Eur J Nutr (2010) 49:91–99
DOI 10.1007/s00394-009-0053-7

ORIGINAL CONTRIBUTION

Predictors of adherence to a Mediterranean-type diet in the PREDIMED trial

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Received: 1 April 2009 / Accepted: 15 August 2009 / Published online: 4 September 2009

Abstract
Background Determinants of dietary changes obtained with a nutritional intervention promoting the Mediterranean diet have been rarely evaluated.
Aim To identify predictors of higher success of an intervention aimed to increase adherence to a Mediterranean diet (MeDiet) in individuals at high cardiovascular risk participating in a trial for primary prevention of cardiovascular disease: the PREDIMED (PREvención con DIeta MEDiterránea) trial. Candidate predictors included demographic and socioeconomic characteristics, cardiovascular risk factors, and baseline dietary habits.
Methods A total of 1,048 asymptomatic subjects aged 55–80 years allocated to the active intervention groups (subjects in the control group were excluded). Participants' characteristics were assessed at baseline among subjects.

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Dietary changes were evaluated after 12 months. Main outcome measures were: attained changes in five dietary goals: increases in (1) fruit consumption, (2) vegetable consumption, (3) monounsaturated fatty acid (MUFA)/saturated fatty acid (SFA) ratio, and decreases in (4) sweets and pastries consumption, (5) and meat consumption. Univariate and multivariate logistic regression analyses were used to examine associations between the candidate predictors and likelihood of attaining optimum dietary change (improved adherence to a MeDiet).

Results Among men, positive changes toward better compliance with the MeDiet were more frequent among non-diabetics, and among those with worse dietary habits at baseline (higher consumption of meat, higher SFA intake, lower consumption of fruit and vegetables). Among women, marital status (married) and worse baseline dietary habits (high in meats, low in fruits and vegetables) were the strongest predictors of success in improving adherence to the MeDiet.

Conclusions Some participant characteristics (marital status and baseline dietary habits) could contribute to predicting the likelihood of achieving dietary goals in interventions aimed to improve adherence to a MeDiet, and may be useful for promoting individualized long-term dietary changes and improving the effectiveness of dietary counseling.

Keywords Dietary predictors · Dietary adherence · Mediterranean diet · Cardiovascular risk · PREDIMED study

Introduction

Diet-related chronic diseases [type 2 diabetes, cardiovascular disease (CVD), obesity, and some cancers] are a serious public health concern in Western countries [12, 36], and may reach epidemic proportions in developed and developing countries in the next two decades [2].

Preventive actions aimed to reduce the prevalence and incidence of major chronic disease such as CVD could have a great impact [23]. Specifically, a means for achieving this goal consists of acquiring favorable dietary changes.

During the last two decades, many studies have shown that the Mediterranean-type diet (MeDiet) could prevent CVD and also protect against diabetes and several forms of cancer [3, 7, 15, 16, 20, 27].

However, it is very difficult to achieve effective dietary modifications in practice [10, 11, 30, 37], although it is crucial to find out which are the predictive factors for success in acquiring and adhering to improved dietary habits. Several studies have addressed these predictors [14, 28, 29, 35]. Up to now, the most important predictors of failure to achieve these changes are some sociodemographic characteristics, general health status [35], and lifestyle and psychological factors [28]. However, fewer studies have evaluated the predictors of dietary response to a nutritional intervention promoting the MeDiet, and have observed the influence of anthropometric, metabolic, socioeconomic, and sociodemographic variables [8, 9, 24].

The aim of this study was to identify predictors of long-term compliance to a dietary intervention emphasizing a MeDiet. These data come from the PREDIMED (PREvención con DIeta MEDiterránea) trial, the first large randomized controlled trial for the primary prevention of chronic disease that allocates participants to one of three dietary patterns, two MeDiet with different fat sources—mixed nuts or olive oil and one low-fat diet (control group) [7, 37].

Methods

Study population

The present study was conducted within the framework of the PREDIMED trial. Details of the trial protocol have been published elsewhere [7, 25, 37]. The PREDIMED study is an ongoing multicenter, randomized, controlled, single-blinded 4-year trial. The protocol was approved by the review boards of all participating centers, according to the Helsinki Declaration [34]. The recruitment of 7,300 participants in primary care centers affiliated to ten Spanish teaching hospitals took place between October 2003 and March 2009.

The PREDIMED trial is designed to assess the effects of the MeDiet on major cardiovascular events, using groups of participants assigned to one of three different dietary patterns. The assessment of selection criteria was performed by the participants' usual primary care physicians. The participants, aged 55–80 years, fulfilled at least one of the following criteria: type 2 diabetes or three or more CVD risk factors (smoking, hypertension, dislipemia, obesity, or family history of CVD). All participants provided written informed consent.

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Dietary intervention

The PREDIMED dietitians from each clinical center received specific training and were responsible for the dietary education intervention. The message was always adapted to the participants' beliefs, preferences, and clinical conditions. Each participant in the control group had a first interview with a dietitian and received a leaflet with the recommendations based on American Heart Association guidelines and verbal instructions on the skills needed to adopt this type of diet [7] (http://www.predimed.org). No further visits were scheduled for the control group until the 12-month follow-up medical assessment. On the other hand, the intervention in the MeDiet groups consisted of: (a) quarterly individual motivational interviews which included positive and individualized recommendations to follow the corresponding MeDiet, (b) quarterly group sessions separated for each of these intervention groups, (c) written material with descriptions of typical Mediterranean foods, seasonal shopping lists, meal plans, and cooking recipes, and (d) free provision of virgin olive oil (1 L/week) or mixed nuts (30 g/day) [37].

Dietary assessment

Data on dietary intake were collected at baseline and during the 12-month follow-up visit. All participants were also asked to complete a 137-item semi-quantitative food-frequency questionnaire (FFQ) previously validated in Spain [18]. The frequencies were registered in nine categories that ranged from "never or almost never" to "≥6 times/day". The baseline adherence to the typical MeDiet was also measured by a simplified 14-item assessment questionnaire, an extension of a previously validated short questionnaire [17]. Energy and nutrient intake were derived using Spanish food composition tables [19, 21].

Assessment of the dietary outcome

The outcome was defined as not attaining an adequate dietary response to one of the MeDiets after 12-month follow-up. The baseline and the 12-month follow-up FFQs were used and included five items to calculate a dietary response score: any increase in the consumption of fruits, vegetables and the MUFA/SFA ratio and any decrease in the consumption of the meat group and in the group of sweets and pastries. A score was built assigning values of 0 or 1 to each of these five items. This score was calculated adding 1 point for any increase in the consumption of fruit, vegetables or in the MUFA/SFA ratio or for any decrease in the consumption of meat or sweets and pastries. Thus, the potential range of the estimated score was 0–5 points, with 5 meaning maximum adherence and 0 meaning minimum adherence to the dietary goals. Finally, the score was categorized in two groups: subjects with ≥4 points (success) versus subjects with <4 points (failure).

Assessment of non-dietary variables

During the baseline visit, sociodemographic data and information regarding physical activity gathered with the validated Spanish version of the Minnesota questionnaire were collected [5, 6].

Blood pressure was measured in triplicate with a validated semi-automatic oscillometer (Omrom HEM-705CP, Hoofddorp, the Netherlands). Weight was taken using calibrated scales (TBF-300A Body Composition Analiser/Scale, TANITA©, Tokyo, Japan). Height measured using a wall-mounted stadiometer (Seca 242, HealthCheck Systems, Brooklyn, NY, USA) by trained nurses.

Potential predictors

The potential predictors were intervention group, sex, age, marital status, educational level, occupation, smoking, baseline body mass index, hypertension, diabetes, hypercholesterolemia, baseline physical activity, baseline 14-item score, baseline consumption of fruits, vegetables, meat, sweets, fish, legumes, cereals and alcohol, the baseline intake of MUFA/SFA ratio, total energy, lipids, carbohydrates, proteins, cholesterol, fiber, and SFA.

Statistical methods

Data for the first 1,066 participants followed up for 1 year, with complete information for the baseline and for the 12-month follow-up FFQ and assigned to one of the two MeDiets were available. 18 subjects were excluded because of extreme baseline total energy intake (<800 or >4,000 kcal/day in men and <500 or >3,500 kcal/day in women) [33]. Thus, the effective sample size was 1,048 (509 men and 539 women).

Dietary intakes were adjusted for total energy intake using the residuals method [32].

Quantitative variables were categorized into tertiles for all participants and separately for sex for the stratified analyses, always considering the lowest tertile as the reference. Chi-square tests were used to assess differences for proportions between groups. Logistic regression models were fitted to assess the association between several characteristics and the probability of reaching an adequate dietary change (≥4 beneficial changes). An odds ratio (OR) greater than one expresses a suboptimal attainment of the intended goals, whereas OR lower than 1 means higher success. Moreover, we fitted multiple linear regression models to evaluate the association between some baseline characteristics and the absolute change in the score.

In addition, sensitivity analyses were conducted to assess the association between candidate predictor variables and the following outcomes: (a) achieving ≥3 or ≥2 points out of 5 possible points, (b) increasing nut and olive oil consumption, and (c) increasing ≥2 points or ≥3 points in the baseline 14-item score. Finally, multiple regression models were fitted to evaluate the association between candidate predictor variables and changes in the 14-item score or in the 5-item score (both as continuous variables and 12 months after the intervention).

All *P* values presented are two-tailed and statistical significance was defined a priori at $P < 0.05$. Data analyses were performed using SPSS 15.0 (SPSS Inc, Chicago, IL, USA).

Results

Among the 1,048 participants, the average age was 67.1 years. Tables 1, 2, and 3 show the baseline characteristics of the participants according to sex, showing, within each characteristic, the percentage of participants who attained the highest success (≥4 of five potential positive changes) in improving their adherence to a MeDiet after 1 year of follow-up. A higher success, evaluated to achieve at least four of five favorable changes at 1-year dietary intervention, was observed among men and younger or non-diabetic participants and in both men and women with lower baseline consumption of fruits, vegetables, and fish with lower baseline fiber intake. However, separate multivariable logistic regression models were fitted for men and women, because the response to the dietary intervention according to other variables differed greatly between them.

The results for the multivariable models are shown in Table 4. In men, the independent predictors for not meeting ≥4 dietary goals or changes related to baseline variables were: having a previous history of diabetes and having a high baseline consumption of fruits and vegetables. However, having family history of CVD at baseline or several characteristics of a worse dietary profile at baseline (high consumption of meat, high intake of carbohydrates or SFA) were associated with higher success or ≥4 favorable changes. In women, not being married, having diabetes and having higher baseline consumption of fruits, vegetables or fish were associated with a higher likelihood of not meeting ≥4 of the intended goals. In addition, having a high baseline consumption of meat and sweets-pastries was a significantly predictor of success. When the dietary profile at 12 months of those who attained ≥4 out of the five intended goals and those who did not were compared, the former group exhibited a healthier profile with significant differences for all food groups with the exception of fish and nuts ($P = 0.16$ and $P = 0.32$, respectively).

On the other hand, when we considered the absolute change in the score as dependent variable, the potential predictor variables were very similar, and the percentage of explained variability in the 5-item score was 21.3 and 25.3% for men and women, respectively.

Table 1 Percentage (*n*) or participants, according to sociodemographic variables, achieving a higher success in reaching an adequate dietary change (≥4 out of 5 points of improved adherence to Mediterranean diet) after 1 year

Condition	Percentage of participants with ≥4 changes		
	All ($n = 1{,}048$)	Men ($n = 509$)	Women ($n = 539$)
Overall	40.2	42.0	39.4
Age group			
<65 years	43.2 (431)	44.2 (249)	41.8 (182)
≥65 years	38.1 (617)	40.0 (260)	36.7 (357)
Marital status			
Married	41.1 (824)	41.0 (479)	41.4 (365)
Single, widowed, divorced, others	36.6 (224)	52.0 (50)	32.2 (174)
Educational level			
Secondary school or higher	39.2 (260)	39.4 (170)	38.9 (90)
Primary school or none	40.5 (788)	43.4 (339)	38.3 (449)
Occupation			
Retired	38.5 (600)	40.7 (410)	33.7 (190)
Worker, housewife, unemployed or unfit	42.4 (448)	47.5 (99)	41.0 (349)
Smoking (cig/day)			
Never smokers	40.0 (625)	41.4 (145)	39.6 (480)
Past smokers	40.7 (258)	41.9 (227)	32.3 (31)
Current smokers	40.0 (165)	43.1 (137)	25.0 (28)

An adequate dietary change was defined as meeting at least four out of five goals regarding changes of dietary habits in 1 year

All *P* values of chi square were <0.001

Table 2 Percentage (*n*) or participants, according to physiologic variables, achieving a higher success in reaching an adequate dietary change (≥4 out of 5 points of improved adherence to Mediterranean diet) after 1 year

Condition	Percentage of participants with ≥4 changes		
	All ($n = 1{,}048$)	Men ($n = 509$)	Women ($n = 539$)
Body mass index (kg/m^2)			
<30	40.9 (624)	41.3 (329)	40.3 (295)
≥30	39.2 (424)	43.3 (180)	36.1 (244)
Hypertension			
Yes	40.8 (814)	44.7 (367)	37.6 (447)
No	38.0 (234)	35.2 (142)	42.4 (92)
Diabetes			
Yes	33.1 (517)	33.6 (271)	32.5 (246)
No	47.1 (531)	51.7 (238)	43.3 (293)
Hypercholesterolemia			
Yes	40.1 (676)	42.3 (300)	38.3 (376)
No	40.3 (372)	41.6 (209)	38.7 (163)
Family history of CHD			
Yes	40.8 (169)	50.0 (68)	34.7 (101)
No	40.0 (879)	40.8 (441)	39.3 (438)
Physical activity			
T1	38.9 (334)	44.8 (163)	35.7 (171)
T2	41.5 (335)	42.1 (164)	39.5 (172)
T3	41.4 (333)	41.6 (161)	40.4 (171)

An adequate dietary change was defined as meeting at least four out of five goals regarding changes of dietary habits in 1 year

All *P* values of chi square were <0.001

CHD coronary heart disease; *T1* first tertile; *T2* second tertile; *T3* third tertile

In addition, when the score was introduced as a continuous variable, participants without a previous history of diabetes and those with lower baseline consumption of fruits or vegetables or higher consumption of meat or sweets-pastries exhibited a significant improvement in 12-month adherence to a MeDiet (data not shown). On the other hand, as expected, men and women who already had a higher baseline adherence to a MeDiet exhibited a smaller change, and a previous history of diabetes was inversely associated with the 12-month change in the 14-item baseline score (as a continuous variable) only among women (data not shown).

When the cut-off point was changed (either ≥2 or ≥3 favorable changes out of the five possible changes) the results were consistent. Among women and men the ORs were similar for diabetes (range 1.4–2.0), and for a higher baseline consumption of fruit, vegetables, and meat (ranges 1.8–3.3; 2.8–4.1, and 0.3–0.5, respectively). On the other hand, in women and men the most important predictive factor for not meeting an increase of ≥2 or ≥3 points on the 14-item score after 1-year follow-up was having already a high value in the MeDiet score at baseline.

Among men, a higher baseline total energy intake (OR range 1.3–1.7), or a high intake of fat (OR range 1.8–3.4), fiber (OR range 1.6–1.7) and a higher baseline MUFA/SFA ratio (1.8–3.8) were significantly associated with lower increases in the consumption of olive oil or nuts. Among women, a higher success was associated with having a higher baseline consumption of meat (OR 0.6).

Discussion

To our knowledge, this is the first prospective study assessing the factors associated with higher success in improving adherence to a MeDiet in a large randomized trial with community-dwelling participants at high cardiovascular risk in the Mediterranean area.

In both men and women the strongest predictors of successful dietary changes were low baseline consumption of fruits and vegetables, among men having a family history of CVD, and among women, being married. Having diabetes at baseline predicted a lower likelihood of success in both men and women.

Consistently with the literature, failure to meet the dietary goals was usually found among older participants [31, 35], which may be explained because our participants had deeply rooted dietary habits and they were already fairly adherent to the MeDiet pattern at baseline [8, 26].

In contrast to previous findings [14, 31], success was lower among women, in spite of the fact that women are usually more motivated to respond to health messages focused on diet [14]. A reason that may explain this is that their baseline dietary patterns were closer to the intended dietary goals than those of men, and a healthier diet at baseline was a major predictor of not attaining the intended changes.

On the other hand, married men and non-married women were less likely to achieve the intended dietary goals, perhaps because married women have generally more responsibility for food purchasing and preparing meals [4], and thus they could more easily adopt the intended changes.

Although other studies [24, 29] found a positive association between educational level and adherence to a MeDiet, we did not. The main reason that may explain this finding is that in the PREDIMED study population the between-subject variability in educational levels is small, because the proportion of highly educated subjects, specifically a university degree, was very small (7.6%), especially among women.

Considering cardiovascular risk factors, in men and women, the best predictor of success to improve the

Table 3 Percentage (*n*) or participants, according to baseline dietary characteristics, achieving a higher success in reaching an adequate dietary change (≥4 out of 5 points of improved adherence to Mediterranean diet) after 1 year

Condition	Percentage of participants with ≥4 changes		
	All ($n = 1{,}048$)	Men ($n = 509$)	Women ($n = 539$)
Baseline 14-item score			
1–7	48.2 (224)	50.0 (110)	46.5 (114)
8–9	36.6 (388)	39.1 (184)	34.3 (204)
>9	39.2 (436)	40.5 (215)	38.0 (221)
Fruit consumption at baseline			
T1	47.9 (349)	51.2 (170)	45.6 (180)
T2	42.9 (350)	42.9 (170)	41.7 (180)
T3	29.8 (349)	32.0 (169)	27.9 (179)
Vegetable consumption at baseline			
T1	52.4 (349)	58.0 (169)	49.4 (180)
T2	40.6 (350)	42.1 (171)	37.4 (179)
T3	27.5 (349)	26.0 (169)	28.3 (180)
Meat consumption at baseline			
T1	32.7 (349)	35.9 (170)	28.3 (180)
T2	44.6 (350)	48.8 (170)	41.1 (180)
T3	43.3 (349)	41.4 (169)	45.8 (179)
Sweets and pastries consumption at baseline			
T1	30.7 (349)	33.7 (169)	31.7 (180)
T2	39.7 (350)	39.8 (171)	36.1 (180)
T3	50.1 (349)	52.7 (169)	47.5 (179)
Fish consumption at baseline			
T1	44.7 (349)	46.7 (169)	42.8 (180)
T2	41.7 (350)	45.0 (171)	37.8 (180)
T3	34.1 (349)	34.3 (169)	34.6 (179)
Legume consumption at baseline			
T1	41.5 (349)	42.9 (170)	38.9 (180)
T2	38.3(350)	41.4 (169)	35.8 (179)
T3	40.7 (349)	41.8 (170)	40.6 (180)
Cereal consumption at baseline			
T1	40.4 (349)	41.8 (170)	39.4 (180)
T2	41.4 (350)	40.8 (169)	39.7 (179)
T3	38.7 (349)	43.5 (170)	36.1 (180)
Alcohol consumption at baseline			
0 g/day	39.8 (332)	38.7 (62)	40.0 (270)
>0 and <20 g/day in women, <30 g/day in men	40.3 (573)	42.0 (333)	37.9 (240)
>20 g/day in women, >30 g/day in men	40.6 (143)	43.9 (114)	27.6 (29)
Total energy intake at baseline			
T1	35.0 (349)	36.5 (170)	33.9 (180)
T2	43.1 (350)	42.8 (170)	41.9 (179)
T3	42.4 (349)	47.3 (169)	39.4 (179)
Dietary fat intake at baseline			
T1	41.5 (349)	43.5 (170)	39.7 (179)
T2	39.7 (350)	40.0 (170)	38.7 (181)
T3	39.3 (349)	42.6 (169)	36.9 (179)
MUFA/SFA ratio at baseline			
T1	41.0 (349)	41.4 (169)	40.2 (179)
T2	42.9 (350)	48.0 (171)	38.3 (180)
T3	36.7 (349)	36.7 (169)	36.7 (180)
Total carbohydrate intake at baseline			
T1	39.8 (349)	39.1 (169)	38.3 (180)
T2	37.4 (350)	40.9 (171)	37.8 (180)
T3	43.3 (349)	46.2 (169)	39.1 (179)
Protein intake at baseline			
T1	38.4 (349)	43.5 (170)	33.3 (180)
T2	43.4 (350)	44.7 (170)	40.0 (180)
T3	38.7 (349)	37.9 (169)	41.9 (180)
Cholesterol intake at baseline			
T1	37.5 (349)	42.6 (169)	30.7 (179)
T2	42.6 (350)	42.4 (170)	44.4 (180)
T3	40.4 (349)	41.2 (170)	40.0 (180)
Fiber intake at baseline			
T1	49.9 (349)	53.3 (169)	45.8 (179)
T2	40.9 (350)	42.9 (170)	38.1 (181)
T3	29.8 (349)	30.0 (170)	31.3 (179)
Saturated fat intake at baseline			
T1	35.2 (349)	36.7 (169)	34.4 (180)
T2	46.3 (350)	48.5 (171)	42.5 (179)
T3	39.0 (349)	40.8 (169)	38.3 (180)

An adequate dietary change was defined as meeting at least four out of five goals regarding changes of dietary habits in 1 year

All *P* values of chi square were <0.001

T1 first tertile; *T2* second tertile; *T3* third tertile

adherence to a MeDiet was not being diabetic at baseline. The difficulty of changing the dietary habits of diabetics, also observed in previous studies [1, 22], may be explained by the fact that the diagnosis of this disease might have led to beliefs or even medical advice which is not always consistent with the intended intervention, making it more difficult to achieve many favorable changes. Thus, a low fat diet has been consistently used in Spain to treat patients with diabetes and other CVD risk factors; despite the increasing evidence of the MeDiet effectiveness, its use in primary health care settings is still very low, since it takes a long time for evidence to filter through into practice. This

Table 4 Multivariable OR [95% confidence interval (CI)] for not meeting ≥4 dietary goals according to baseline characteristics among men and women

Outcome	Men Multivariate OR[a] (95% CI)	Men Linear regression coefficients (95% CI)	Women Multivariate OR[a] (95% CI)	Women Linear regression coefficients[b] (95% CI)
Marital status				
Married			1 (ref)	0 (ref)
Single, widowed, divorced, others			1.6 (1.1–2.4)	−0.07 (−0.25 to 0.10)
Diabetes				
No	1 (ref)	0 (ref)	1 (ref)	0 (ref)
Yes	1.8 (1.2–2.8)	0.25 (0.04–0.45)	1.5 (1.0–2.2)	0.19 (0.01–0.36)
Family history of CHD[b]				
No	1 (ref)	0 (ref)		
Yes	0.6 (0.3–1.0)	−0.18 (−0.46 to 0.09)		
Fruit consumption at baseline				
T1	1 (ref)	0 (ref)	1 (ref)	0 (ref)
T2	1.3 (0.8–2.1)	−0.04 (−0.27 to 0.19)	1.2 (0.8–1.9)	−0.16 (−0.36 to 0.05)
T3	2.6 (1.5–4.3.)	−0.36 (−0.59 to −0.12)	2.6 (1.5–4.3)	−0.58 (−0.79 to −0.38)
Vegetable consumption at baseline				
T1	1 (ref)	0 (ref)	1 (ref)	0 (ref)
T2	1.7 (1.0–2.7)	−0.37 (−0.60 to −0.15)	1.6 (1.0–2.5)	−0.30 (−0.50 to −0.09)
T3	3.4 (2.0–5.7)	−0.68 (−0.91 to −0.44)	2.7 (1.6–4.5)	0.51 (−0.73 to −0.29)
Meat consumption at baseline				
T1	1 (ref)	0 (ref)	1 (ref)	0 (ref)
T2	0.4 (0.2–0.6)	0.50 (0.27–0.73)	0.5 (0.3–0.7)	0.36 (0.16–0.56)
T3	0.4 (0.3–0.8)	0.48 (0.24–0.72)	0.3 (0.2–0.6)	0.58 (0.38–0.78)
Carbohydrate intake at baseline				
T1	1 (ref)	0 (ref)		
T2	0.7 (0.4–1.2)	0.09 (−0.14 to 0.32)		
T3	0.4 (0.2–0.7)	0.27 (0.01–0.55)		
Saturated fat intake at baseline				
T1	1 (ref)	0 (ref)		
T2	0.5 (0.3–0.9)	0.25 (0.01–0.49)		
T3	0.5 (0.3–0.9)	0.28 (0.01–0.55)		
Sweet and pastries consumption at baseline				
T1			1 (ref)	0 (ref)
T2			0.8 (0.5–1.3)	0.15 (−0.05 to 0.35)
T3			0.6 (0.4–1.0)	0.36 (0.15–0.57)
Fish consumption at baseline				
T1			1 (ref)	0 (ref)
T2			1.2 (0.8–2.0)	−0.02 (−0.22 to 0.18)
T3			1.2 (0.8–2.0)	0.07 (−0.27 to 0.14)
R^2 (% explained variance)		0.213		0.252

Regression coefficients (95% CI) for the absolute change in the score as continuous variable according to baseline characteristics

An adequate dietary change was defined as meeting at least four out of five goals regarding changes of dietary habits in 1 year

T1 first tertile; *T2* second tertile; *T3* third tertile

[a] Adjusted for all variables in the table, study center and group or intervention. Among men: fruit (T1 <260.8 g/day, T2 260.9–395.1 g/day, T3 >395.2 g/day), vegetable (T1 <248.5 g/day, T2 248.6–337.4 g/day, T3 >337.5 g/day), meat (T1 <127.6 g/day, T2 127.7–171.2 g/day, T3 >171.3 g/day), carbohydrate (T1 <234.3 g/day, T2 234.4–272.0 g/day, T3 >272.1 g/day) and saturated fat intake (T1 <24.7 g/day, T2 24.8–28.7 g/day, T3 >28.7 g/day). Among women: fruit (T1 <281.6 g/day, T2 281.7–409.6 g/day, T3 >409.7 g/day), vegetable (T1 <251.0 g/day, T2 251.0–337.0 g/day, T3 >337.1 g/day), meat (T1 <112.8 g/day, T2 112.8–149.7 g/day, T3 >149.7 g/day), sweet (T1 <8.4 g/day, T2 8.5–23.6 g/day, T3 >23.7 g/day) and fish (T1 <76.4 g/day, T2 76.5–110.1 g/day, T3 >110.2 g/day)

[b] Coronary heart disease

finding suggests that diabetics should receive a more intensive dietary counseling than other subjects, based on more frequent and individual contacts with the dietitians or on easy closed messages, for example. However, future trials on specific counseling and education for diabetics are needed.

As expected, having baseline dietary habits which are farther away from the study goals predicted a higher success rate in reaching the intended dietary goals. This same association was also observed in the women's health initiative dietary modification trial [36]. There may well be a threshold of dietary change beyond which extraordinary efforts are needed. Also, greater success was achieved among participants with a low baseline consumption of typically "healthy" Mediterranean foods (fruits, vegetables, and fish) and among those with high consumption of less "healthy" foods (meat or sweets). All these findings may also be explained because of regression toward the mean, and thus the participants with worst nutritional profile at baseline might tend to improve their nutritional profile at 1 year, whereas the best subjects at baseline will tend to do worse.

Our study has some limitations. First, the study sample is not representative of the general population, but the potential benefits arising from improved lifestyles among high-risk subjects are large. Second, it is possible that unmeasured factors that might also be strong predictors of our outcome may not have been accounted for. Nevertheless, a wide array of baseline participants' characteristics, most of which were not related to success or failure in the intervention, were assessed [7]. Third, the FFQ relies on self-reported information, and some subjects may have distorted their actual food intake (social desirability bias). However, the use of a previously validated FFQ [18] and previous findings about the correlation between self-reported dietary intake and biomarkers of compliance in this study population [7, 37] support the reliability of this information. Fourth, one critical point concerning trials is the applicability of the results to free-living subjects. In this regard, one strength of the PREDIMED trial is that it includes community-dwelling participants similar to those in primary care settings [13]. Finally, residual confounding might be a possible explanation of our findings, as it is the case in any other epidemiological study. Nonetheless, the vast amount of baseline information collected [7] makes this unlikely.

In summary, our results suggest that there are some baseline characteristics that could help to identify which subjects will respond better to a dietary intervention promoting a MeDiet, but further research is needed. Finally, if our findings are confirmed, they could prove useful for the development of targeted interventions in order to improve the design of large-scale interventions to change dietary habits in free-living populations.

Acknowledgments The authors thank the participants for their enthusiastic collaboration, the PREDIMED personnel for excellent assistance and the personnel of all primary care centers affiliated, especially to Beatriz San Julian, Pilar Buil Cosiales, Javier Díez Espino, Ana García-Arellano, Julia Wärnberg, Jordi Salas- Salvadó, José Lapetra, Maria Isabel Covas, Manolo Serrano and Jackeline Alvarez. We gratefully acknowledge the Instituto de Salud Carlos III (ISCIII) and other funding sources (see below).

Conflict of interest statement Spanish Government (Instituto de Salud Carlos III, RTIC RD06/0045, Fondo de Investigaciones Sanitarias, FIS PI04/0233, PI04/2239, PI05/2368, PI05/1839, PI081943, PI07/0312, PI04/2241, PI05/0976, PI07/0240, and PE 087/0819), CIBEROBN, "CIBER Fisiopatologia de la Obesidad y Nutricion (CIBEROBN) is an initiative of ISCIII"), the Navarra Government (PI41/2005), Generalitat Valenciana (ACOMP06109). Fundación Patrimonio Comunal Olivarero and Hojiblanca SA (Málaga, Spain), California Walnut Commission (Sacramento, CA), Borges SA (Reus, Spain) and Morella Nuts SA (Reus, Spain) donated the olive oil, walnuts, almonds, and hazelnuts, respectively, used in the study. None of the funding sources played a role in the design, collection, analysis or interpretation of the data or in the decision to submit this manuscript.

References

1. Ballesteros-Pomar MD, Rubio-Herrera MA, Gutiérrez-Fuentes JA, Gómez-Gerique JA, Gómez-de-la-Cámara A, Pascual O, Gárate I, Montero R, Campiña S (2000) Dietary habits and cardiovascular risk in the Spanish population: the DRECE study (I). Diet and cardiovascular events risk in Spain. Ann Nutr Metab 44:108–114
2. Belahsen R, Rguibi M (2006) Population health and Mediterranean diet in southern Mediterranean countries. Public Health Nutr 9:1130–1135
3. Benetou V, Trichopoulou A, Orfanos P, Naska A, Lagiou P, Boffetta P, Trichopoulos D (2008) Greek EPIC cohort conformity to traditional Mediterranean diet and cancer incidence: the Greek EPIC cohort. Br J Cancer 99:191–195
4. Beresford SA, Curry SJ, Kristal AR, Lazovich D, Feng Z, Wagner EH (1997) A dietary intervention in primary care practice: the eating patterns study. Am J Public Health 87:610–616
5. Elosua R, Garcia M, Aguilar A, Molina L, Covas MI, Marrugat J (2000) Validation of the Minnesota leisure time physical activity questionnaire in Spanish women. Investigators of the MARATDON Group. Med Sci Sports Exerc 32:1431–1437
6. Elosua R, Marrugat J, Molina L, Pons S, Pujol E (1994) Validation of the Minnesota leisure time physical activity questionnaire in Spanish men. The MARATHOM Investigators. Am J Epidemiol 139:1197–1209
7. Estruch R, Martínez-González MA, Corella D, Salas-Salvadó J, Ruiz-Gutiérrez V, Covas MI, Fiol M, Gómez-Gracia E, López-Sabater MC, Vinyoles E, Arós F, Conde M, Lahoz C, Lapetra J, Sáez G, Ros E (2006) PREDIMED study investigators effects of a Mediterranean-style diet on cardiovascular risk factors: a randomised trial. Ann Intern Med 145:1–11
8. Giuseppe R, Bonanni A, Olivieri M, Castelnuovo AD, Donati MB, Gaetano G, Cerletti C, Iacoviello L (2008) Adherence to Mediterranean diet and anthropometric and metabolic parameters in an observational study in the 'Alto Molise' region: The MOLI-SAL project. Nutr Metab Cardiovasc Dis 18:415–421
9. Goulet J, Lamarche B, Lemieux S (2007) Factors influencing the dietary response to a nutritional intervention promoting the

Mediterranean food pattern in healthy women from the Quebec City metropolitan area. Health Educ Res 22:718–726
10. Group DPPR (2002) Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. N Engl J Med 346:393–403
11. Howard BV, Van Horn L, Hsia J, Manson JE, Stefanick ML, Wassertheil-Smoller S, Kuller LH, LaCroix AZ, Langer RD, Lasser NL, Lewis CE, Limacher MC, Margolis KL, Mysiw WJ, Ockene JK, Parker LM, Perri MG, Phillips L, Prentice RL, Robbins J, Rossouw JE, Sarto GE, Schatz IJ, Snetselaar LG, Stevens VJ, Tinker LF, Trevisan M, Vitolins MZ, Anderson GL, Assaf AR, Bassford T, Beresford SA, Black HR, Brunner RL, Brzyski RG, Caan B, Chlebowski RT, Gass M, Granek I, Greenland P, Hays J, Heber D, Heiss G, Hendrix SL, Hubbell FA, Johnson KC, Kotchen JM (2006) Low-fat dietary pattern and risk of cardiovascular disease: the women's health initiative randomised controlled dietary modification trial. JAMA 295:655–666
12. James PT, Rigby N, Leach R (2004) The obesity epidemic, metabolic syndrome and future prevention strategies. Eur J Cardiovasc Prev Rehabil 11:3–8
13. Krauss RM, Eckel RH, Howard B, Appel LJ, Daniels SR, Deckelbaum RJ, Erdman JW Jr, Kris-Etherton P, Goldberg IJ, Kotchen TA, Lichtenstein AH, Mitch WE, Mullis R, Robinson K, Wylie-Rosett J, St Jeor S, Suttie J, Tribble DL, Bazzarre TL (2000) AHA dietary guidelines: revision 2000: a statement for healthcare professionals from the Nutrition Committee of the American Heart Association. Stroke 31:2751–2766
14. Kristal AR, Hedderson MM, Patterson RE, Neuhouser M (2001) Predictors of self-initiated, healthful dietary change. J Am Diet Assoc 101:762–766
15. Martinez-Gonzalez MA, Sanchez-Villegas A (2004) The emerging role of Mediterranean diets in cardiovascular epidemiology: monounsaturated fats, olive oil, red wine or the whole pattern? Eur J Epidemiol 19:9–13
16. Martínez-González MA, de la Fuente-Arrillaga C, Nunez-Cordoba JM, Basterra-Gortari FJ, Beunza JJ, Vazquez Z, Benito S, Tortosa A, Bes-Rastrollo M (2008) Adherence to Mediterranean diet and risk of developing diabetes: prospective cohort study. BMJ 336:1348–1351
17. Martinez-Gonzalez MA, Fernandez-Jarne E, Serrano-Martinez M, Wright M, Gomez-Gracia E (2004) Development of a short dietary intake questionnaire for the quantitative estimation of adherence to a cardioprotective Mediterranean diet. Eur J Clin Nutr 58:1550–1552
18. Martin-Moreno JM, Boyle P, Gorgojo L, Maisonneuve P, Fernandez-Rodriguez JC, Salvini S, Willett WC (1993) Development and validation of a food frequency questionnaire in Spain. Int J Epidemiol 22:512–519
19. Mataix J (2003) Tablas de composición de alimentos (Spanish food composition tables), 4th edn. Universidad de Granada, Granada (in Spanish)
20. Mitrou PN, Kipnis V, Thiébaut AC, Reedy J, Subar AF, Wirfält E, Flood A, Mouw T, Hollenbeck AR, Leitzmann MF, Schatzkin A (2007) Mediterranean dietary pattern and prediction of all-cause mortality in a US population: results from the NIH-AARP diet and health study. Arch Intern Med 167:2461–2468
21. Moreiras O, Carvajal A, Cabrera L (2005) Tablas de composición de alimentos (Food composition tables), 9th edn. Ediciones Pirámide, Madrid (in Spanish)
22. Patterson RE, Kristal AR, White E (1996) Do beliefs, knowledge, and perceived norms about diet and cancer predict dietary change? Am J Public Health 86:1394–1400
23. Popkin BM, Kim S, Rusev ER, Du S, Zizza C (2006) Measuring the full economic costs of diet, physical activity and obesity-related chronic diseases. Obes Rev 7:271–293
24. Rodrigues SS, Caraher M, Trichopoulou A, de Almeida MD (2008) Portuguese households' diet quality (adherence to Mediterranean food pattern and compliance with WHO population dietary goals): trends, regional disparities and socioeconomic determinants. Eur J Clin Nutr 11:1263–1272
25. Salas-Salvadó J, Garcia-Arellano A, Estruch R, Marquez-Sandoval F, Corella D, Fiol M, Gómez-Gracia E, Viñoles E, Arós F, Herrera C, Lahoz C, Lapetra J, Perona JS, Muñoz-Aguado D, Martínez-González MA, Ros E (2008) PREDIMED investigators components of the mediterranean-type food pattern and serum inflammatory markers among patients at high risk for cardiovascular disease. Eur J Clin Nutr 62:651–659
26. Sanchez-Villegas A, Martinez JA, De Irala J, Martinez-Gonzalez MA (2002) Determinants of the adherence to an "a priori" defined Mediterranean dietary pattern. Eur J Nutr 41:249–257
27. Serra-Majem L, Roman B, Estruch R (2006) Scientific evidence of interventions using the Mediterranean diet: a systematic review. Nutr Rev 64:S27–S47
28. Steptoe AP, Perkins-Porras L, Rink E, Hilton S, Cappuccio FP (2004) Phychological and social predictors of changes in fruit and vegetable consumption over 12-months following behavioral and nutrition education counselling. Health Psychol 23:574–581
29. Tinker LF, Rosal MC, Young AF, Perri MG, Patterson RE, Van Horn L, Assaf AR, Bowen DJ, Ockene J, Hays J, Wu L (2007) Predictors of dietary change and maintenance in the women's health initiative dietary modification trial. J Am Diet Assoc 107:1155–1166
30. Tuomilehto J, Lindstrom J, Eriksson JG, Valle TT, Hamalainen H, Ilanne-Parikka P, Keinanen-Kiukaanniemi S, Laakso M, Louheranta A, Rastas M, Salminen V, Uusitupa M, Finnish Diabetes Prevention Study Group (2001) Prevention of type 2 diabetes mellitus by changes in lifestyle among subjects with impaired glucose tolerance. N Engl J Med 344:1343–1350
31. Tur JA, Romaguera D, Pons A (2004) Adherence to the Mediterranean dietary pattern among the population of the Balearic Islands. Br J Nutr 92:341–346
32. Willett WC, Howe GR, Kushi LH (1997) Adjustment for total energy intake in epidemiologic studies. Am J Clin Nutr 65:1220S–1228S; discussion 1229S–1231S
33. Willett WC (1998) Issues in analysis and presentation of dietary data. Nutritional epidemiology. Oxford University Press, New York
34. WMA (2004) World Medical Association Declaration of Helsinki, Tokyo
35. Women's Health Initiative Study Group (2004) Dietary adherence in the women's health initiative dietary modification trial. J Am Diet Assoc 104:654–658
36. World Health Organization (2003) Diet, nutrition and the prevention of chronic diseases. World Health Organ Tech Rep Ser 916:i–viii, 1–149, backcover
37. Zazpe I, Sánchez-Taínta A, Estruch R, Lamuela-Raventos R, Schröder H, Salas-Salvadó J, Corella D, Fiol M, Gómez-Gracia E, Aros F, Ros E, Ruíz-Gutierrez V, Iglesias P, Conde-Herrera M, Martínez-González MA (2008) A large randomised individual and group intervention conducted by registered dietitians increased adherence to Mediterranean-type diets: the PREDIMED study. J Am Diet Assoc 108:1134–1144