DOI: https://doi.org/10.1080/07315724.2015.1102102

Influence of a Mediterranean dietary pattern on body fat distribution: Results of the PREDIMED-Canarias Intervention Randomized Trial

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Short running title: Mediterranean Diet and Body Fat Distribution

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ABSTRACT

Objective: To assess the influence of a Mediterranean dietary pattern (MeDiet) on anthropometric and body composition parameters in one of the centers of the PREDIMED randomized dietary trial.

Subjects/Settings: 351 Canarian free-living subjects aged 55 to 80 years, with type 2 diabetes or ≥3 cardiovascular risk factors.

Intervention: Participants were randomly assigned to one of three different dietary interventions: MeDiet+extra-virgin olive oil (EVOO), MeDiet+nuts (walnuts and almonds, hazelnuts) or a control low-fat diet. Total energy intake was ad libitum.

Outcome measures: Changes in anthropometric measures [weight, Body Mass Index (BMI) and waist circumference (WC)], body fat distribution, energy and nutrient intake after 1 year. Body composition [percentage of total body fat (%TBF), total fat mass (TFM), free fat mass (FFM), percentage of truncal fat (%TrF) truncal fat mass (TrFM)] and total body water (TBW) were estimated by octapolar electrical impedance analysis.

Statistical analyses: Paired t-tests were conducted to assess within-group changes. ANOVA tests were used to assess the effect of the dietary intervention on the percentage change in anthropometric variables, body composition and dietary intake profile. All pairwise comparisons that were statistically significant in ANOVA were subsequently adjusted using the Benjamini-Hochberg test, which penalizes for multiple comparisons.

Results: After 1-year of intervention, significant within-group reductions in all the anthropometric variables were observed for the MeDiet+EVOO and the control group. The MeDiet+nuts group exhibited a significant reduction in WC and TBW. The control group showed a significant increase in the %TBF and a reduction in TBW . The control group showed a significant increase in the percentage of total body fat, and a reduction in total body water TBW. However, we did not find any between-group significant differences in anthropometric or body composition changes.

Conclusions:

Mediterranean diets enriched with EVOO or specific mixed nuts (walnuts, almonds, hazelnuts) that contain approximately 40% total fat can be alternative options to low-fat diets for weight maintenance regimes in older overweight or obese adults.

Key Words: Mediterranean diet, obesity, body composition, body fat, octapolar bioimpedance analysis, PREDIMED Study.

INTRODUCTION

In 2008, the World Health Organization (WHO) estimated that there were 500 million obese (defined as BMI ≥ 30 Kg/m^2) individuals in the world and that 1.4 billion adults over age 20 were overweight (BMI 25-29.9 Kg/m^2). Projections estimate that by the year 2020, type 2 diabetes mellitus (DM2) and cardiovascular disease (CVD), disorders closely related to obesity, will contribute to three-quarters of all deaths worldwide [1].

According to Aranceta et al [2] and Perez-Rodrigo et al [3], in the year 2000, the obesity prevalence in Spain was 14.5% in adults aged 25-60 years. In the Canary Islands, located in the Atlantic Ocean, southwest border of the European Union, obesity prevalence exceeds the national average. Obesity rates for the Canary Islands (35.7 %) were similar to those found in the USA in adults aged 20 and over, and the prevalence of morbid obesity (6.3%) was even higher [3-5]. Moreover, according to a representative sample of the Canary Islands Nutrition Survey [Encuesta Nutricional de Canarias, ENCA] the prevalence of metabolic syndrome 24.4% [6] is considered to be elevated in this region. Finally, the Canary Islands rank first in Spain with respect to ischaemic heart disease and DM2 mortality rates, with CVD being the leading cause of death in the region [6-8].

However, from an epidemiological standpoint the Canarian population, being predominantly European culturally and ethnically Caucasian, and preserving the aborigin population genetics [9], has been little studied.

The traditional Mediterranean diet (MeDiet), which is moderately high in fat, is increasingly being promoted as a healthy dietary pattern and has been associated with a lower risk of obesity or weight gain [10-12]. In addition, several clinical trials suggest that the Mediterranean diet is beneficial for weight loss [13-16].

The findings from the Canary Islands Nutrition Survey (ENCA) [17] conducted in 1997-1998 in a representative sample of 2,600 people aged 6- 75 years, revealed that the Canarian population had the lowest consumption of vegetables in Spain and an elevated consumption of potatoes (boiled and fried). Whole milk consumption was very high and meat and fish intake was relatively low [6,17,18].

The aim of this study was to evaluate whether the substitution of a current diet for a Mediterranean dietary pattern within a Canarian population had any effect on anthropometric variables such as weight, body mass index (BMI) or waist circumference (WC) and on body composition parameters. Moreover, it intended to compare the effect of three distinct dietary profiles: the Mediterranean diet supplemented with extra-virgin olive oil, the Mediterranean diet supplemented with nuts (walnuts, almonds, hazelnuts) and the control diet (Low Fat Diet) on these parameters.

METHODS

The present study was conducted within the framework of the PREDIMED study (Prevención con Dieta Mediterránea trial) in a group of 351 Canarian subjects. The PREDIMED study is a multicentre, randomized, single-blind, parallel-group clinical trial that aimed to evaluate the effect of the Mediterranean diet on cardiovascular mortality. The design of the PREDIMED trial has been described elsewhere [19]. Briefly, the trial included 7,447 participants who were randomly allocated to one of three arms: 1) a traditional Mediterranean diet supplemented with extra virgin olive oil (MeDiet+EVOO); 2) a traditional Mediterranean diet supplemented with 30g of nuts (15g walnuts, 7.5g almonds, 7.5 g hazelnuts) per day (MeDiet+nuts); or 3) a control (low-fat) diet. The primary cardiovascular composite end-point included either non-fatal acute myocardial infarction, non-fatal stroke, or cardiovascular death.

Subjects

Eligible subjects for this analysis were community dwelling and attended the PREDIMED network centre in Santa María de Guía, Gran Canaria, Spain. Men [55–80 years of age] and women [60–80 years of age] were included if they were free of CVD at baseline but had either DM2 or met at least three of the following risks factors: smoking, hypertension, elevated low-density lipoprotein cholesterol levels, low high-density lipoprotein cholesterol levels, overweight/obesity or a family history of premature coronary heart disease (CHD). Of the 418 eligible subjects, 67 were excluded for a variety of reasons (as shown in Fig. 1). The final sample consisted of 351 subjects, with 117 individuals assigned to each study arm. Of the 351 study participants, 305 [87%] completed the one year follow-up assessment.

Ethics

The ethics protocol was approved by the review boards of all participating centers, according to the Helsinki Declaration [20]. All participants provided written informed consent.

Measurements

Exposure assessment: Dietary intervention

A trained dietitian was responsible for all aspects of the intervention and assisted participants in completing a 137 item validated food frequency questionnaire [FFQ] [21]. Participants assigned to the control group received personal advice together with a leaflet with written recommendations for following a low-fat diet [22].

Participants in the MeDiet intervention groups were given personalized advice for dietary changes aimed to achieve a diet closest to the traditional MeDiet. Moreover, for each MeDiet intervention group, a 1-hour group session with a maximum of 20 participants per session, was scheduled after inclusion in the study. The group sessions consisted of informational talks and the provision of written material with descriptions of the principal foods, seasonal shopping lists, meal plans and cooking recipes. Finally, depending on the group assigned to, participants were given complimentary extra virgin olive oil (50 g/d) or packets of walnuts and almonds (30 g/d) at no cost. To improve compliance and taking family needs into account, participants in the corresponding Mediterranean groups were given excess extra virgin olive oil or additional packs of nuts.

In the three groups, the general guidelines included positive recommendations to increase the consumption of vegetables, fruits, legumes, fish and seafood, and white meats instead of red meats. Negative recommendations included limiting and/or eliminating presumed detrimental foods (red and processed meats, fat-rich dairy products, commercial pastries, snacks, and sugar-sweetened beverages). No total calorie restriction was advised, nor was physical activity promoted. A 14-point score of adherence to the Mediterranean Diet (described below) was administered to the two MeDiet groups, being the main tool to assess change in dietary habits, and a similar 9-point score [excluding the recommendations regarding olive oil and nuts consumption] was administered to participants in the control group (low-fat diet). All participants had free and continuous access to their nutritionist throughout the study.

Outcome assessment

Changes in anthropometric and body composition measurements

At baseline examination and after 1-year of follow-up, trained nutritionists or nurses performed anthropometric and body composition measurements that were recorded. Weight (to the nearest 100 g) and height (to the nearest 0,1 cm) were measured in light clothing and without shoes with calibrated scales and a wall-mounted stadiometer, respectively. BMI was calculated as weight (in kilogram) divided by the square of height (in meters). WC was measured midway between the lowest rib and the iliac crest using an anthropometric tape [23]. Obesity was defined as a BMI > 30 kg/m^2. Abdominal obesity was defined as a WC > 102 cm in men and 88 cm in women [24].

For participants with missing values of weight and WC (4,3%) at the one year visit, we used the most recent available data collected in the clinical history.

The body fat distribution was estimated by octapolar bioelectrical impedance equipment BC-418 (Tanita Corp., Tokyo, Japan). The measurements were always performed in a well-ventilated room with constant temperature and humidity, in a fasting state, within the early hours of the morning (8-10 am) and with a resting state of at least fifteen minutes. Dual energy X-ray absorptiometry (DXA) was used as the reference method ("gold standard"). Body composition was calculated using the estimates derived from the regression analysis with the height, weight and sex as independent variables. " According to preliminary studies intra-day accuracy and between days impedance measurements were 0.970 and 2.2%, respectively [25, 26]. This model had been calibrated for those between the ages of 18-84.

The Bioelectrical Impedance Analysis (BIA) variables used in the present study were the percentage of total body fat (%TBF), total fat mass (TFM), percentage of truncal fat (%TrF), truncal fat mass (TrFM) and total body water (TBW). Currently, the Basal Metabolic Rate (BMR) estimation recursion formula developed by Tanita, the manufacturer of body composition analyzers, is based on their research and applies multiple regressive analysis using fat free mass (FFM), thus providing a higher degree of accuracy in the individual differences in body composition [27].

Changes in the adherence to the traditional Mediterranean Diet, nutrient and energy intake

Adherence to the traditional MeDiet was assessed through a validated 14-item questionnaire designed for this purpose [28, 29]. Energy, nutrients, fiber and alcohol intake were determined administering a previously validated semi-quantitative questionnaire [21, 30]. The nutrient database was updated using the latest available information from the food composition tables for Spain [31]. Both questionnaires were administered at baseline and after 1-year of follow-up.

Other covariate assessment

Other socio-demographic and clinical variables were obtained using a 47-ítem general questionnaire that collected information on lifestyle such as smoking, health conditions, socio-demographic variables, occupation status, medical diagnoses, and medication use (Table 1). Physical activity was assessed using the validated Spanish version of the Minnesota Leisure-Time Physical Activity Questionnaire [32].

Statistical analysis

All analyses were performed in accordance with an intention-to-treat approach.

Baseline characteristics are presented according to intervention group, as mean and standard deviation (SD) for quantitative traits and n (%) for categorical variables. Normality was assumed taking into account the size of the sample.

The paired t-test was used to assess the within-group changes in anthropometric and body composition variables and within-group changes in energy, nutrients and alcohol intake after 1-year of follow up in each intervention group.

ANOVA tests were applied to between-group comparisons to assess the effect of the type of dietary intervention on the change in anthropometric and body composition variables and in dietary intake profiles (values expressed as percentages of change). All pairwise comparisons that were statistically significant in the ANOVA analysis were subsequently corrected through the Benjamini-Hochberg test, which adjusts for multiple comparisons.

To evaluate the possible effect-modification by sex and age on the association between the type of intervention and changes in anthropometric and body composition variables, two product terms were created and included in the statistical models: 1) type of intervention x sex and 2) type of intervention x age groups. . Statistical significance was defined as $P < 0.05$.

The SPSS software package for Windows version 19.0, was used for statistical analyses.

RESULTS

Table 1 shows the baseline characteristics of participants according to each intervention group. The three groups were balanced regarding ethnic origin, socio-demographic characteristics, cardiovascular risk factors, occupational status, educational level, medications, and adiposity, except for WC in the control group. The controls showed a baseline mean WC value that was significantly higher than that observed in the MeDiet groups.

Changes in anthropometric and body composition variables for each study arm after 1-year of follow-up

We observed significant reductions in all anthropometric variables after one year of intervention in the MeDiet+EVOO and in the control group. A significant reduction in the MeDiet+nuts group was only seen for WC (Table 2).

The control group showed an increase in %TBF (P=0.02) and a decrease in TBW (p=0.001). MeDiet+nuts group showed a decrease in TBW (p=0.013). (Table 2).

Effects of dietary intervention on the annual change of anthropometric and body composition variables expressed as percentages

There were no significant between-group differenced in the anthropometric and body composition variables (Table 3).

Compliance with the dietary intervention

To complete the analyses, we investigated the effectiveness of the nutrition intervention after 1-year of follow-up. Table 4 shows the macronutrient distribution at baseline and changes after 1-year of follow-up according to the three study groups. A significant reduction in energy intake was observed in the MeDiet+nuts and in the control groups whereas non-significant changes in energy intake were observed in the participants assigned to the MeDiet+EVOO. The estimated intake of protein decreased in the MeDiet+nuts group and increased in the MeDiet+EVOO and control groups, for MUFA (the control group also significantly showed an increase of MUFA), for PUFA (significantly increased in the MeDiet+nuts group), for fiber (significantly decreased in the MeDiet + EVOO group), for alcohol (significantly decreased in the MeDiet+EVOO and increased in the MeDiet+nuts group), and for cholesterol (significantly decreased in all 3 groups).

Moreover, participants assigned to the MeDiet groups significantly reduced their carbohydrate intake and increased their total fat intake, the latter mainly as monounsaturated fatty acids (MUFA). In fact, although all the all study arm participants reported similar adherence to the Mediterranean diet at baseline, scores on the 14-item Mediterranean-diet screener increased during follow-up in participants assigned to both Mediterranean-diet groups whereas these scores remained unchanged in the control group.

We observed significant between-group differences for changes in energy and macronutrient intake when we compared the three study groups (Table 5). Observed decreases in total energy intake (-15.7%) and in saturated fatty acid intake (-3.1%) were higher in participants assigned to the control group. On the other hand, a significant increase in MUFA intake was observed for the MeDiet+EVOO (5.1%) as compared to the other two groups ($P<0.001$). Moreover, whereas the groups allocated to an active intervention with the MeDiet substantially increased their adherence to the Mediterranean diet (around 26-27%), a modest change (increment of 7.1%) was also observed among participants assigned to the control group ($P<0.001$ for the between-group comparison).

To consider the possible effect-modification by sex and age in the reported associations, several product-terms were created. Two product-terms were statistically significant (sex*truncal fat, age*truncal fat) (interaction P= 0.013 and interaction P=0.046, respectively). For this reason, we conducted analyses stratified by sex and age to assess the effect of the type of intervention on the annual change (as a percentage) of % TrF. We observed a significant increase in percentage of truncal fat in both women and subjects aged 55 to 70 years old assigned to the control group as compared to the change observed for participants assigned to any of the Mediterranean diets (Figure 2).

DISCUSSION

The present study is, to our knowledge, the first randomized controlled clinical trial focused on the effect of a Mediterranean type diet on body fat composition and distribution in a free living population. The retention rate during the first year was greater than 90%. The study population included participants from the PREDIMED center of the Canary Islands, whose eating habits differ from the typical pattern of the Mediterranean diet as the *questionnaire of adherence to Mediterranean Diet* [27, 28] has confirmed mean baseline score was 8.2 points for the Canarian sample as compared to 8.6 points in the total sample of PREDIMED study participants- (N=7,447) [33].

After one year of intervention, a significant reduction in all the anthropometric variables was found for the MeDiet+EVOO group and the control group. In contrast, those participants randomized to the MeDiet+nuts only decreased in WC after the intervention, but not in other anthropometric indexes. For body composition variables, no changes were observed after the dietary intervention with the exception of a significant increase in the percentage of total body fat observed among participants assigned to the control group and the significant decreases in TBW in both the MeDiet+nuts and control groups. Nevertheless, the most relevant finding in this analysis is the lack of effect by the type of intervention as compared to controls for annual changes in both anthropometric and body composition parameters among Canarian participants of the PREDIMED trial.

The significant findings for the anthropometric and body composition variables in the context of the significant changes in energy and nutrient intake for each of the groups were: a) MeDiet + EVVO group: body weight, BMI, WC were significantly reduced, and also we observed a decrease in the caloric intake, carbohydrate, dietetic fiber, alcohol and cholesterol. However, the total fat and MUFA intake increased significantly. b) MeDiet + nuts group: WC,TBW, caloric intake, proteins, carbohydrate, alcohol and cholesterol were significantly reduced; and c) Control group (Low fat diet): In this group we observed a significant reduction of all the anthropometric variables (weight, BMI, WC) and % TBF, associated with the significant reduction in the caloric PUFA and cholesterol intake (Table 2 and 4).

Our findings are consistent with the results obtained in other studies that have evaluated the effect of diets with varying macronutrient composition on body composition [34]. However, the majority of studies are clinical trials involving caloric restriction. For example, Souza et al., published a clinical trial showing that 424 subjects administered calorically restricted diets with varying contributions of macronutrients lost more fat than lean mass with no significant changes in body composition, abdominal or liver fat, regardless of the macronutrient distribution in all diets analysed [35]. In another study, Brehm et al [36] compared the effects of two hypocaloric diets, one rich in MUFA and the other rich in carbohydrates (CHO), on anthropometric, metabolic and body composition parameters in diabetic subjects. The authors concluded that diets rich in MUFA could be a healthy alternative to conventional low-fat diets without any negative impact on body weight and body composition, cardiovascular risk factors or glycemic control. These results are applicable to our sample in which 57 % are diabetics..

Nevertheless, unlike the previously cited studies, the participants in our study were not subjected to calorie restriction but rather to a qualitative change in the usual dietary pattern. After 1-year of follow-up participants in the control group [low-fat diet] showed a significant reduction in total energy intake [around 16%], whereas the reduction of caloric intake was much less in both MeDiet groups (MeDiet +EVVO: 6.2 % and MeDiet + nuts: 3.9%). Therefore, it would be expected that control group subjects would have a greater reduction in anthropometric and body composition variables than subjects assigned to the intervention groups, but this did not occur. A possible explanation is due to that reported by other authors in reference to overestimate the calories in nuts. Previous studies have suggested that lipids from nuts are poorly absorbed. Thus, the energy contained in the nuts that is metabolized is less than that predicted by the Atwater general factors. Recent research has shown that Atwater calculations overestimate the energy content of other tree nuts by 5 – 32%. Two randomized controlled trial (RCT) one conducted by Baer DJ et al with walnuts [37] and one more conducted by Novotny with pistachios [38] reported this overestimation. The energy content of walnuts that was metabolized was found to be 5.22 Kcal/g (146 Kcal/serving) as compared to the Atwater-calculated amount of 6.61 Kcal/g (185 kcal/serving). On the other hand, energy value that could be metabolized from pistachios would be 5 % lower than the value currently accepted and calculated using the Atwater general factors. Also, another study [39] conducted to assess the energy value of almonds in the human diet found a 32%

overestimation of their energy content when the measured energy value was compared with the value calculated from the Atwater factors showed.

Considering the results of these authors, the calories derived from nuts would have been overestimated in the MeDiet + nuts group. This fact could explain why no significant differences were found in anthropometric and body composition variables.

With respect to studies analyzing ad libitum diets, our results are comparable with those observed by other authors. For example, Due et al., using DXA evaluated weight and body composition changes in overweight and obese individuals assigned to three types of diets administered ad libitum for six months [40]. The authors concluded that the composition of the diets had no significant effects on the prevention of weight regain. However, these authors found that a fat-rich diet, in particular high in MUFA, produced less body fat accumulation than the control diet. In this trial, subjects assigned to the control group increased their body fat percentage, albeit not significantly. One explanation of the disagreement between studies may be due to the method applied for analyzing body composition.

Our results are consistent with those published by other authors which have shown that some components of the MeDiet, such as a high intake of whole grains [41-43], dietary fiber [44] and MUFA [45] were inversely associated with abdominal adipose tissue accumulation, regardless of body weight. In this context, it is relevant to mention one of the key components of the Mediterranean diet - namely the issue ofnuts. Due to their high caloric content, there is concern that nut consumption could cause an increase in body weight. However, much evidence suggests that the digestibility of fat from whole nuts (pistachio, almonds, walnuts) may be much lower than that for other food sources [37-39]. The results of our study support that the consumption of nuts does not promote weight gain, in accordance with findings reported by large observational longitudinal studies incorporating good control for confounding [46-51].

When the effect of the type of intervention -the Mediterranean diet supplemented with extra-virgin olive oil, Mediterranean diet supplemented with nuts and the control diet (Low Fat Diet) – was analyzed by sex and age groups, differences according to the type of diet assigned were found. Women and those participants aged > 70 years assigned to the control diet showed a significant increase in their % TrF after one year of intervention. To corroborate our results with more accuracy, we are conducting a new intervention trial, the PREDIMED-PLUS study (ongoing): Effect of a hypocaloric Mediterranean diet and physical activity promotion on the primary prevention of cardiovascular disease, registered in the Register of Clinical Trials of London (ISRCTN35739639). The results of this intervention will contribute to clarify these questions.

Some possible explanations for the lack of effect observed in our study are as follows: 1) low statistical power due to insufficient sample size; 2) follow- up limited to 1-year; 3) the participants were not prescribed a hypocaloric diet; 4) difficulty for increasing adherence to a low-fat diet in participants assigned to the control group due to several reasons: contamination bias occurring when patients do not follow the protocol for their assigned treatment and as such, the resultant "treatment contamination" can produce misleading findings [52]; moreover, the information obtained through the media about the Mediterranean diet could affect compliance of subjects assigned to the low-fat control diet; and 5) after the age of 70, some weight loss may be attributed to the aging process itself. Studies of healthy older adults report that weight loss of approximately 0.1-0.2 kg per year due to aging alone is considered normal [53].

A non-differential information bias may have occurred in both dietary exposure (collected through questionnaires) and body composition results (bioelectrical impedance equipment). This non-differential misclassification bias leads to the estimation of the association between Mediterranean diet adherence and body adiposity towards zero.

As such, given the aforementioned limitations, results should be interpreted with due caution.

CONCLUSION

The findings observed in this study showed that the increase in total fat intake with a higher proportion of monounsaturated fatty acids and without caloric restriction which we obtained in the PREDIMED trial was not associated with any significant weight gain or abdominal obesity in an elderly population at high cardiovascular risk.

This implies that, despite its characteristic fat composition of almost 40% of total energy intake, the Mediterranean Diet may be considered as an effective alternative in reducing and maintaining body weight and appears to be as safe as a low-fat diet.

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ACKNOWLEDGEMENTS

The authors thank the participants for their enthusiastic collaboration, the PREDIMED personnel for excellent assistance and the personnel of the "Santa María de Guía" primary care centre, especially to Maldonado Díaz I, Álvarez Álvarez JB, Deniz S, Sarmiento de la Fe F, Simón García C, Falcón Sanabria I, Macías Gutiérrez B, Santana Santana AJ, García Pastor J, Domínguez H, Medina Castellano CD.

We gratefully acknowledge the Instituto de Salud Carlos III [ISCIII] and other funding sources [see below].

FUNDERS

Supported by the official funding agency for biomedical research of the Spanish government, Instituto de Salud Carlos III [ISCIII], through grants provided to research networks specifically developed for trials: Spanish Government [Instituto de Salud Carlos III [ISCIII], Fondo de Investigaciones Sanitarias. Ministerio de Sanidad y Consumo RTIC RD06/0045/0009, Centro de Investigación Biomédica en Red de

Fisiopatología de la Obesidad y Nutrición [CIBERobn]], PI 2007/050 Agencia Canaria de Investigación, Innovación y Sociedad de la Información. Gobierno de Canarias.

***Conflict of interest statement**

Dr. Estruch reports serving on the board of and receiving lecture fees from the Research Foundation on Wine and Nutrition [FIVIN]; serving on the boards of the Beer and Health Foundation and the European Foundation for Alcohol Research [ERAB]; receiving lectures fees from Cerveceros de España and Sanofi-Aventis; and receiving grant support through his institution from Novartis.

Dr. Salas-Salvadó reports serving on the board of and receiving grant support through his institution from the International Nut and Dried Fruit Council; receiving consulting fees from Danone;

Dr. Serra-Majem reports serving on the boards of the Mediterranean Diet Foundation and the Beer and Health Foundation, and receiving grant support through his institution from Eroski and Nestlé.

Figure 1. Flowchart of study participants. The diagram includes detailed information on the excluded participants.

Figure 2. Effect modification of the type of dietary intervention on the annual percentage change in percentage of truncal fat (%TrF) a) by sex; b) by age group.

Table 1. Baseline Characteristics of the Study Participants according to the group of Intervention

Characteristics	MeDiet+ EVOO n = 117	MeDiet+nuts n = 117	Control n = 117
Sex (%)			
Men	35.9	35.9	30.2
Women	64.1	64.1	69.8
Age groups (%)			
55 - 69 years	59.0	61.5	60.3
70 - 80 years	41.0	38.5	39.7
Educational level (%)			
Primary school	86.3	84.6	91.4
Secondary	11.1	7.7	6.8
University	0.9	0.9	0.9
Marital status %			
Married	79.5	71.8	67.5
Widower	12.8	19.7	25.6
Divorced or Single	7.7	8.5	6.9
Employment status (%)			
Retired	58.1	66.7	59
Housewives	22.2	18.8	21.4
Workers	11.1	11.1	14.6
Others	8.6	3.4	5.0
Anthropometric variables			
Weight (Kg) (mean, SD)	78.7 (11.0)	80.2 (11.8)	79.3 (12.2)
BMI (Kg/m²) (mean, SD)	30.6 (3.6)	31.1 (3.9)	31.3 (3.9)
WC (cm) (mean, SD)	100.3 (8.9)	102.6 (9.3)	103.1 (8.9)*
Overweight or Obesity (%)	94.9	92.3	97.4
Body fat composition variables			
% TBF (mean, SD)	35.0 (7.7)	36.4 (7.6)	37.1 (7.1)
TFM (Kg) (mean, SD)	27.7 (7.4)	29.5 (8.0)	29.6 (8.7)
%FTr (mean, SD)	32.9 (7.0)	34.4 (5.8)	34.9 (7.3)
TrFM (Kg) (mean, SD)	14.0 (3.8)	15.4 (3.8)	15.1 (3.9)
Prevalence of diseases (%)			
Hypertension	82.9	83.8	82.9
Dyslipidemia	85.5	76.1	78.6
Diabetes	59.0	57.3	53.8
Medications (%)			
Aspirin or other antiplatelet agents	46.2	40.2	32.5
Anti-hypertensive agents	81.2	81.2	74.4
Lipid-lowering agents	63.2	47.0	48.7
Insulin	12.0	12.0	9.4
Oral hypoglycaemic drugs	38.5	41.9	32.5
Heart medications	18.8	18.8	19.7
Antidepressants, tranquilizers	41.0	42.7	45.3

MeDiet= Mediterranean Diet; EVOO= Extra-Virgin Olive Oil; SD = Standard Deviation; BMI= Body Mass Index; WC= Waist Circumference, %TBF=percentage Total Body Fat; TFM= Total Fat Mass; %TrF= Percentage Truncal Fat; TrFM= Truncal Fat Mass; TBW= Total Body Water.

**P value obtained through independent samples t-test*

Table 2. Anthropometric (weight, BMI and WC) and body composition variables (%TBF, TFM, FFM, %TrF, TrFM and TBW) at baseline and their changes after 1year of follow-up in each intervention group.

Variable	MeDiet+EVOO		MeDiet+nuts		Control diet	
	n = 112	P	n = 102	P	n = 98	P
Anthropometric						
Weight (Kg)						
Baseline mean, SD)	77.9 (10.8)		80.3 (12.3)		79.4 (12.4)	
1-year Δ (CI 95%)	-1.0 (-1.7 a -0.3)	0.008	-0.5 (-1.2 a 0.3)	0.197	-1.0 (-1.7 a -0.2)	0.012
BMI (Kg/m²)						
Baseline mean, SD	30.7 (3.7)		31.2 (3.9)		31.4 (3.9)	
1-year Δ (CI 95%)	-0.5 (-0.6 a -0.01)	0.012	-0.5 (-0.6 a 0.2)	0.314	-0.4 (-0.7 a -0.03)	0.033
WC (cm)						
Baseline mean, SD	100.5 (8.7)		102.6 (9.3)		103.4 (9.3)	
1-year Δ (CI 95%)	-1.1 (-2.3 a -0.02)	0.046	-2.3 (-3.4 a -1.1)	<0.001	-3.1 (-4.3 a -1.8)	< 0.001
Body composition						
% TBF						
Baseline mean, SD	35.0 (7.7)		36.4 (7.6)		37.1 (7.1)	
1-year Δ (CI 95%)	-0.2 (-1.0 a 0.5)	0.529	0.6 (-0.3 a 1.5)	0.211	1.0 (0.2 a 1.7)	0.02
TFM (Kg)						
Baseline mean, SD	27.7 (7.4)		29.5 (8.0)		29.6 (8.7)	
1-year Δ (CI 95%)	-0.1 (-0.9 a 0.7)	0.809	-0.1 (-0.7 a 0.9)	0.802	0.4 (-0.4 a 1.2)	0.350
FFM (Kg)						
Baseline mean, SD	50.3 (8.9)		50.0 (8.6)		48.4 (8.3)	
1-year Δ (CI 95%)	-0.1 (-1.3 a 0.8)	0.081	-0.6 (-1.4 a 0.1)	0.115	-1.5 (-2.1 a -0.8)	0.343
% TrF						
Baseline mean, SD	32.9 (7.0)		34.4 (5.8)		34.9 (7.3)	
1-year Δ CI (95%)	-0.2 (-1.1 a 0.7)	0.627	0.9 (-0.7 a 2.3)	0.244	1.1(-0.9 a 3.0)	0.284
TrFM (Kg)						
Baseline mean, SD	14 (3.8)		15.4 (3.8)		15.1 (3.9)	
1-year Δ (CI 95%)	-0.2 (-0.6 a 0.2)	0.380	0.1 (-0.8 a 0.9)	0.915	0.3 (-0.8 a 1.5)	0.551
TBW (Kg)						
Baseline mean, SD	37.1 (7.4)		37.0 (7.3)		36.1 (6.3)	
1-year Δ (CI 95%)	-0.3 (-1.0 a 0.4)	0.451	-0.6 (-1.1 a -0.1)	0.013	-0.7 (-1.2 a -0.3)	0.001

BMI= Body Mass Index; WC= Waist Circumference; MeDiet= Mediterranean Diet; EVOO= Extra-Virgin Olive Oil; %TBF=percentage Total Body Fat; FFM= Free Fat Mass; TFM= Total Fat Mass; %TrF= Percentage Truncal Fat; TrFM= Truncal Fat Mass; TBW= Total Body Water; SD=Standard Deviation; CI= Confidence interval
1-year Δ = difference 1-year – baseline evaluation
P value obtained through paired t-test

Table 3. Percentage of change in the anthropometric (weight, BMI and WC) and body composition variables (%TBF, TFM, FFM, %TrF, TrFM and TBW) during the first year of follow up according to intervention groups.

Variable	MeDiet+EVOO n = 112	MeDiet+nuts n = 102	Control diet n = 98	P
Anthropometric				
Weight (Kg)				0.657
%1-year Δ (CI 95%)	-1.1 (-2.0 to –0.2)	-0.7 (-1.7 to 0.3)	-1.2 (-2.2 to -0.3)	
BMI (Kg/m²)				0.877
%1-year Δ (CI 95%)	-1.1 (-2.0 to -0.2)	-0.8 (-2.3 to 0.8)	-1.1 (-2.2 to 0.2)	
WC (cm)				0.061
%1-year Δ (CI 95%)	-0.9 (-2.0 to 0.2)	-2.2 (-3.3 to -1.0)	-2.9 (-4.1 to -1.6)	
Body composition				
% TBF				0.136
%1-year Δ (CI 95%)	-0.1 (-2.4 to 2.2)	1.3 (-1.4 to 3.8)	3.3 (1.0 to 5.7)	
TFM (Kg)				0.390
%1-year Δ (CI 95%)	0.5 (-2.4 to 3.4)	-0.2 (-2.8 to 2.4)	2.6 (-0.4 to 5.5)	
FFM				0.110
%1-year Δ (CI 95%)	-1,0 (-2.4 to 0.3)	-0.8 (-2.4 to 0.8)	-2.8 (-4.0 to -1.6)	
% TrF				0.124
%1-year Δ (CI 95%)	0.2 (-2.8 to 3.3)	3.9 (-0.7 to 8.5)	6.9 (0.8 to 13.1)	
TrFM (Kg)				0.100
%1-year Δ (CI 95%)	-0.6 (-4.1 to 2.9)	2.3 (-3.8 to 8.4)	9.0 (-0.2 to 18.1)	
TBW (Kg)				0.786
%1-year Δ (CI 95%)	-1.2 (-2.4 to -0.1)	-1.4 (-2.9 to -0.01)	-1.9 (-3.3 to -0.5)	

BMI= Body Mass Index; WC= Waist Circumference; MeDiet= Mediterranean Diet; EVOO= Extra-Virgin Olive Oil;
%TBF=percentage Total Body Fat; TFM= Total Fat Mass; FFM= Free Fat Mass; %TrF= percentage Truncal Fat; TrFM= Truncal Fat Mass; TBW= Total Body Water
SD=Standard Deviation; CI= Confidence interval
*% 1-year Δ= [(difference 1-year – baseline)/baseline]*100*
P value obtained through ANOVA for the comparison between the three intervention groups

Table 4. Energy and nutrient intake at baseline and their changes after one year of follow-up in each intervention group.

	MeDiet+EVOO n =112	P	MeDiet+nuts n = 106	P	Control diet n = 87	P
Energy (Kcal/day)						
Baseline mean, SD	2.347 (527.4)		2.319 (623.3)		2.368 (578.9)	
1-year Δ (CI 95%)	91.9 (– 94.2 to +11.2)	0.08	-144.7 (-243.2 to -46.2)	0.004	-425.0 (-556.9 to -293.2)	< 0.001
Protein (%)						
Baseline mean, SD	16.4 (2.6)	0.008	16.1 (2.5)	0.002	16.2 (2.9)	< 0.001
1-year Δ (CI 95%)	1.0 (0.3 to 1.8)		-1.2 (0.4 to 2.0)		4.1 (3.0 to 5.1)	
Carbohydrate (%)						
Baseline mean, SD	49.8 (6.9)		47.0 (6.2)		49.9 (6.5)	
1-year Δ (CI 95%)	-4.8 (-6.1 to -3.5)	< 0.001	-2.6 (-3.8 to -1.3)	< 0.001	0.2 (-1.1 to 1.6)	0.324
Fat (%)						
Baseline mean SD	32.7 (5.7)		35.8 (5.6)		33.4 (5.8)	
1-year Δ (CI 95%)	6.2 (5.0 to 7.4)	< 0.001	3.23.2 (2.1 to 4.2)	< 0.001	-0.8 (-1.8 to 0.6)	0.324
SFA (%)						
Baseline mean, SD	8.5 (2.7)		9.0 (2.2)		9.0 (2.4)	
1-year Δ (CI 95%)	0.1 (-0.4 to +0.6)	0.551	-0.1 (-0.5 to +0.3)	0.509	0.7 (0.2 to 1.2)	0.003
MUFA (%)						
Baseline mean, SD	14.3 (3.3)		15.9 (3.6)		13.9 (3.0)	
1-year Δ (CI 95%)	5.9 (5.1 to 6.8)	< 0.001	2 .0 (1.2 to 2.8)	< 0.001	0.9 (0.1 to 1.6)	0.019
PUFA (%)						
Baseline mean, SD	6.3 (2.6)		6.8 (2.7)		6.3 (2.9)	
1-year Δ (CI 95%)	-0.2 (-0.8 to 0.3)	0.394	1.1 (0.5 to 1.6)	< 0.001	-0.3 (-0.9 to 0.4)	0.392
Fibre (g/1000 Kcal)						
Baseline mean, SD	15.9 (3.8)		14.4 (3.6)		14.3 (4.0)	
1-year Δ (CI 95%)	-1.6 (-2.4 to -0.8)	< 0.001	-0.003 (-0.7 to 0.7)	0.991	0.2 (-0.6 to 1.1)	0.561
Alcohol (%)						
Baseline mean, SD	1.1 (2.5)		1.1 (2.7)		0.6 (1.6)	
1-year Δ (CI 95%)	-0.3 (-0.6 to -0.02)	0.035	0.5 (-0.8 to -0.1)	0.027	0.1 (-0.3 to +0.2)	0.549
Cholesterol (mg/d)						
Baseline mean, SD	310.8 (135.5)		310.8 (129.3)		332.7 (99.3)	
1-year Δ (CI 95%)	-41.5 (-67.7 to -15.3)	0.004	-36.8 (-60.2 to -13.4)	0.001	-66.6 (-93.7 to -39.5)	< 0.001
14-Point Mediterranean score						
Baseline mean, SD	8.7		8.3		7.8	
1-year Δ (CI 95%)	1.8 (1.4 to 2.2)	0.009	2.0 (1.6 to 2.4)	0.011	0.3 (-0.2 to 0.7)	0.609

EVOO= Extra-Virgin Olive Oil; SFA= Saturated Fatty Acids; MUFA= Monounsaturated Fatty Acid; PUFA= Polyunsaturated Fatty Acid;
D=Standard Deviation; CI= Confidence interval
1-year Δ= difference 1-year – baseline evaluation; P value obtained through paired t test

Table 5. Percentage of change in energy and nutrients intake during the first year of follow up according to intervention groups.

	MeDiet+EVOO n = 112	MeDiet+nuts n = 106	Control n = 87	P
Energy (Kcal/d)				< 0.001
%1-year Δ (CI 95%)	-0.8 (-5.2 to 3.5)	-3.0 (-7.0 to 1.1)	-15.7 (-20.5 to -10.9)	
Protein (%)				< 0.001
%1-year Δ (CI 95%)	1.0 (0.3 to 1.8) †	1.2 (0.4 to 1.9) §	4.1 (3.1 to 5.2)	
Carbohydrate (%)				< 0.001
%1-year Δ (CI 95%)	-4.8(6.1 to -3.5)	-2.5 (-3.7 to -1.3)	0.3 (-1.0 to 1.6)	
Fat (%)				< 0.001
%1-year Δ (CI 95%)	4.1 (2.1 to 5.8)	0.4 (-1.5 to 2.6) §	-9.3 (-11.9 to -6.8)	
SFA (%)				< 0.001
%1-year Δ (CI 95%)	-0.6 (-1.3 to +0.1) †⌘	-0.8 (-1.5 to -0.2) §	-3.1 (-4.1 to -2.2)	
MUFA (%)				< 0.001
%1-year Δ (CI 95%)	5.1 (4.1 to 6.0)	0.8 (-0.2 to -1.9)	-2.8 (-3.9 to -1.7)	
PUFA (%)				< 0.001
%1-year Δ (CI 95%)	-0.6 (-1.2 to +0.03)	-0.6 (-0.04 to 1.3)	-1.9 (-2.8 to -1.0)	
Fibre (g/1000 Kcal)	-5.8	4.1	7.0	0.005
%1-year Δ (CI 95%)	(-1.3 to -0.3) †⌘	(-1.4 to 9.5)	(0.7 to 13.3)	
Alcohol (%)				0.68
%1-year Δ (CI 95%)	-2.6 (-42.2 to 37.0)	-12.8 (-50.2 to 24.5)	-12.8 (-50.2 to 24.5)	
Cholesterol (mg/d)				0.795
%1-year Δ (CI 95%)	-2.2 (-10.8 to -15.3)	-2.0 (-10.4 to 6.4)	-17.1 (-24.7 to -9.5)	
14-Point Mediterranean score				< 0.001
%1-year Δ (CI 95%)	26.71 (20.7 to 32.8) †	27.9 (21.5 to 34.3) §⌘	7.1 (0.9 to 13.4)	

EVOO= Extra-Virgin Olive Oil; SFA= Saturated Fatty Acids; MUFA= Monounsaturated Fatty Acid; PUFA= Polyunsaturated Fatty Acid;
CI= Confidence interval
*% 1-year Δ = [(difference 1-year – baseline)/baseline]*100*
P value obtained through ANOVA for the comparison between the three intervention groups
† The differences between MeDiet + EVOO and control group were statistically significant (P < 0.05). (Benjamini -Hochberg post-test correction).
§ The differences between MeDiet + nuts and control group were statistically significant (P < 0.05). (Benjamini -Hochberg post-test correction).
⌘The differences between MeDiet + EVOO and MeDiet + nuts were statistically significant (P < 0.05). (Benjamini -Hochberg post-test correction).