6	56.0 ± 16.0	53.5 ± 8.7	0.729
LDL-C (mg/dL)	Baseline	125.7 ± 36.8[a]	120.4 ± 23.9	0.766
	Month 6	114.2 ± 32.7[b]	119.5 ± 25.8	0.479
Triglycerides (mg/dL)	Baseline	124.5 ± 61.0	123.8 ± 57.9[a]	0.938
	Month 6	112.9 ± 49.8	106.8 ± 52.3[b]	0.570

Data are expressed as means ± SD. *P*-values refer to between-group comparisons (T-tests). Different letters in the same column indicate significant differences between baseline and month 6 within the same treatment group, $P<0.05$ (repeated-measure T-test) for blood parameters, and among time points within the same treatment group (repeated-measure ANOVA with the Bonferroni *post hoc* test) for all other variables.

and < 0.008 for month 2, $p < 0.001$ for month 3, $p = 0.001$ and < 0.001 for month 4, $p = 0.018$ and $= 0.001$ for month 5, and $p = 0.04$ and $= 0.002$ for month 6, respectively, for fruit and vegetables). Similarly, in the LP group, frequencies of fruit and vegetable consumption increased from baseline to all other time points ($p = 0.001$ and < 0.001 for month 1, $p = 0.007$ and $= 0.001$ for month 2, and $p = 0.012$ and $= 0.014$ for month 6, respectively, for fruit and vegetables, while $p = 0.044$ for month 3 only for fruit, $p = 0.014$ for month 5 only for vegetables).

Moreover, in the HP group, frequencies of consumption of sweets and desserts decreased from baseline to month 3 ($p = 0.014$), while in the LP group, some between time differences were found for sweets and desserts for which the frequency of consumption was higher at baseline than in month 1 ($p = 0.006$), month 2 ($p = 0.011$) and month 3 ($p = 0.003$), and for bread for which the frequency of consumption was higher at month 1 than at month 4 ($p = 0.004$).

Subjective health-related quality of life

Perceived health-related quality-of-life scores are presented in Table 4. Total quality of life was similar between treatment groups at baseline, month 3 and month 6. Between-group differences were not found for PCSs and MCSs or for single dimensions except for the GH at baseline and at month 3, which was significantly lower in the HP group than in the LP group ($p = 0.007$ and $p = 0.034$, respectively).

In the HP group, a significant improvement of the total quality of life ($p = 0.030$) was registered, and the score was significantly higher at month 6 than at baseline ($p = 0.033$). Similarly, the PCS increased over time ($p = 0.005$) and was significantly lower at baseline than at month 3 (p

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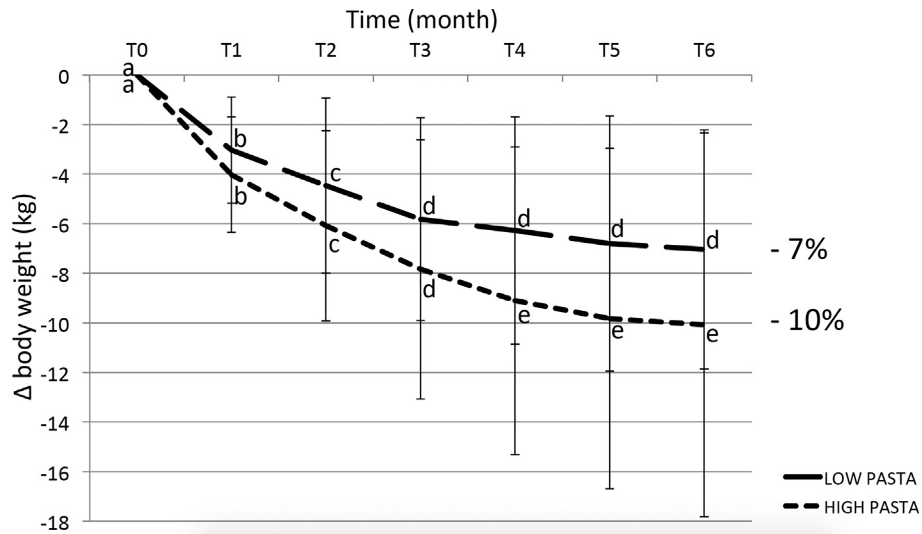

Figure 2 Body weight change from baseline to month 6 for each treatment group. Data are presented as means SD. Different letters indicate significant differences among time points within the same treatment group (repeated-measure ANOVA).

$= 0.009$) and month 6 ($p = 0.033$). When the eight dimensions were considered singularly, differences over time within the HP group were observed for PF ($p = 0.007$), BP ($p = 0.002$) and GH ($p = 0.009$). PF perception increased from baseline to month 3 and month 6 ($p = 0.040$ and $p = 0.027$, respectively), while perception only increased from baseline to month 6 for BP ($p = 0.006$) and for GH ($p = 0.027$). No differences were found among time points within the LP group for summary components and for individual dimensions except for PF ($p = 0.010$), that increased from baseline to month 6 ($p = 0.035$).

Discussion

These 6-month dietary interventions based on energy-restricted Mediterranean Diet were successful in the treatment of subjects with obesity. Both HP and LP low-energy Mediterranean diets induced a significant and progressive body weight reduction during the dietary intervention. Our results are in agreement with other studies where the Mediterranean Diet was positively associated with body weight reduction and management, especially with a restricted energy intake [24–26]. In our interventional study, pasta consumption as part of a low-energy Mediterranean dietary pattern did not show a beneficial effect on body weight. On the contrary, pasta consumption was found to be inversely associated with BMI in the Moli-sani [17] and the INTERMAP [23] observational studies, as also reported in a recent meta-analysis on the effect of pasta consumption on body weight and BMI [27]. In our study, both HP and LP diets induced significant reduction in body weight, WC and HC, confirming that an energy-restricted Mediterranean diet could be strategic for reducing central obesity [28]. Moreover, the reduction in body weight was mainly attributed to a significant loss in FM, for both treatment groups, highlighting a healthy change in participants' body composition [29].

Beneficial effects were also observed for glycemic control, with an improvement of glucose and insulin concentrations and HOMA-IR index in both groups, and on the lipid metabolism, with TC and triglyceride concentrations decreased after the HP and the LP intervention, respectively, and HDL increased following the HP diet. These results support previous findings that a low-energy diet can be effective in improving glycemic control and lipid profiles [30–32], and are of major interest as overweight and obesity are associated with the increased risk of diabetes and other CVDs [33–35].

In addition to the expected reduction in energy intake during the 6-month intervention, the weekly consumption of healthy foods, such as fruit and vegetables, was increased in both treatment groups. The increased intake of fruit and vegetables could have helped in weight loss since a high consumption of fruits and vegetables has been previously associated with body weight reduction [36], even if participants did not reach the recommendation of five servings a day.

Interestingly, HP diet improved the perceived health-related quality of life over time, in particular of the physical component. In previous studies, Mediterranean-type diets have been associated with higher psychological resilience [37] and health-related quality of life [38], even if it is not possible to identify the role of pasta within this Mediterranean dietary pattern. Considering others besides these studies on the Italian population, physical and psychological distress are inversely associated with healthy dietary patterns, while a positive association has been observed with Western-like diets and processed food consumption [39,40].

To the best of our knowledge, this is the first study exploring the effect of weight-loss diet including HP or LP consumption on body weight and composition, metabolic outcomes and the perceived quality of life. The major strength of the study was the intervention design based on

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Table 3 Daily energy and nutrient intakes and carbohydrate-based food consumption over a week for each treatment group at baseline and during the 6-month intervention (PP analysis).

Nutrient	Time	High Pasta (n = 25)	Low PASTA (n = 24)	*p* value
Energy (kJ/day) (kcal/day)	Baseline	9557.1 ± 3698.3 (2283.1 ± 883.5)	9735.4 ± 5028.6 (2325.7 ± 1201.3)	0.888
	Month 3	8069.8 ± 2646.8 (1927.8 ± 632.3)	7600.1 ± 2529.2 (1815.6 ± 604.2)	0.529
	Month 6	7444.8 ± 2260.9 (1778.5 ± 540.1)	8330.1 ± 2383.1 (1990.0 ± 569.3)	0.188
Proteins (g/day) [% Energy]	Baseline	103.7 ± 43.7 [19.0 ± 6.0]	96.1 ± 60.2 [16.5 ± 5.9]	0.615
	Month 3	97.9 ± 45.3 [20.1 ± 5.8]	97.9 ± 38.5 [22.1 ± 6.6]	1.000
	Month 6	83.0 ± 35.9 [18.2 ± 5.0]	88.6 ± 36.2 [18.2 ± 7.2]	0.587
Fats (g/day) [% Energy]	Baseline	89.1 ± 39.6 [35.1 ± 8.1]	97.2 ± 70.3 [35.2 ± 8.7]	0.620
	Month 3	77.3 ± 33.7 [35.4 ± 7.5]	71.7 ± 32.5 [34.6 ± 9.2]	0.553
	Month 6	67.2 ± 28.1 [32.8 ± 7.6]	75.1 ± 31.0 [33.4 ± 7.7]	0.356
Carbohydrates (g/day) [% Energy]	Baseline	255.9 ± 121.4 [44.7 ± 10.6]	262.1 ± 114.5[a] [47.4 ± 11.3]	0.856
	Month 3	204.7 ± 66.8 [43.3 ± 9.0]	194.0 ± 82.0[b] [43.0 ± 13.2]	0.617
	Month 6	210.0 ± 56.7 [49.0 ± 10.5]	239.3 ± 82.3[a] [48.2 ± 10.5]	0.151
Sugars (g/day)	Baseline	95.7 ± 55.0	98.6 ± 56.6	0.858
	Month 3	70.9 ± 29.6	71.7 ± 25.4	0.923
	Month 6	68.4 ± 28.9	87.5 ± 37.4	0.051
Fiber (g/day)	Baseline	19.7 ± 10.3	19.7 ± 12.4	0.985
	Month 3	19.3 ± 9.1	19.5 ± 9.8	0.929
	Month 6	21.3 ± 10.1	20.4 ± 8.1	0.718
Alcohol (g/day) [% Energy]	Baseline	8.2 ± 19.9 [2.0 ± 4.7]	5.1 ± 15.3 [1.8 ± 6.0]	0.547
	Month 3	5.4 ± 12.3 [2.0 ± 4.3]	2.7 ± 7.5 [1.2 ± 3.3]	0.362
	Month 6	3.3 ± 8.3 [1.3 ± 3.3]	4.0 ± 12.1 [1.6 ± 5.4]	0.815
Food group				
Pasta (times/week)	Baseline	6 (5–7)	3 (2–3)	<**0.001***
	Month 1	5 (5–6)	2 (1–3)	<**0.001***
	Month 2	5 (5–6)	2 (1–3)	<**0.001***
	Month 3	5 (5–6)	2 (1–4)	<**0.001***
	Month 4	5 (5–6)	2 (2–3)	<**0.001***
	Month 5	5 (5–5)	2 (1–3)	<**0.001***
	Month 6	5 (5–6)	2 (1–3)	<**0.001***
Rice (times/week)	Baseline	1 (1–1)	1 (1–1)	0.958
	Month 1	1 (0–1)	1 (0–2)	0.054
	Month 2	1 (0–2)	1 (0–2)	0.721
	Month 3	1 (0–2)	1 (0–2)	0.651
	Month 4	1 (0–2)	1 (0–2)	0.842
	Month 5	1 (0–2)	1 (0–2)	0.556
	Month 6	1 (0–1)	1 (0–2)	0.882
Other cereals (times/week)	Baseline	0 (0–1)	1 (0–2)	**0.044***
	Month 1	0 (0–1)	1 (0–2)	**0.007***
	Month 2	0 (0–1)	0 (0–1)	0.768
	Month 3	0 (0–0)	0 (0–1)	0.079
	Month 4	0 (0–1)	0 (0–1)	0.379
	Month 5	0 (0–1)	0 (0–1)	0.466
	Month 6	0 (0–1)	0 (0–1)	0.712
Bread and substitutes (times/week)	Baseline	7 (7–7)	7 (7-7)[ab]	0.171
	Month 1	6 (5–11)	9 (6–13)[a]	0.145
	Month 2	7 (4–9)	7 (4–12)[ab]	0.371
	Month 3	8 (5–11)	9 (4–11)[ab]	0.817
	Month 4	7 (5–10)	6 (2–10)[b]	0.240
	Month 5	7 (5–12)	9 (3–12)[ab]	0.857
	Month 6	6 (3–9)	7 (4–12)[ab]	0.554

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Table 3 (*continued*)

Nutrient	Time	High Pasta (n = 25)	Low PASTA (n = 24)	*p* value
Pizza (times/week)	Baseline	1 (0–1)	1 (1–2)	**0.030***
	Month 1	1 (0–1)	1 (0–1)	0.200
	Month 2	1 (0–1)	1 (1–1)	0.054
	Month 3	1 (0–1)	1 (1–1)	0.175
	Month 4	1 (1–1)	1 (0–2)	0.895
	Month 5	1 (1–1)	1 (1–1)	0.237
	Month 6	1 (1–2)	1 (0–2)	0.637
Potatoes and tubers (times/week)	Baseline	1 (1-1)[a]	1 (1–1)	**0.048***
	Month 1	1 (0–1)[b]	0 (0–1)	0.300
	Month 2	1 (0–2)[ab]	1 (0–2)	0.925
	Month 3	0 (0–2)[ab]	0 (0–1)	0.869
	Month 4	1 (0–2)[ab]	1 (0–2)	0.308
	Month 5	0 (0–2)[ab]	1 (0–2)	0.888
	Month 6	1 (0–2)[ab]	1 (0–2)	0.823
Legumes (times/week)	Baseline	1 (0–1)	1 (0–1)	0.631
	Month 1	0 (0–2)	0 (0–1)	0.537
	Month 2	1 (0–2)	0 (0–1)	**0.005***
	Month 3	1 (0–2)	0 (0–1)	0.057
	Month 4	1 (1–3)	0 (0–1)	**0.018***
	Month 5	1 (0–3)	0 (0–1)	0.125
	Month 6	1 (0–2)	0 (0–1)	**0.040***
Fruit (times/week)	Baseline	7 (4–7)[b]	7 (4–7)[b]	0.886
	Month 1	9 (7–16)[a]	13 (7–15)[a]	0.703
	Month 2	10 (6–15)[a]	9 (5–14)[a]	0.818
	Month 3	12 (8–17)[a]	9 (5–14)[a]	0.193
	Month 4	12 (7–15)[a]	9 (5–12)[a]	0.133
	Month 5	11 (5–15)[a]	9 (5–14)[ab]	0.458
	Month 6	12 (7–14)[a]	9 (5–13)[ab]	0.495
Vegetables (times/week)	Baseline	7 (5–7)[b]	7 (5–7)[b]	0.810
	Month 1	12 (8–13)[a]	11 (7–12)[a]	0.545
	Month 2	11 (6–13)[a]	10 (8–14)[a]	0.817
	Month 3	12 (7–13)[a]	10 (7–12)[ab]	0.227
	Month 4	12 (9–13)[a]	10 (5–12)[ab]	0.078
	Month 5	11 (8–13)[a]	9 (7–12)[a]	0.433
	Month 6	10 (7–13)[a]	9 (7–12)[a]	0.439
Breakfast cereals (times/week)	Baseline	0 (0–0)	0 (0–0)	0.648
	Month 1	0 (0–2)	0 (0–3)	0.802
	Month 2	0 (0–4)	1 (0–3)	0.633
	Month 3	0 (0–6)	0 (0–2)	0.216
	Month 4	0 (0–4)	0 (0–0)	0.179
	Month 5	0 (0–3)	0 (0–0)	0.166
	Month 6	0 (0–4)	0 (0–0)	0.080
Sweets and desserts (times/week)	Baseline	9 (7–10)[a]	8 (7–11)[a]	0.800
	Month 1	7 (3–7)[ab]	6 (3–7)[b]	0.424
	Month 2	3 (2–7)[b]	6 (1–7)[b]	0.621
	Month 3	3 (1–7)[b]	5 (3–7)[b]	0.266
	Month 4	7 (1–9)[ab]	7 (4–8)[ab]	0.824
	Month 5	6 (3–8)[ab]	7 (4–8)[ab]	0.559
	Month 6	6 (2–8)[ab]	6 (3–8)[ab]	0.912

Data are expressed as means SD, or median (IR). *P*-values refer to between-group comparisons (* significantly different from the ManneWhitney non-parametric test). Different letters in the same column indicate significant differences among time points within the same treatment group, P < 0.05 (repeated-measure ANOVA with the Bonferroni post hoc test for nutrients and repeated-measure Friedman non-parametric test with the DunneBonferroni post hoc pairwise comparisons for carbohydrate-based food groups).
Numbers in bold are significant p values.

subject's food preferences that may have led to a better adherence to the dietary prescription. The compliance with the dietary prescriptions, an essential part of each useful dietary intervention [41], was also improved by giving specifically designed recipe books to encourage the participants cooking and eating high-quality food. Moreover, food preferences could have led to a better weight maintenance after the end of the dietary intervention, with body weight remaining constant in both treatment groups from month 6 to month 12.

However, this study has some limitations. Even if participants were similar between the two treatment groups for all the considered variables except the consumption of pasta, the quasi-experimental design without randomization might impact the interpretation of results. However, as stated before, the choice guaranteed a better adherence

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Table 4 Quality-of-life perception score for each dimension for each treatment group during the 6-month intervention (PP analysis).

Parameters	Time	High Pasta (n = 25)	Low Pasta (n = 24)	*p* value
Physical function	Baseline	75 (58–85)[a]	75 (44–90)[a]	0.896
	Month 3	85 (70–95)[b]	90 (73–94)[ab]	0.968
	Month 6	85 (70–95)[b]	90 (51–95)[b]	0.936
Role limitation physical problems	Baseline	75 (13–100)	100 (31–100)	0.241
	Month 3	100 (50–100)	100 (75–100)	0.579
	Month 6	100 (38–100)	100 (50–100)	0.945
Bodily pain	Baseline	52 (41–72)[a]	67 (32–100)	0.657
	Month 3	74 (46–100)[ab]	61 (44–96)	0.591
	Month 6	84 (64–100)[b]	74 (41–100)	0.323
General health	Baseline	55 (39–67)[a]	70 (51–76)	**0.007***
	Month 3	65 (45–74)[ab]	71 (62–82)	**0.034***
	Month 6	67 (45–79)[b]	67 (52–82)	0.602
Vitality	Baseline	45 (40–63)	48 (30–65)	0.680
	Month 3	55 (45–73)	58 (41–65)	0.778
	Month 6	55 (45–78)	50 (40–70)	0.371
Social function	Baseline	75 (50–94)	75 (50–87)	0.584
	Month 3	87 (50–100)	69 (50–97)	0.799
	Month 6	87 (56–100)	75 (62–100)	0.652
Role limitation emotional problems	Baseline	100 (33–100)	100 (33–100)	0.696
	Month 3	100 (66–100)	100 (66–100)	0.890
	Month 6	100 (33–100)	100 (66–100)	0.614
Mental health	Baseline	68 (58–80)	70 (57–80)	0.976
	Month 3	68 (48–88)	70 (57–84)	0.825
	Month 6	72 (60–86)	68 (60–80)	0.872
Physical component summary	Baseline	254 (178–298)[a]	288 (176–349)	0.190
	Month 3	311 (243–347)[b]	320 (254–357)	0.575
	Month 6	315 (256–348)[b]	340 (217–367)	0.741
Mental component summary	Baseline	292 (199–324)	288 (177–324)	0.779
	Month 3	301 (225–341)	300 (230–335)	0.912
	Month 6	290 (203–354)	300 (230–350)	0.772
Total Quality of Life	Baseline	516 (397–627)[a]	532 (366–661)	0.596
	Month 3	615 (456–678)[ab]	617 (443–688)	0.881
	Month 6	617 (482–697)[b]	587 (425–700)	0.873

Data are expressed as median (IR). *P*-values refer to between-group comparisons (* significantly different from the Mann–Whitney non-parametric test). Different letters in the same column indicate significant differences among time points within the same treatment group, $P<0.05$ (repeated-measure Friedman non-parametric test with the Dunn–Bonferroni *post hoc* pairwise comparisons).
Numbers in bold are significant p values.

to the assigned treatment. Other limitations of the study are the small sample size and a considerable number of dropouts (around 30%). Nevertheless, the ITT analysis confirmed and reinforced the results obtained from the PP analysis. Furthermore, the small number of male participants in respect to women made it impossible to explore sex differences. However, the similar characteristics of participants enrolled in the two dietary groups and the sex distribution, which is representative of the normal population of the research clinic in which the trial was performed, give robustness to our findings. The absence of a follow-up longer than 1 year would hinder long-term effect on both body weight and healthy dietary habits maintenance. Lastly, the 24-h dietary recall was used only every three months to collect food consumption data, whereas more frequent assessments and/or using food records would have led to more accurate results.

In conclusion, a low-energy Mediterranean diet could constitute a beneficial nutritional strategy for weight loss if appropriately adjusted to reflect local food availability and individual's habits. The presented results are of major public health importance since no consensus exists concerning the best diet for successful weight management. Weight-loss program may benefit from incorporating preferences and previous habits, not excluding specific foods (e.g. pasta). Future investigations should consider larger populations and should be more focused on behavioral factors that often undermine long-term healthy eating habits.

Authors' contribution

AR designed research, analyzed data, performed statistical analysis and wrote the manuscript; MT conducted research, collected data and helped in data interpretation; AC and LB conducted research and helped in data interpretation; BB helped to conduct research and interpret data; MC helped to write the manuscript and in data interpretation; FB provided a critical review of the manuscript; EDA designed and conducted research, provided critical review and had primary responsibility for final content; FS designed research, helped in data

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interpretation, wrote the manuscript, and had primary responsibility for final content. All authors have read and approved the final manuscript.

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Declaration of Competing Interest

The authors declare no competing of interest.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.numecd.2020.02.013.

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