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Validity of the energy-restricted Mediterranean Diet Adherence Screener

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Data Share Statement:

Data described in the manuscript, code book, and analytic code will be made available upon request pending on application and approval by the steering committee of the PREDIMED-Plus study.

Background: Short dietary assessment tools can be useful to estimate food intake and diet quality in large-scale epidemiological studies with time constraints.

Objective: To determine the concurrent validity of the 17-item energy-restricted Mediterranean Adherence Screener (er-MEDAS) used in the PREDIMED (PREvención con DIeta MEDiterránea)-Plus trial and to analyse its capacity to detect 1-year changes in diet and cardiometabolic risk factors.

Methods: Validation study nested in the PREDIMED-Plus (n=6760, 55 to 75 years). Dietary data were collected by the 17-item er-MEDAS and a 143-item validated semiquantitative food frequency questionnaire (FFQ) at baseline and after 1-year intervention. Cardiometabolic risk markers were measured at both time points. A Mediterranean diet (MedDiet) score was derived from both instruments. Concurrent validity was evaluated by Pearson and intra-class correlation coefficients (ICC) and Bland and Altman limits of agreement. Construct validity was evaluated by assessing 1-year changes in FFQ-reported dietary intake and cardiometabolic profile changes in relation to changes in er-MEDAS.

Results: A moderate to good correlation between the MedDiet score calculated by both measurement instruments was found: r=0.61 and ICC=0.60 (p<0.001, both). Agreement of each of the er-MEDAS items ranged from 55.4% to 85.0% with a moderate mean concordance (kappa=0.41. Between baseline and 1-year follow-up, energy intake measured by the FFQ decreased by 242 kcal, whilst Mediterranean food consumption increased in participants with the highest increase in the er-MEDAS MedDiet score An increase in the er-MEDAS MedDiet score ratings was associated with a decrease in BMI, waist circumference, triglycerides, fasting glucose, diastolic blood pressure, and triglycerides/HDL-cholesterol ratio ($p<0.001$ for all), and with an increase in HDL-cholesterol ($p=0.006$).

Conclusion: The er-MEDAS shows a modest to good concurrent validity compared with FFQ. It shows acceptable construct validity, as a greater er-MEDAS score was associated with more favourable dietary and cardiometabolic profiles over time.

Keywords: validity, validation, short screener, diet

1. Introduction

Obesity is a chronic disease of epidemic proportions with well-recognized detrimental effects on health (1). The prevalence of obese adults has nearly tripled worldwide from 1974 (1). The European Health Interview Survey (EHIS) showed that almost one in six adults in the European Union are obese (2). Therefore, the development of effective obesity intervention programs is one of the most important health policy challenges.

Among the main drivers of the obesity pandemic are unhealthy dietary habits. The Mediterranean diet (MedDiet), an optimal dietary pattern against non-communicable diseases (3,4), is also associated with both physical and mental health (5). In 2004 we showed for the first time that adherence to the MedDiet was inversely associated with body mass index (BMI) and the prevalence of obesity in a cross-sectional study of Spanish adults (6). Numerous observational studies confirmed this finding (7–11) and results from randomized controlled trials (RCTs) have provided promising evidence on the efficacy of the MedDiet for weight loss in adults (12–17). Recent data from the interim analysis of the PREDIMED (PREvención con DIeta MEDiterránea)-Plus trial showed a significant and clinically meaningful reduction of more than a 5% in several anthropometric variables in the intervention group compared to the control group (18). Adequate dietary assessment instruments are needed for monitoring adherence to the MedDiet in intervention studies and for dietary counselling in clinical practice. In large-scale epidemiological studies, adherence to the MedDiet is estimated by a composite score including specific foods characterizing the MedDiet through dietary records, 24-hour recalls, or food frequency questionnaires (FFQ). However, these procedures are time consuming and there is great added value in developing simpler tools to assess dietary intake. For this reason, we developed and validated (19) the Mediterranean Diet Adherence Screener (MEDAS) in the framework of the PREDIMED study (20). The MEDAS consists of 14 questions on food consumption and behaviors in older Spanish adults, with no notion of quantity restriction. The ongoing PREDIMED-Plus study aims to determine the effect of an energy-restricted MedDiet on cardiovascular events in older Spanish adults at high cardiometabolic risk (21). To ensure the monitoring of dietary compliance in the trial, we developed the energy-restricted Mediterranean Diet Adherence Screener (er-MEDAS). This screener is modified from MEDAS and includes 3 additional items. The modifications aimed to capture the dimension of moderation of food consumption, which in turn should lead to energy restriction.

The aim of the present study was to determine the concurrent validity of the er-MEDAS in participants of the PREDIMED-Plus study. Additionally, we aimed to analyse construct validity, i.e., whether an increase in the adherence to the MedDiet measured by the er-MEDAS was associated with favourable dietary and cardiometabolic changes after one year of the PREDIMED-Plus dietary intervention.

2. Methods

2.1 Study design

This validation study was nested in the ongoing PREDIMED-Plus clinical trial. A detailed description of the study protocol has been published (21) and further information can be found at http://predimedplus.com/. Interims results of the PREDIMED-Plus study on the effect of the interventions on cardiometabolic risk factors and inflammation-related variables have also been reported (15,18). In short, PREDIMED-Plus is an on-going, 6-year, multi-centre RCT conducted in Spain to assess the effect of a lifestyle intervention on the primary prevention of cardiovascular diseases (CVD) in at-risk individuals. From October 2013 to December

2016, 6874 participants were recruited in 23 Spanish centers. Participants were randomly assigned in a 1:1 ratio to one of two groups: an intensive weight-loss intervention group based on an energy-restricted MedDiet, individualized promotion of physical activity (PA), and behavioral support or a control group, which included an unrestricted-energy MedDiet and usual health care. This clinical trial was registered at the International Standard Randomized Controlled Trial registry (ISRCTN89898870; registration date, 24 July 2014).

2.2 Study participants

Men aged 55 to 75 years and women aged 60 to 75 years at high risk of CVD were included if they had overweight or obesity (BMI ≥27 and <40 kg/m2) and met at least 3 diagnostic criteria of metabolic syndrome, defined according to the International Diabetes Federation and the American Heart Association and National Heart, Lung and Blood Institute (19).

Of the 6874 participants, 114 were excluded due to missing data on diet and/or educational status. Analysis of relative and absolute validity of the er-MEDAS was performed in the 6760 remaining participants. For the analysis of the construct validity we included i) dietary variables: 5845 participants were included with complete dietary data at baseline and at 1 year of follow-up. ii) cardiometabolic risk factors: 5369, participants were available with complete data on BMI, waist circumference (WC), total cholesterol, HDL-cholesterol, LDL-cholesterol, triglycerides, fasting glucose, and blood pressure at baseline and 1 year of follow-up. Research Ethics Committees of all participating centres approved the study protocol, which was conducted following the standards of the Declaration of Helsinki. All participants provided written informed consent.

2.3 Dietary assessment

Registered dietitians collected data on dietary intake by the er-MEDAS and a validated semi-quantitative 143-item FFQ (20). Both questionnaires were administered at baseline and yearly.

The 17-item er-MEDAS includes 14 items on food consumption and 3 items on eating behaviours. The er-MEDAS is based on the previously validated 14-item MEDAS and was modified as follows:

a) Five items from the original MEDAS were maintained without modification: Do you prefer to eat chicken, turkey or rabbit instead of beef, pork, hamburgers or sausages?; How many servings of vegetables do you consume per day?; How many pieces of fruit (including fresh-squeezed juice) do you consume per day?; How many servings of pulses do you consume per week?; How many servings of fish/seafood do you consume per week?

b) Eight items were modified: "Do you use olive oil as the principal source of fat for cooking?" was changed to "Do you use virgin olive oil as the principal source of fat for cooking?"; "How many servings of butter, margarine, or cream do you consume per day?" was reworded to "How many servings of butter, margarine, or cream do you consume per week?"; "How many servings of red meat, hamburger, or sausages do you consume per day? was modified to "per week"; the text "not homemade" was deleted in "How many times do you consume commercial (not homemade) pastry such as cookies or cake per week?"; the item "How many carbonated and/or sugar-sweetened beverages do you consume per day? was reworded to "How many carbonated and/or sugar-sweetened beverages do you consume per week?; the frequency of consumption was changed from 7 or more cups/week to 7 to 14 cups/day for women and 14 to

21 cups/day for men for the item "Do you drink wine? How much do you consume per week?"

c) Four new items were included: Do you add sugar to your beverages (coffee, tea)?; How many servings of white bread do you consume per day?; How many servings of whole grain bread or whole grain pasta do you consume per week?; How many servings of refined bread, rice and/or pasta do you consume per week?

d) The item "how much olive oil do you consume per day (including that used in frying, salads, meals eaten away from home, etc.)" was deleted from the screener.

Compliance with each of the 17 items was scored with 1 point. Therefore, the total er-MEDAS score range was 0–17, with 0 meaning null adherence and 17 meaning maximum adherence. The item corresponding to sofrito (a sauce made of tomato, onion and garlic slowly simmered in olive oil), item #12 of the er-MEDAS, was not included because this item was not part of the FFQ. The detailed scoring criteria for each item are shown in table 2.

Detailed information about the development, reproducibility, and validity of the 143-item FFQ has been previously reported (20). In brief, for each item, a typical portion size was included, and consumption frequencies were recorded in nine categories that ranged from "never or almost never" to "≥6 times/day". Conversion of food consumption into energy and nutrient intake was performed by using a computer program based on available information in food composition tables.

Food intake data recorded on the FFQ were grouped into the food-based dietary components of the er-MEDAS for analysis. The relative validity of the er-MEDAS was assessed by comparing dietary data derived from the er-MEDAS with the corresponding data collected from the validated full-length FFQ.

2.4 Biological markers

Samples of fasting blood were collected after an overnight fast and biochemical analyses were performed for fasting plasma glucose, total cholesterol, HDL-cholesterol, and triglyceride concentrations in local laboratories using standard enzymatic methods, whereas LDL-cholesterol was calculated by the Friedewald formula when triglycerides were inferior to 400 mg/dL. Blood pressure measurements were obtained by duplicate after the participant had rested for five minutes. Each measurement was obtained with a validated semiautomatic oscillometer (Omron HEM-705CP), ensuring the use of the proper cuff size for each participant. The average of 2 measurements was used for analysis.

2.5 Other variables

Information related to sociodemographic and lifestyle habits, individual and family medical history, smoking status, medical conditions, and medication use was evaluated using self-reported questionnaires.

2.6 Statistical analyses

General linear models were fitted to determine a) baseline association of sociodemographic variables and cardiometabolic risk markers according to quartiles of adherence to the er-MEDAS, and b) construct validity by the association between quartiles of 1-year changes in adherence to the er-MEDAS and changes in FFQ-derived food intake. The linear trend was tested by including quartiles as continuous variables in the models. Polynomial contrasts were used to determine P-linear trends for continuous variables, with a post hoc Bonferroni correction for multiple comparisons. Chi-square tests were used to determine P-linear trends for categorical variables. Additionally, multiple linear regression models were fitted to determine the associations between 1-year changes in adherence to er-MEDAS and corresponding changes in cardiometabolic risk variables.

The relative validity of the er-MEDAS was assessed by calculating Pearson's product–moment correlation coefficients to compare the MedDiet adherence scores derived by the er-MEDAS (test method) and by the FFQ (reference method). Although the two measurements might be strongly correlated, there could be considerable differences across their ranges of values. Therefore, we determined the absolute agreement of categorical variables between the two measurements by cross-classification and kappa statistic. Values of kappa > 0.8 almost signify perfect agreement, between 0.61-0.80 substantial agreement, 0.41-0.60 moderate agreement, 0.21-0.40 fair agreement, and <=0.20 slight agreement (21) .

We further assessed agreement between the scores obtained by er-MEDAS and FFQ using the Bland–Altman method (reference) and the intraclass correlation coefficient (ICC). The Bland–Altman method determines the agreement between two methods by calculating the mean of their differences and regressing it against the average score obtained with the two methods. A mean proportional agreement of 100% between the scores derived by both measurements would signify complete agreement between the methods. A mean difference of 0 would represent complete agreement between the methods. In addition, we analysed possible variations in the level of agreement between methods indicating a proportional bias. For this purpose, we fitted linear regression models, with the mean instrument differences of the MedDiet scores derived by the er-MEDAS and FFQ [er-MEDAS - FFQ)] constituting the dependent variable and the mean score of both [(er-MEDAS + FFQ) / 2)] constituting the independent variable.

Subgroup analyses were performed for sex, age, educational level, and intervention group.

The Statistical Package for the Social Sciences statistical software package version 21.0 (SPSS Inc., Chicago, IL, USA) was used for all analyses. Differences were considered significant if P was <0.05.

3. Results

The baseline sociodemographic characteristics and cardiometabolic risk markers of the participants according to increasing ratings for the er-MEDAS score are shown in **Table 1**. Participants with higher ratings for the er-MEDAS MedDiet score were older and had a lower BMI and waist circumferences, but higher PA levels, and were more likely to be women and non-smokers compared with their lower rating peers. Energy intake and triglycerides were inversely associated with the er-MEDAS whereas the opposite was true for HDL-cholesterol. A lower prevalence of diabetes and hypertension were found for participants with higher ratings of er-MEDAS.

Absolute agreement between the er-MEDAS and FFQ items, measured by cross-classification, ranged from 55.2% for the item “Red and processed meat” to 84.0 % for the item “Butter/margarine/cream” with a mean of 73.8% for all items **(Table 2)**. The degree of agreement was additionally determined with the kappa statistic showing a range from poor (kappa 0.06 for red and processed meat) to good (kappa 0.65 for added sugar) concordance. The mean agreement of all items was moderate (kappa 0.41).

The Pearson coefficient revealed a moderate correlation (0.60, p<0.001) between the scores derived by the er-MEDAS and by the FFQ. Additionally, the intraclass correlation coefficient, an indicator of the degree to which both instruments assigned the same absolute score ratings, showed the same degree of correlation (ICC = 0.60; p<0.001). These findings indicate that the er-MEDAS had a moderate ability to rank participants according to total er-MEDAS MedDiet score ratings.

The mean rating of the MedDiet score was 7.9±2.6 for the er-MEDAS and 7.2±2.4 for the FFQ **(Table 3);** mean difference= 0.70 (95% CI, 0.68-0.78). The er-MEDAS MedDiet score significantly (p<0.001) overestimated by 12% the ratings compared to the corresponding score obtained by the FFQ. Furthermore, this discrepancy slightly but significantly increased [β coefficient 0.127 (95% CI, 0.104-0.151); p<0.001) (**Table 3** and **Figure 1**) with higher score ratings. This proportional bias is unrecognizable in the Bland Altman plot **(Figure 1)** due to the large number of participants in combination with relatively small regression coefficient.

Table 4 shows the association between 1-year change in the er-MEDAS MedDiet score and FFQ-derived energy intake and food consumption. An increase in er-MEDAS score over time was associated with a concomitant decrease in energy intake: participants in the top quartile of changes in the er-MEDAS score showed a daily decrease in 249 kcal. This finding indicates a good construct validity according to the dimension of energy restriction. Additionally, the consumption of traditional Mediterranean foods such as vegetables, fruit, legumes, fish, nuts, whole grain cereals, and olive oil, increased (p<0.001 for all) with increasing ratings of the er-MEDAS score after 1 year. It should be noted that this increase was achieved despite a significant energy reduction (p<0.001). The consumption of non-Mediterranean foods such as meat and refined cereals decreased with increasing ratings of the er-MEDAS score (p<0.001).

Table 5 shows the association between 1-year change in er-MEDAS score and corresponding changes in cardiometabolic risk factors. Changes in the er-MEDAS score were inversely associated with changes in BMI, waist circumference, triglycerides, fasting glucose, and diastolic blood pressure (p<0.001, all), and with increased HDL-cholesterol (p=0.006).

Subgroup analyses were performed to determine the validity of the er-MEDAS by sex, age groups, educational level, and intervention and control groups **(Supplementary table 1).** The ratings for the er-MEDAS PREDIMED-Plus score were higher compared to the corresponding scores derived by the full-length FFQ across all strata. Furthermore, the relative and absolute validity, measured by the Pearson and intraclass correlation coefficients, respectively, showed minimal differences across all strata.

4. Discussion

The rationale for the development of the er-MEDAS was to adequately monitor compliance to an intervention with an energy-restricted MedDiet in the PREDIMED-Plus trial. For this purpose, we substantially modified the original 14-item MEDAS score. In this report we show that a 17-item screener for adherence to an energy-restricted MedDiet (er-MEDAS) disclosed reasonable concurrent validity. Moreover, an increase in the er-MEDAS was associated with favourable 1-year changes in food consumption and the cardiometabolic profile. The er-MEDAS was sensitive to detect a 1-year decrease in energy intake and a concomitant increase in the consumption of characteristic Mediterranean foods. Finally, a favourable change of 6 out of 9 cardiometabolic risk factors was observed with increasing ratings of the PREDIMED Plus-score derived by the er-MEDAS after 1-year of follow up.

Most MedDiet adherence indices are calculated based on data from full length FFQ, 24h recalls or diet records. Individual components of these indices are usually scored based on their median, tertile/quartile population distribution. Therefore, it is not surprising that the resulting composite scores are often positively associated with energy intake if not adjusted for same (22,23). Dietary data from short diet quality screeners do not allow the estimation of energy intake but this can be determined by the administration of other dietary measurement instruments, such as 24-h recalls or a full length FFQ. In the evaluation of the validity of the initial MEDAS, high score ratings were associated with a 123 kcal higher energy intake compared to low adherence in men and no significant differences in women (unpublished data). In other words, the MEDAS can monitor adherence to the *ad libitum* MedDiet but not the energy-restricted variation of this diet. In contrast, we found that baseline energy intake was significantly lower with increasing ratings of the er-MEDAS score, with a difference of 259 kcal between extreme quartiles. In nutritional interventions it is essential that the dietary measurement instrument is sensitive to changes in food consumption. In the present study energy intake decreased and the consumption of typical foods of the Mediterranean diet increased with a concomitant increase of ratings in the er-MEDAS score. Hence, the er-MEDAS has the capacity to detect changes in energy and food consumption in the expected direction. These findings indicate an excellent construct validity of the er-MEDAS. To the best of our knowledge there is no evidence from other validation studies to compare these findings.

An important aspect of the validity of a dietary assessment instrument is the degree of concordance of its food components with the corresponding items of the reference method. The average concordance across 17 items (kappa=0.41) was nearly identical to that found for the 14 items of MEDAS (16). Additionally, kappa values of unmodified questions on dietary consumption and behaviour in the er-MEDAS were similar to those reported in the MEDAS validation study. During dietary monitoring with the er-

MEDAS the question on red and processed meat consumption deserves particular attention because there was essentially no concordance with the reference instrument (kappa = 0.06).

Most dietary assessment validation studies focus on the concurrent validity of food groups and/or nutrients (24,25), and few studies include the validity of a composite score obtained by the questionnaire. Generally, predefined composite scores disclose a moderate to good validity, with a reasonable capacity to rank subjects according to score ratings (16,26–30). The er-MEDAS score showed a higher correlation (r=0.60) than that found for the MEDAS score (r=0.53) (16). A slightly better correlation was reported for the PREDIMED score (ICC = 0.68) of an adapted version of the MEDAS for the Korean population (30). Furthermore, Schroder *et al.* (27) reported a considerable lower concurrent validity (r=0.40) for a modified MedDiet score derived by a short FFQ compared to 12 24-h recalls. Additionally, it deserves to be mentioned that the concurrent validity of the er-MEDAS was similar across groups built by sex, age, educational level, and intervention arm. In general, comparisons of these results are somewhat limited due to the different reference methods used among studies.

We calculated the mean difference between the PREDIMED-Plus score derived by the er-MEDAS and the FFQ to estimate if the er-MEDAS over or underestimated score ratings. The er-MEDAS tends to slightly overestimate these ratings compared to those derived from an FFQ, but this compares favourably with other scores derived from short screeners (27,28,31). Additionally, this overestimation slightly increased with increasing ratings of the er-MEDAS score, which is comparable to findings in other studies (28).

The capacity of a dietary assessment method to correctly detect changes in dietary intake is especially important for the monitoring of nutritional interventions in clinical settings and for dietary counselling. We found that the er-MEDAS score changed after 1 year as a result of the dietary intervention, and that it adequately related to increases in Mediterranean food items and decreases in energy intake. Additionally, the increase in the er-MEDAS score was associated with favourable changes in the cardiometabolic profile of the participants. In a simulation study performed in Spanish adults, Funtikova *et al.* (32) reported similar results for a diet quality score obtained by a short diet quality screener. Each 2-point increase in the MedDiet score derived by the MEDAS score corresponded to a 6 % decrease of CVD events in the PREDIMED trial (33). Future analyses when the PREDIMED-plus trial is completed might reveal the validity of the er-MEDAS to predict hard endpoints such as CVD and cancer.

Our study has some limitations, which are important to mention. The use of an FFQ as the reference method is the major limitation, as it provides biased estimates of true dietary intake (34). Therefore, the correlations provided are not between er-MEDAS in relation to "true" dietary intake, but rather an approximation of it. FFQs have been shown to overestimate "healthy food" items and to underestimate unhealthy foods such as sweetened beverages, snacks, and pastries, therefore they might overestimate overall adherence to a healthy MedDiet. However, it is to be expected that the same "social desirability" bias might apply to answering both an FFQ and the er-MEDAS, so that adherence to a MedDiet may be overestimated with both instruments. There are also strengths to this study, such as the large sample size and the presentation of data on the concurrent, absolute, and construct validity of the er-MEDAS. Furthermore, construct validity was determined with prospective data.

5. Conclusion

In conclusion, the 17-item er-MEDAS questionnaire of adherence to an energy-restricted MedDiet discloses a modest to good concurrent validity and can adequately detect changes in dietary intake over time. Finally, 1-year changes in the er-MEDAS were predictive of concurrent changes in cardiometabolic risk factors.

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Conflict of interest

Dr. Salas-Salvadó reports serving on the board of and receiving grant support through his institution from the International Nut and Dried Fruit Council, and Eroski Foundation. Reports serving in the Executive Committee of the Instituto Danone Spain and on the Scientific Committee of the Danone International Institute. He has received research support from Patrimonio Comunal Olivarero, Spain; and Borges S.A., Spain. Reports receiving consulting fees or travel expenses from Danone; Eroski Foundation, Instituto Danone—Spain, and Abbot Laboratories.

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Figure 1

Bland-Altman plot for the agreement of the er-MEDAS score derived from the er-MEDAS and the food frequency questionnaire (n = 6760).

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Table 1. General characteristics of the study population according to adherence to the energy-reduced Mediterranean Diet Score (er-MEDAS).

	Adherence to the er-MEDAS				
	1st quartile	2nd quartile	3rd quartile	4th quartile	p for trend
n	1629	1813	1752	1566	
er-MEDAS score (unit)	5.0 (1-6)	7.3 (7-8)	9.5 (9-10)	12.1 (11-17)	-
Allocated to intervention group (n, %)	766 (51.1%)	824 (49.9%)	837 (52.5%)	743 (51.7%)	0.437
Women (n, %)	565 (37.7%)	789 (47.8%)	814 (51.0%)	814 (56.7%)	<0.001
Age, years	64.2 (5.1)	65.0 (4.9)	65.2 (4.8)	65.6 (4.8)	<0.001
Education higher than primary (n, %)	794 (53.0%)	817 (49.5%)	813 (51.0%)	736 (51.3%)	0.532
Current smokers (n, %)	268 (17.9%)	252 (15.3%)	207 (13.0%)	164 (11.5%)	<0.001
BMI, kg/m^2	32.7 (3.44)	32.7 (3.53)	32.5 (3.44)	32.1 (3.37)	<0.001
Waist circumference, cm	109 (9.57)	108 (9.92)	107 (9.72)	106 (9.09)	<0.001
Physical activity, MET·min·day	233 (102;432)	242 (120;474)	300 (134;500)	330 (173;550)	<0.001
Energy intake, kcal/day	2570 (663)	2421 (639)	2362 (580)	2311 (585)	<0.001

Hypertension (n, %)	1262 (85.0%)	1378 (84.0%)	1333 (84.0%)	1169 (81.7%)	0.024
Diabetes (n, %)	340 (22.7%)	459 (27.9%)	465 (29.2%)	433 (30.3%)	<0.001
Hypercholesteremia n, (%)	1027 (69.7%)	1130 (68.9%)	1085 (68.3%)	1031 (72.0%)	0.230
Systolic blood pressure, mm/Hg	139 (16.3)	140 (16.7)	139 (17.0)	139 (17.4)	0.992
Diastolic blood pressure, mmHg	80.3 (10.2)	80.9 (10.1)	81.0 (9.65)	81.0 (9.54)	0.080
Fasting glucose, mg/dl	112 (28.0)	114 (29.4)	114 (28.5)	113 (30.4)	0.326
Total cholesterol, mg/dl	197 (38.3)	197 (38.0)	196 (38.0)	197 (36.7)	0.834
HDL-cholesterol, mg/dl	46.6 (11.3)	47.9 (12.3)	48.8 (11.5)	49.2 (12.0)	<0.001
LDL-cholesterol, mg/dl	122 (39.9)	122 (44.6)	121 (43.6)	122 (39.3)	0.982
Triglycerides, mg/dl	160 (78.8)	156 (83.4)	148 (71.9)	144 (71.7)	<0.001
HbA1c (%)	6.08 (0.84)	6.16 (0.90)	6.13 (0.85)	6.07 (0.88)	0.705

Values are presented as means (range for er-MEDAS; SD all others) or median [interquartile range] for continuous variables and n (%) for categorical variables.

BMI: body mass index; er-MEDAS: energy-restricted Mediterranean diet adherence screener (values from 0 to 17 points); HbA1c: glycosylated hemoglobin.

Table 2 Absolute agreement between frequency and habits of dietary food intake as measured with the 17-item energy-reduced Mediterranean diet adherence screener (er-MEDAS) and the 143-item food frequency questionnaire (FFQ).

	Frequency[1]	er-MEDAS[2]	FFQ[3]	Kappa	95%CI[4]	Absolute agreement (%)
1. Do you use olive oil as the principal source of fat for cooking?	Yes	79.2	67.3	0.51	0.49;0.53	80.3
2. How many servings of vegetables do you consume per day? Count garnish and side servings as ½ point; a full serving is 200 grams.	≥ 2	36.9	26.5	0.23	0.21;0.25	66.2
3. How many pieces of fruit (including fresh-squeezed juice) do you consume per day?	≥ 3	46.9	34.1	0.37	0.35;0.39	69.0
4. How many servings of red meat, hamburger, or sausages do you consume per week? A full serving is 100-150 grams.	<= 1	47.3	3.7	0.06	0.05;0.07	55.3
5. How many servings (12 g) of butter, margarine, or cream do you consume per week?	< 1	79.8	75.7	0.55	0.53;0.57	84.2
6. How many carbonated and/or sugar-sweetened beverages do you consume per week?	< 1	74.5	78.2	0.34	0.31;0.37	76.2
7. How many servings (150 g) of pulses do you consume per week?	≥ 3	19.5	21.0	0.38	0.35;0.41	80.0
8. How many servings of fish/seafood do you consume per week? (100-150 g of fish, 4-5 pieces or 200 g of seafood)	≥ 3	46.6	71.2	0.35	0.33;0.37	66.7
9. How many times do you consume pastry such as cookies, cake, or sweets per week?	< 3	58.4	49.9	0.44	0.42;0.46	72.1

10. How many times do you consume nuts per week? (1 serving=30 grams) per week?	≥ 3	40.8	37.3	0.51	0.49;0.53	76.4
11. Do you prefer to eat chicken, turkey or rabbit instead of beef, pork, hamburgers or sausages?	Yes	73.6	59.9	0.37	0.35;0.39	71.5
13. Do you add sugar to your beverages (coffee, tea)?	No	63.6	58.1	0.65	0.63;0.67	83.3
14. How many servings of white bread do you consume per day (1 serving = 75g)?	≤ 1	44.7	68.4	0.40	0.37;0.42	69.0
15. How many servings of whole grain bread/pasta/rice do you consume per week?	≥ 5	27.1	35.4	0.58	0.56;0.60	81.2
16. How many servings of refined bread, rice and/or pasta do you consume per week?	< 3	30.3	21.1	0.39	0.37;0.41	76.3
17. Do you drink wine? How much do you consume per week?	♂ 14-21 cups ♀ 7-14 cups	23.1	11.4	0.47	0.44;0.50	84.6

[1]Criterion to score 1 point. Otherwise, 0 recorded. [2] Percentage of participants scoring 1 on the re-MEDAS. [3] Percentage of participants scoring 1 on the full-length food frequency questionnaire (FFQ). [4] 95 % confidence interval of Kappa; [5] Tablespoon = 13.5g; [6] 1 cup = 100 ml.

The item corresponding to sofrito (a sauce made of tomato, onion and garlic slowly simmered in olive oil), item #12, was not included because this item was not part of the FFQ

Table 3 Correlation coefficients and between-method agreement measurements of the energy-restricted Mediterranean diet adherence score derived by the 17-item er-MEDAS and the reference method (143-item FFQ).

Mean score (SD)	
- According to FFQ	7.2 (2.4)
- According to er-MEDAS	7.9 (2.6)
Difference of means, (95% CI)[1]	0.73 (0.68-0.78)
Ratio of means, %; (95% CI)[2]	117 (116-118)
Regression coefficient[3]	0.127 (0.104-0.151)
Pearson correlation coefficient	0.61
Intraclass correlation coefficient	0.60

[1] calculated as: er-MEDAS – FFQ

[2] calculated as: [er-MEDAS/FFQ] * 100

[3] Regression coefficients (β) between mean of the er-MEDAS and mean differences (independent variable) between the er-MEDAS and the er-MEDAS obtained by the reference method

Table 4. One-year changes in daily energy intake and food consumption derived by the food frequency questionnaire according to quartiles of 1-year changes in the energy restricted Mediterranean adherence score (er-MEDAS)

	1-year changes in the er-MEDAS				
	1st quartile	2nd quartile	3rd quartile	4th quartile	p for trend
n	1629	1813	1752	1566	
Energy (kcal)	-65.1 (17.2)	-94.8 (16.2)	-150.7 (15.5)	-248.9 (13.7)	<0.001
Vegetables (g)	-4.3 (4.5)	24.8 (4.2)	33.3 (4.0)	63.8 (3.6	<0.001
Vegetables (g/1000kcal)	1.1 (2.0)	14.9 (2.0)	23.1 (2.0)	41.0 (2.0)	<0.001
Fruits (g)	6.0 (6.6)	34.8 (6.3)	49.0 (6.0)	76.7 (5.3)	<0.001
Fruits (g/1000kcal)	7.2 (3.0)	21.3 (3.0)	32.2 (2.0)	48.0 (2.0)	<0.001
Legumes (g)	1.1 (0.4)	3.1 (0.4)	4.1 (0.4)	6.7 (0.3)	<0.001
Legumes (g/1000kcal)	0.8 (0.2)	1.8 (0.2)	2.5 (0.2)	3.9 (0.1)	<0.001
Refined cereals (g)	-8.9 (2.6)	-28.7 (2.4)	-46.4 (2.3)	-82.2 (2.1)	<0.001
Refined cereals (g/1000kcal)	-2.6 (0.9)	-10.6 (0.9)	-17.2 (0.8)	-30.5 (0.8)	<0.001
Whole grain cereals	-2.0 (1.2)	13.6 (2.0)	20.6 (1.9)	45.6 (1.7)	<0.001
Whole grain cereals (g/1000kcal)	-0.4 (0.9)	6.4 (0.8)	10.1 (0.8)	21.5 (0.7)	<0.001
Meat (g)	-9.5 (1.7)	-12.4 (1.6)	-17.8 (1.6)	-26.8 (1.4)	<0.001

Meat (g/1000kcal)	-2.8 (0.7)	-3.4 (0.7)	-4.4 (0.6)	-5.1 (0.6)	<0.001
Fish (g)	-3.6 (1.5)	2.7 (1.4)	17.0 (1.3)	20.0 (1.2)	<0.001
Fish (g/1000kcal)	-0.4 (0.7)	2.5 (0.6)	7.7 (0.6)	13.1 (0.5)	<0.001
Nuts (g)	8.6 (0.7)	10.9 (0.6)	15.2 (0.6)	18.3 (0.5)	<0.001
Nuts (g/1000kcal)	4.4 (0.3)	5.3 (0.2)	7.3 (0.2)	8.9 (0.2)	<0.001
Oilve oil (g)	4.5 (0.6)	5.7 (0.5)	5.5 (0.5)	5.6 (0.5)	<0.001
Olive oil (g/1000kcal)	3.5 (0.2)	3.1 (0.2)	3.6 (0.2)	4.1 (0.2)	<0.001

Adjusted for sex, age, and intervention group. Values are expressed in mean and standard error.

Table 5 Multiple adjusted regression coefficients[1] and 95% confidence interval (CI) for the association between 1-year changes in the Mediterranean diet score derived by the energy-restricted Mediterranean diet adherence[2] screener (er-MEDAS) and 1-year changes in cardiovascular risk factors in 5033 participants of the PREDIMED Plus trial.[1]

	Change in risk factor for each 2-point change in the Energy-restricted Mediterranean diet score n=5369		
Dependent variable	Regression coefficient	95% CI	P value
Body mass index[1] (kg/m^2)	**-0.224**	-0.251; -0.198	<0.001
Waist circumference[1] (cm)	**-0.624**	-0.713; -0.536	<0.001
Total cholesterol (mg/dl)	-0.032	-0.856; 0.191	0.213
LDL-cholesterol[3] (mg/dl)	0.146	-0.422; 0.714	0.614
HDL-cholesterol[4] (mg/dl)	**0.186**	0.054; 0.317	0.006
Total cholesterol:HDL-cholesterol ratio	-0.013	-0.028; 0.002	0.085
Triglycerides:HDL-cholesterol ratio	**-0.062**	-0.092; -0.032	<0.001
Triglycerides (mg/dl)	**-2.877**	-3.877; -1.867	<0.001
Fasting blood glucose[3,4] (mg/dl)	**-0.994**	-1.356; -0.631	<0.001
Systolic blood pressure (mm Hg)	0.066	-0.222; 0.354	0.654
Diastolic blood pressure (mm Hg)	**-0.268**	-0.407; -0.129	<0.001

[1] Linear regression analyses adjusted for sex, age, smoking status, leisure-time physical activity, intervention group, educational level, and baseline level of the corresponding cardiovascular risk factor.

[2] Mean change + 3 SD 3.1; maximum changes -7 and + 13

[3] High-density lipoprotein.

[4] Low-density lipoprotein.

Figure

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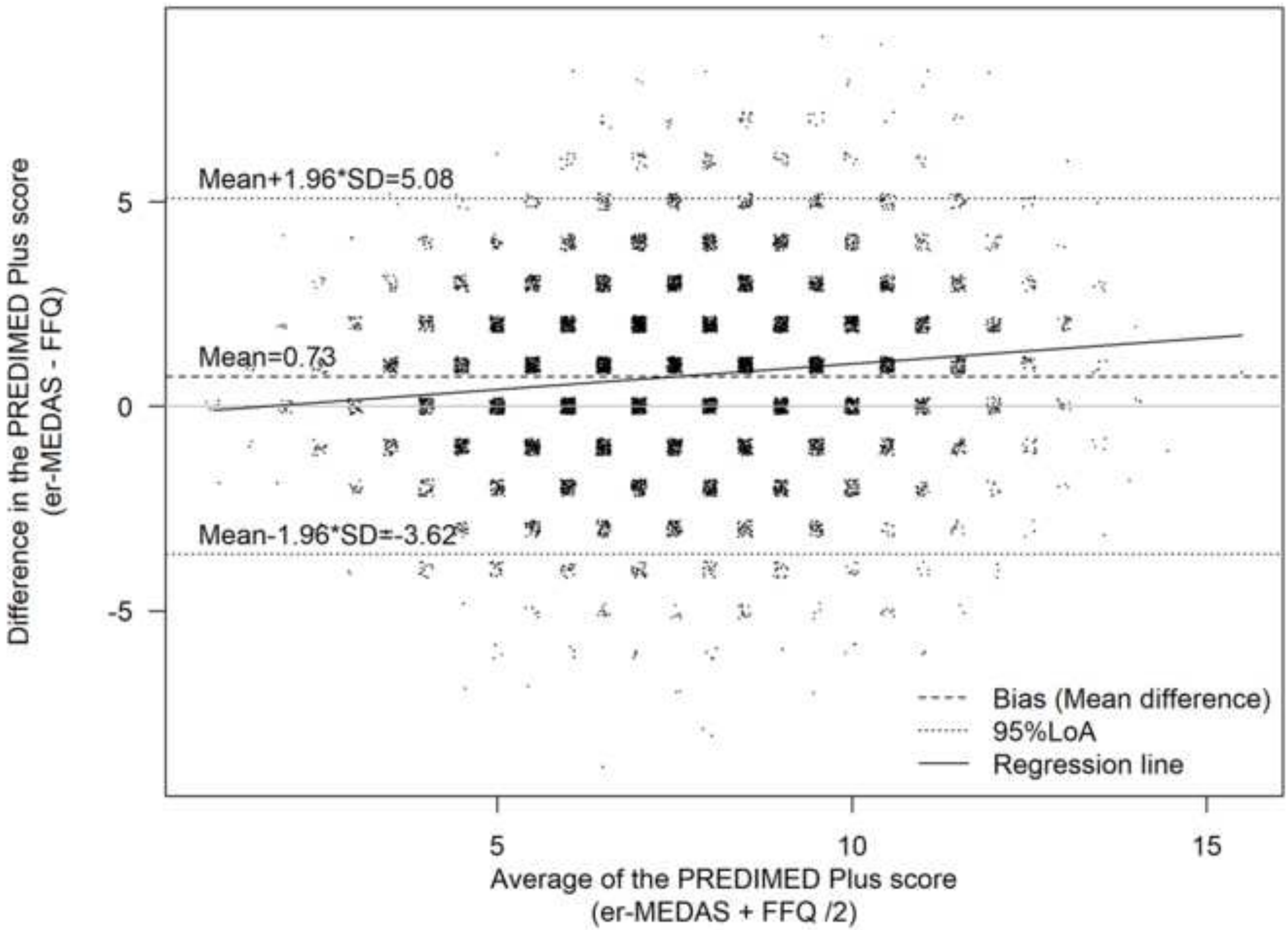

Online Supplemental Material

Supplementary Table 1 Correlation coefficients and between-method agreement measurements of the energy-restricted Mediterranean diet adherence score derived by the 17-item er-MEDAS and the reference method (136-item FFQ) according to sex, age, education, and intervention group.

Sex		
	Men n= 3493	Women n= 3267
Mean (SD)		
- FFQ	6.8 (2.3)	7.6 (2.3)
- Screener er-MEDAS	7.6 (2.6)	8.3 (2.6)
Difference of means, (95% CI)[1]	0.77 (0.70;0.85)	0.68 (0.61;0.76)
Proportions of means, %; (95% CI)[2]	118 (117;120)	115 (113;116)
Regression coefficient (95% CI)[3]	0.134 (0.102;0.167)	0.124 (0.090;0.158)
ICC[4] (er-MEDAS vs FFQ)	0.60	0.59
r[5] (er-MEDAS vs FFQ)	0.60	0.59
Age, years	≤65 n= 3631	>65 n= 3129
Mean (SD)		
- FFQ	7.0 (2.4)	7.4 (2.3)
- Screener er-MEDAS	7.7 (2.6)	8.1 (2.6)
Difference of means, (95% CI)[1]	0.72 (0.64;0.79)	0.74 (0.67;0.82)
Proportions of means , %; (95% CI)[2]	117 (116;119)	116 (114;117)
Regression coefficient (95% CI)[3]	0.121 (0.088;0.153)	0.134 (0.099;0.169)
ICC (er-MEDAS vs FFQ)[4]	0.61	0.60
r (er-MEDAS vs FFQ)[5]	0.60	0.60
Education	Primary n=3289	>Primary n=3471
Mean (SD)		
- FFQ	7.2 (2.3)	7.2 (2.4)
- Screener er-MEDAS	7.9 (2.6)	7.9 (2.6)
Difference of means, (95% CI)[1]	0.71 (0.64;0.79)	0.75 (0.67;0.82)
Proportions of means , %; (95% CI)[2]	116 (115;118)	117 (116;118)
Regression coefficient (95% CI)[3]	0.136 (0.102;0.170)	0.119 (0.086;0.153)

ICC (er-MEDAS vs FFQ)[4]	0.60	0.61
r (er-MEDAS vs FFQ)[5]	0.60	0.61
Intervention group	Control n= 3416	Intervention n= 3344
Mean (SD)		
- FFQ	7.2 (2.4)	7.2 (2.3)
- Screenet er-MEDAS	8.0 (2.6)	7.9 (2.6)
Difference of means, (95% CI)[1]	0.75 (0.68;0.83)	0.71 (0.63;0.79)
Proportions of means‡ , %; (95% CI)[2]	117 (115;118)	117 (115;118)
Regression coefficient (95% CI)[3]	0.130 (0.096;0.164)	0.125 (0.099;0.158)
ICC (er-MEDAS vs FFQ)[4]	0.62	0.59
r (er-MEDAS vs FFQ)[5]	0.62	0.59

[1] calculated as: er-MEDAS – FFQ

[2] calculated as: [er-MEDAS/FFQ] * 100

[3] Regression coefficients (β) between mean (dependent variable) and mean differences (independent variable) of the er-MEDAS score obtained by the test and the reference method

[4] Intraclass correlation coefficient

[5] Pearson correlation coefficient

Supplementary Table 2.

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