Supplementary Online Content

Sayón-Orea C, Razquin C, Bulló M, et al. Effect of a nutritional and behavioral intervention on energy-reduced Mediterranean diet adherence among patients with metabolic syndrome [published October 15, 2019]. *JAMA*. doi:10.1001/jama.2019.14630

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This supplementary material has been provided by the authors to give readers additional information about their work.

Supplemental eTable 1. Definitions of scores capturing the four dietary patterns.

	17-item Energy-reduced Mediterranean Diet (er-MedDiet, 0-17 points)	Mediterranean Diet Score (MDS, 0 to 9 points), Trichopoulou	Mediterranean Diet Adherence Screener (MEDAS, 0-14 points)	Prime Diet Quality Score (PDQS, 0-42 points)
Positively weighted components	Olive oil as main culinary fat ≥ 2 servings/d vegetables ≥ 3 servings/d fruits ≥ 3 servings/wk legumes ≥ 3 servings/wk fish ≥ 3 servings/wk nuts Preference of poultry (chicken, turkey, or rabbit) over red meats (beef, pork, lamb, hamburgers, or sausages) ≥ 2 servings/wk olive oil sauce with tomato, garlic, onion, or leek (sofrito) ≥5 servings/wk of whole grain cereals	MUFA:SFA[a] Vegetables[a] Fruits and nuts[a] Legumes[a] Fish [a] Cereals[a]	Olive oil as main culinary fat ≥ 4 tbs/d olive oil ≥ 2 servings/d vegetables ≥ 3 servings/d fruits ≥ 3 servings/wk legumes ≥ 3 servings/wk fish ≥ 3 servings/wk nuts Preference of poultry (chicken, turkey, or rabbit) > red meats (beef, pork, hamburgers, or sausages) ≥ 2 servings/wk olive oil sauce with tomato, garlic, onion, or leek (sofrito)	Dark leafy green vegetables[c] Cruciferous vegetables[c] Carrots[c] Other vegetables[c] Whole citrus fruits[c] Other whole fruits[c] Legumes[c] Nuts[c] Poultry[c] Fish[c] Eggs[c] Whole grains[c] Liquid vegetable oils[c]
Negatively weighted components	<1 servings/wk red or processed meats <1 servings/wk butter or margarine or cream <1 servings/wk carbonated sugar-sweetened beverages <3 servings/wk commercial bakery, cakes, biscuits, or pastries Avoidance of any added sugar to beverages ≤ 1 serving/d of white bread < 3 servings/wk of refined grain, pasta or white rice	Meat and meat products[b] Dairy products[b]	<1 serving/d red or processed meats <1 serving/d butter or margarine or cream <1 serving/d carbonated sugar-sweetened beverages <2 servings/wk commercial bakery, cakes, biscuits, or pastries	Red meat[d] Potatoes[d] Processed meat[d] Whole fat dairy[d] Refined grains & baked goods[d] Sugar sweetened beverages[d] Fried foods obtained away from home[d] Sugary desserts and ice cream[d]
Alcohol	2-3 glasses/d for men 1-2 glasses/d for women	5-25 g/d (women) 10-50 g/d (men)	≥7 glasses/wk of wine	

[a] One point if the consumption was ≥ the sex specific median
[b] One point if the consumption was ≤ the sex specific median
[c] 0 points if the consumption was between 0–1 serving/wk; 1 point if the consumption was between 2–3 servings/wk and 2 points if the consumption was ≥4 servings/week.
[d] 0 points if the consumption was ≥4 servings/week; 1 point if the consumption was between 2–3 servings/wk and 2 points if the consumption was between 0–1 serving/week.

Supplemental eTable 2. Baseline dietary variables and their changes by randomized treatment group: Foods and foods groups.

	MULTIPLE IMPUTATION: ALL RANDOMIZED PARTICIPANTS			
Food and food groups	**Intervention group**	**Intervention group**	**Between-group difference**	
	N=3,272	**N=3,311**		**p value**
Olive oil (g/week)				
Baseline, median (IQR)	350 (175, 350)	350 (175, 350)		
6-month change	28 (23 to 33)	32 (28 to 37)	-4 (-11 to 2)	0.20
12-month change	36 (31 to 41)	44 (39 to 49)	-8 (-15 to -2)	0.02
Refined olive oil (g/week)				
Baseline, median (IQR)	0 (0, 70)	0 (0, 70)		
6-month change	-38 (-41 to -34)	-34 (-38 to -31)	-3 (-8 to 1)	0.17
12-month change	-39 (-42 to -35)	-39 (-42 to -35)	0 (-5 to 5)	0.93
Extra-virgin olive oil (g/week)				
Baseline, median (IQR)	175 (70, 350)	175 (70, 350)		
6-month change	65 (59 to 70)	66 (61 to 71)	-1 (-9 to 6)	0.71
12-month change	75 (69 to 80)	83 (77 to 88)	-8 (-16 to -1)	0.04
Nuts (g/week)				
Baseline, median (IQR)	60 (28, 165)	60 (14, 165)		
6-month change	120 (114 to 126)	72 (66 to 77)	49 (41 to 57)	<0.001
12-month change	117 (111 to 123)	82 (76 to 87)	35 (27 to 43)	<0.001
Fruits (g/week)				
Baseline, median (IQR)	2,287 (1,523, 3,200)	2,287 (1,494, 3,281)		
6-month change	344 (287 to 401)	158 (104 to 213)	186 (107 to 265)	<0.001
12-month change	430 (370 to 491)	233 (177 to 289)	197 (118 to 276)	<0.001
Vegetables (g/week)				
Baseline, median (IQR)	2,168 (1,621, 2,814)	2,130 (1,596, 2,863)		
6-month change	330 (292 to 368)	142 (106 to 178)	188 (135 to 241)	<0.001
12-month change	347 (306 to 389)	137 (100 to 175)	210 (157 to 263)	<0.001
Cereals (g/week)				
Baseline, median (IQR)	877 (627, 1432)	870 (645, 1432)		
6-month change	-165 (-186 to -143)	-75 (-95 to -55)	-89 (-119 to -60)	<0.001
12-month change	-205 (-227 to -183)	-99 (-120 to -79)	-106 (-135 to -77)	<0.001
Whole grains (g/week)				
Baseline, median (IQR)	109 (0, 525)	98 (0, 525)		
6-month change	274 (254 to 293)	61 (42 to 79)	213 (186 to 240)	<0.001
12-month change	228 (207 to 248)	59 (40 to 78)	169 (142 to 196)	<0.001

Refined grains (g/week)				
Baseline, median (IQR)	779 (425, 1475)	779 (412, 1474)		
6-month change	-538 (-562 to -515)	-192 (-214 to -170)	-346 (-378 to -314)	<0.001
12-month change	-535 (-559 to -510)	-226 (-249 to -203)	-309 (-340 to -277)	<0.001

IQR, Interquartile range, Baseline data are median (IQR)
6-month and 12-month change are means (95% CI) calculated using mixed effect models taking into account site and intra-cluster correlations (couples) as random factors.

Supplemental eTable 2 (cont). Baseline dietary variables and their changes by randomized treatment group. Foods and food groups.

	MULTIPLE IMPUTATION: ALL RANDOMIZED PARTICIPANTS			
Food and food groups	**Intervention group**	**Control group**	**Between-group difference**	
	N=3,272	**N=3,311**		**p value**
Legumes (g/week)				
Baseline, median (IQR)	120 (88, 180)	120 (88, 176)		
6-month change	37 (34 to 41)	17 (14 to 21)	20 (15 to 25)	<0.001
12-month change	39 (36 to 43)	18 (15 to 22)	21 (16 to 26)	<0.001
Fish (g/week)				
Baseline, median (IQR)	673 (472, 918)	682 (475, 918)		
6-month change	101 (88 to 114)	41 (29 to 53)	59 (42 to 77)	<0.001
12-month change	105 (91 to 119)	29 (17 to 42)	75 (58 to 93)	<0.001
Meat (g/week)				
Baseline, median (IQR)	993 (760, 1263)	994 (776, 1271)		
6-month change	-109 (-123 to -95)	-78 (-92 to -65)	-31 (-50 to -11)	0.002
12-month change	-116 (-130 to -101)	-107 (-120 to -93)	-9 (-28 to 10)	0.37
Red meat (g/week)				
Baseline, median (IQR)	290 (150, 497)	300 (150, 520)		
6-month change	-115 (-123 to -106)	-67 (-75 to -59)	-48 (-59 to -36)	<0.001
12-month change	-120 (-129 to -111)	-81 (-89 to -72)	-39 (-51 to -28)	<0.001
Processed meat (g/week)				
Baseline, median (IQR)	227 (143, 317)	227 (143, 322)		
6-month change	-63 (-68 to -57)	-45 (-50 to -39)	-18 (-26 to -10)	<0.001
12-month change	-63 (-69 to -57)	-52 (-57 to -46)	-11 (-19 to -3)	0.007
Pastries (g/week)				
Baseline, median (IQR)	121 (42, 275)	114 (42, 261)		
6-month change	-109 (-116 to -102)	-49 (-56 to -42)	-60 (-69 to -50)	<0.001
12-month change	-109 (-116 to -102)	-60 (-67 to -53)	-49 (-59 to -39)	<0.001
Dairy (g/week)				
Baseline, median (IQR)	2100 (1532, 2959)	2200 (1548, 3597)		
6-month change	16 (-34 to 66)	-137 (-184 to -90)	153 (84 to 222)	<0.001
12-month change	-41 (-95 to 12)	-190 (-239 to -141)	149 (80 to 218)	<0.001
Total yogurt (g/week)				
Baseline, median (IQR)	375 (58, 875)	375 (58, 875)		
6-month change	119 (97 to 141)	9 (-11 to 30)	110 (80 to 140)	<0.001
12-month change	88 (64 to 111)	-4 (-25 to 17)	92 (62 to 122)	<0.001

Fermented dairy (g/week)				
Baseline, median (IQR)	550 (300, 975)	575 (300, 1025)		
6-month change	97 (74 to 120)	-5 (-27 to 16)	102 (71 to 134)	<0.001
12-month change	72 (47 to 96)	-16 (-38 to 7)	87 (56 to 119)	<0.001

IQR, Interquartile range. Baseline data are median (IQR)
6-month and 12-month change are means (95% CI) calculated using mixed effect models taking into account site and intra-cluster correlations (couples) as random factors.

Supplemental eTable 2 (cont). Baseline dietary variables and their changes by randomized treatment group. Foods and food groups.

	MULTIPLE IMPUTATION: ALL RANDOMIZED PARTICIPANTS			
Food and food groups	**Intervention group**	**Control group**	**Between-group difference**	
	N=3,272	**N=3,311**		**p value**
Low-fat dairy (g/week)				
Baseline, median (IQR)	658 (0, 1,775)	687 (0, 1,775)		
6-month change	326 (279 to 373)	68 (23 to 113)	258 (193 to 323)	<0.001
12-month change	267 (217 to 318)	-4 (-50 to 42)	271 (206 to 336)	<0.001
Whole-fat dairy (g/week)				
Baseline, median (IQR)	0 (0, 375)	0 (0, 375)		
6-month change	-174 (-196 to -151)	-110 (-132 to -88)	-63 (-95 to -32)	<0.001
12-month change	-160 (-184 to -135)	-101 (-123 to -78)	-59 (-91 to -27)	<0.001
Total alcohol intake (g/week)				
Baseline, median (IQR)	32 (5, 98)	36 (5, 103)		
6-month change	-13 (-16 to -10)	-6 (-9 to -3)	-7 (-11 to -3)	0.001
12-month change	-12 (-15 to -9)	-4 (-7 to -1)	-8 (-12 to -3)	<0.001
Red wine (g/week)				
Baseline, median (IQR)	33 (0, 29)	4 (0, 29)		
6-month change	1 (-1 to 3)	2 (0 to 4)	-1 (-4 to 1)	0.36
12-month change	2 (0 to 4)	3 (1 to 5)	-1 (-4 to 1)	0.37

IQR, Interquartile range
Baseline data are median (IQR)
6-month and 12-month change are means (95% CI) calculated using mixed effect models taking into account site and intra-cluster correlations (couples) as random factors.

Supplemental eTable 3. Sensitivity analysis. Baseline, 6-month and 12-month changes in quality dietary scores by randomized treatment group: completers only.

	COMPLETERS ONLY			
Variable	**Intervention group**	**Control group**	**Between-group difference**	
	n=2,862 (6 mo) n=2,833 (12 mo)	**n=2,883 (6 mo) n=2,943 (12 mo)**		**p value**
17-item er-MedDiet (0 to 17)*				
Baseline, mean (SD)	8.5 (2.6)	8.6 (2.7)		
6-month change	4.1 (4.0 to 4.2)	1.8 (1.7 to 1.9)	2.3 (2.2 to 2.5)	<0.001
12-month change	4.3 (4.2 to 4.4)	2.0 (1.9 to 2.1)	2.3 (2.1 to 2.4)	<0.001
MDS (Trichopolou 0 to 9)				
Baseline, mean (SD)	4.3 (1.7)	4.3 (1.6)		
6-month change	0.2 (0.1 to 0.2)	-0.3 (-0.4 to -0.3)	0.5 (0.4 to 0.6)	<0.001
12-month change	0.2 (0.1 to 0.2)	-0.3 (-0.4 to -0.3)	0.5 (0.4 to 0.6)	<0.001
MEDAS (0 to 14)				
Baseline, mean (SD)	7.6 (1.9)	7.6 (1.9)		
6-month change	2.5 (2.5 to 2.6)	1.4 (1.3 to 1.5)	1.1 (1.0 to 1.3)	<0.001
12-month change	2.7 (2.7 to 2.8)	1.6 (1.6 to 1.7)	1.1 (1.0 to 1.2)	<0.001
PDQS (0 to 42)				
Baseline, mean (SD)	21.0 (3.7)	21.0 (3.7)		
6-month change	4.6 (4.5 to 4.8)	2.3 (2.1 to 2.4)	2.4 (2.2 to 2.6)	<0.001
12-month change	4.7 (4.5 to 4.8)	2.4 (2.3 to 2.5)	2.3 (2.1 to 2.5)	<0.001

Baseline data are means (SD). 6-month and 12-month change are means (95% CI) calculated using mixed effect models incorporating site and intra-cluster correlations (couples) as random factors.
er-MedDiet, Energy reduced Mediterranean Diet; MDS, Mediterranean Diet Score, MEDAS, Mediterranean Diet Adherence Screener; PDQS, Prime Diet Quality Score. The direction of all 4 food patterns is the same: a higher score means a higher quality of the overall dietary pattern. The possible ranges were 0-17 for er-MedDiet, 0-9 for the MDS, 0-14 for MEDAS, and 0-42 for PDQS.

The minimum ***clinically important difference (MCID***) can be considered ***1 point for the MDS***, because a 2 point increment (roughly corresponding to one standard deviation) was associated in the fully adjusted model with a 25% relative reduction in all-cause mortality (Trichopoulou et al. N Engl J Med 2003;348:2599-608, Table 4), coefficient = log(0.75) = -0.2877. Therefore, 1 point in the MDS (corresponding to 0.5 SD) will lead to a 13% relative risk reduction corresponding to a hazard ratio of 0.87, namely exp(-0.2877/2) = 0.87, which can be considered higher than a minimal clinically significant effect from the subjective point of view of a patient.

For the MEDAS, in the PREDIMED trial, assessed as an observational study, and controlling for potential confounding, 1-point increment was associated with a 10% reduction in the risk of the composite primary cardiovascular end-point (multivariable-adjusted hazard ratio= 0.90, 95% CI, 0.85-0.96) and with a 6% reduction in total mortality (multivariable-adjusted hazard ratio= 0.94, 95% CI, 0.89-0.99) (unpublished data). Therefore, 1 point should represent a sufficiently important difference for an individual patient.

The 17-item er-MedDiet score basically captures the 14-items of MEDAS with some additions (sufficiently explained in our main manuscript) that have been repeatedly associated with benefits in previous observational studies with good control for confounding. Therefore, a 1-point difference can be also accepted as a minimum clinically important difference.

For the PDQS (range 0 to 42, SD=3.7), the minimum clinically important difference will represent probably a 2-point increment, given its wider range**.**

*The number of participants included in this analysis was: for the intervention group at 6 months n=3,030 and at 12 months n=2,971 and for the control group at 6 months n=3,090 and at 12 months n=3,095

Supplemental eTable 4. Sensitivity analysis. Baseline, 6-month and 12-month changes in food items by randomized treatment group: completers only.

	COMPLETERS ONLY			
Variable	**Intervention group**	**Control group**	**Between-group difference**	
	n=2,862 (6 mo) n=2,833 (12 mo)	**n=2,883 (6 mo) n=2,943 (12 mo)**		**p value**
Total olive oil (g/week)				
Baseline, mean (SD)	350 (175, 350)	350 (175, 350)		
6-month change	26 (22 to 31)	29 (25 to 34)	-3 (-10 to 3)	0.34
12-month change	34 (30 to 39)	42 (38 to 47)	-8 (-15 to -1)	0.02
Refined olive oil (g/week)				
Baseline, median (IQR)	0 (0, 70)	0 (0, 70)		
6-month change	-37 (-41 to -33)	-34 (-38 to -31)	-3 (-8 to 3)	0.32
12-month change	-39 (-43 to -35)	-39 (-43 to -35)	0 (-6 to 5)	0.95
Extra virgin olive oil (g/week)				
Baseline, median (IQR)	175 (70, 350)	175 (70, 350)		
6-month change	63 (57 to 68)	63 (58 to 69)	0 (-8 to 7)	0.90
12-month change	73 (68 to 79)	81 (76 to 87)	-8 (-16 to 0)	0.05
Nuts (g/week)				
Baseline, median (IQR)	60 (28, 165)	60 (14, 165)		
6-month change	120 (115 to 126)	71 (65 to 76)	50 (42 to 57)	<0.001
12-month change	117 (111 to 123)	82 (77 to 88)	35 (27 to 43)	<0.001
Fruits (g/week)				
Baseline, median (IQR)	2287 (1523, 3200)	2287 (1494, 3281)		
6-month change	349 (292 to 406)	165 (108 to 222)	184 (104 to 265)	<0.001
12-month change	435 (379 to 491)	244 (188 to 299)	192 (113 to 270)	<0.001
Vegetables (g/week)				
Baseline, median (IQR)	2173 (1640, 2811)	2135 (1607, 2886)		
6-month change	330 (291 to 368)	136 (98 to 174)	193 (139 to 247)	<0.001
12-month change	350 (311 to 388)	141 (103 to 179)	209 (155 to 263)	<0.001
Cereals (g/week)				
Baseline, median (IQR)	885 (641, 1432)	877 (645, 1432)		

6-month change	-172 (-194 to -151)	-80 (-102 to -59)	-92 (-122 to -61)	<0.001
12-month change	-212 (-233 to -190)	-106 (-127 to -84)	-106 (-136 to -75)	<0.001

IQR, Interquartile range
Baseline data are median (IQR)
6-month and 12-month change are means (95% CI) calculated using mixed effect models taking into account site and intra-cluster correlations (couples) as random factors.

Supplemental eTable 4 cont. Sensitivity analysis. Baseline, 6-month and 12-month changes in food items by randomized treatment group: completers only.

	COMPLETERS ONLY			
Variable	**Intervention group**	**Control group**	**Between-group difference**	
	n=2,862 (6 mo) n=2,833 (12 mo)	**n=2,883 (6 mo) n=2,943 (12 mo)**		**p value**
Whole grains (g/week)				
Baseline, median (IQR)	109 (0, 525)	98 (0, 525)		
6-month change	277 (257 to 296)	61 (42 to 81)	215 (188 to 242)	<0.001
12-month change	231 (211 to 250)	61 (42 to 80)	170 (143 to 197)	<0.001
Refined grains (g/week)				
Baseline, median (IQR)	779 (425, 1475)	779 (412, 1474)		
6-month change	-544 (-568 to -519)	-198 (-222 to -174)	-346 (-380 to -311)	<0.001
12-month change	-539 (-563 to -514)	-227 (-252 to -203)	-311 (-346 to -277)	<0.001
Legumes (g/week)				
Baseline, median (IQR)	120 (88, 180)	120 (88, 176)		
6-month change	38 (35 to 42)	18 (14 to 21)	20 (16 to 25)	<0.001
12-month change	40 (37 to 43)	19 (16 to 23)	21 (16 to 25)	<0.001
Fish (g/week)				
Baseline, median (IQR)	673 (472, 918)	682 (475, 918)		
6-month change	101 (88 to 113)	40 (28 to 53)	60 (43 to 78)	<0.001
12-month change	104 (91 to 117)	31 (18 to 44)	73 (55 to 91)	<0.001
Meat (g/week)				
Baseline, median (IQR)	993 (760, 1263)	994 (776, 1271)		
6-month change	-110 (-123 to -96)	-81 (-94 to -67)	-29 (-48 to -10)	0.003
12-month change	-118 (-133 to -104)	-107 (-121 to -93)	-11 (-31 to 9)	0.27
Red meat (g/week)				
Baseline, median (IQR)	290 (150, 497)	300 (150, 520)		
6-month change	-114 (-122 to -106)	-67 (-75 to -59)	-47 (-59 to -35)	<0.001
12-month change	-120 (-129 to -112)	-80 (-89 to -71)	-40 (-53 to -28)	<0.001
Processed meat (g/week)				

Baseline, median (IQR)	227 (143, 317)	227 (143, 322)		
6-month change	-63 (-69 to -57)	-45 (-51 to -39)	-18 (-26 to -9)	<0.001
12-month change	-64 (-70 to -58)	-52 (-58 to -46)	-11 (-20 to -3)	0.01
Pastries (g/week)				
Baseline, median (IQR)	121 (42, 275)	114 (42, 261)		
6-month change	-109 (-116 to -101)	-49 (-57 to -42)	-59 (-70 to -49)	<0.001
12-month change	-109 (-116 to -101)	-60 (-67 to -52)	-49 (-60 to -39)	<0.001

IQR, Interquartile range
Baseline data are median (IQR)
6-month and 12-month change are means (95% CI) calculated using mixed effect models taking into account site and intra-cluster correlations (couples) as random factors.

Supplemental eTable 4 cont. Sensitivity analysis. Baseline and 6- and 12- month changes in food items by randomized treatment group: completers only.

	COMPLETERS ONLY			
Variable	**Intervention group**	**Control group**	**Between-group difference**	
	n=2,862 (6 mo) n=2,833 (12 mo)	**n=2,883 (6 mo) n=2,943 (12 mo)**		**p value**
Dairy (g/week)				
Baseline, median (IQR)	2,100 (1,532, 2,959)	2,200 (1,548, 3,597)		
6-month change	17 (-33 to 67)	-143 (-192 to -93)	159 (89 to 230)	<0.001
12-month change	-39 (-88 to 11)	-186 (-235 to -137)	148 (78 to 218)	<0.001
Total yogurt (g/week)				
Baseline, median (IQR)	375 (58, 875)	375 (58, 875)		
6-month change	119 (98 to 140)	6 (-15 to 27)	113 (83 to 143)	<0.001
12-month change	87 (66 to 109)	-4 (-25 to 17)	91 (61 to 121)	<0.001
Fermented dairy (g/week)				
Baseline, median (IQR)	550 (300, 975)	575 (300, 1,025)		
6-month change	97 (75 to 119)	-9 (-31 to 14)	105 (74 to 137)	<0.001
12-month change	72 (49 to 94)	-15 (-37 to 7)	86 (55 to 118)	<0.001
Low-fat dairy (g/week)				
Baseline, median (IQR)	658 (0, 1,775)	687 (0, 1,775)		
6-month change	327 (280 to 373)	62 (15 to 108)	265 (199 to 331)	<0.001
12-month change	270 (223 to 317)	-1 (-47 to 45)	271 (206 to 337)	<0.001
Whole-fat dairy (g/week)				
Baseline, median (IQR)	0 (0, 375)	0 (0, 375)		
6-month change	-173 (-197 to -149)	-111 (-135 to -87)	-61 (-95 to -27)	0.001
12-month change	-159 (-183 to -134)	-99 (-124 to -75)	-59 (-94 to -25)	0.001
Total alcohol intake (g/week)				
Baseline, median (IQR)	32 (5, 98)	36 (5, 103)		

6-month change	-13 (-16 to -10)	-6 (-9 to -3)	-7 (-11 to -3)	<0.001
12-month change	-12 (-15 to -9)	-4 (-7 to -1)	-8 (-12 to -3)	<0.001
Red wine (g/week)				
Baseline, median (IQR)	4 (0, 29)	4 (0, 29)		
6-month change	1 (-1 to 3)	2 (0 to 4)	-1 (-4 to 2)	0.38
12-month change	2 (0 to 4)	3 (1 to 5)	-1 (-4 to 2)	0.40

IQR, Interquartile range
Baseline data are median (IQR)
6-month and 12-month change are means (95% CI) calculated using mixed effect models taking into account site and intra-cluster correlations (couples) as random factors.

Supplemental eTable 5. Sensitivity analysis. Baseline values, 6-month and 12-month changes in nutrient intake by randomized treatment group: completers only.

	COMPLETERS ONLY			
Variable	**Intervention group**	**Control group**	**Between-group difference**	
	n=2,862 (6 mo) n=2,833 (12 mo)	**n=2,883 (6 mo) n=2,943 (12 mo)**		**p value**
Total energy Intake (kcal/d)				
Baseline, mean (SD)	2,355 (544)	2,369 (555)		
6-month change	-173 (-192 to -154)	-78 (-97 to -59)	-95 (-122 to -68)	<0.001
12-month change	-176 (-196 to -157)	-74(-93to -54)	-103 (-130to -75)	<0.001
Total protein (%E)				
Baseline, mean (SD)	16.8 (2.8)	16.8 (2.8)		
6-month change	1.2 (1.1 to 1.3)	0.2 (0.1 to 0.3)	1.0 (0.9 to 1.2)	<0.001
12-month change	1.1 (1.0 to 1.2)	0 (-.1 to .1)	1.1 (1.0 to 1.2)	<0.001
Total carbohydrate (%E)				
Baseline, mean (SD)	40.7 (6.8)	40.4 (6.9)		
6-month change	-3.3 (-3.6 to -3.1)	-1.8 (-2.1 to -1.6)	-1.5 (-1.9 to -1.2)	<0.001
12-month change	-3.7 (-3.9 to -3.4)	-2.3 (-2.5 to -2.0)	-1.4 (-1.8 to -1.1)	<0.001
Total fat (%E)				
Baseline, mean (SD)	39.5 (6.6)	39.7 (6.5)		
6-month change	2.5 (2.2 to 2.7)	1.8 (1.5 to 2.0)	0.7 (0.3 to 1.0)	<0.001
12-month change	2.9 (2.6 to 3.1)	2.3 (2.1 to 2.6)	0.5 (0.2 to 0.9)	0.004
SFA (%E)				
Baseline, mean (SD)	9.9 (2.0)	10.0 (2.0)		
6-month change	-1.0 (-1.1 to -0.9)	-0.6 (-0.6 to -0.5)	-0.4 (-0.6 to -0.3)	<0.001
12-month change	-0.9 (-1.0 to -0.9)	-0.6 (-0.7 to -0.5)	-0.4 (-0.5 to -0.3)	<0.001
MUFA (%E)				
Baseline, mean (SD)	20.5 (4.7)	20.6 (4.6)		
6-month change	3.5 (3.3 to 3.7)	2.3 (2.1 to 2.5)	1.2 (0.9 to 1.4)	<0.001
12-month change	3.9 (3.7 to 4.1)	3.0 (2.8 to 3.2)	0.9 (0.6 to 1.2)	<0.001

Baseline data are means (SD)
E, energy; SFA, saturated fatty acids; MUFA, monounsaturated fatty acids
6-month and 12-month change are means (95% CI) calculated using mixed effect models taking into account site and intra-cluster correlations (couples) as random factors.

Supplemental eTable 5 cont. Sensitivity analysis. Baseline values, 6-month and 12-month changes in nutrient intake by randomized treatment group: completers only.

	COMPLETERS ONLY			
Variable	**Intervention group**	**Control group**	**Between-group difference**	
	n=2,862 (6 mo) n=2,833 (12 mo)	**n=2,883 (6 mo) n=2,943 (12 mo)**		**p value**
Ratio MUFA:SFA				
Baseline, mean (SD)	2.1 (0.5)	2.1 (0.5)		
6-month change	0.6 (0.6 to 0.7)	0.4 (0.4 to 0.4)	0.3 (0.2 to 0.3)	<0.001
12-month change	0.7 (0.6 to 0.7)	0.5 (0.4 to 0.5)	0.2 (0.2 to 0.2)	<0.001
PUFA (%E)				
Baseline, mean (SD)	6.4 (1.9)	6.4 (1.8)		
6-month change	1.3 (1.2 to 1.4)	0.8 (0.7 to 0.8)	0.5 (0.4 to 0.6)	<0.001
12-month change	1.3 (1.2 to 1.3)	0.8 (0.8 to 0.9)	0.4 (0.3 to 0.5)	<0.001
Total alcohol (%E)				
Baseline, median (IQR)	1 (0, 4)	2 (0, 4)		
6-month change	-0.3 (-0.4 to -0.2)	-0.1 (-0.2 to 0)	-0.2 (-0.4 to 0)	0.02
12-month change	-0.3 (-0.4 to -0.1)	0 (-0.1 to 0.1)	-0.3 (-0.4 to -0.1)	0.01
Fiber (g/week)				
Baseline, mean (SD)	184 (63)	182 (60)		
6-month change	40 (37 to 42)	16 (14 to 19)	24 (20 to 27)	<0.001
12-month change	37 (35 to 40)	18 (16 to 21)	19 (16 to 22)	<0.001
Long chain w-3 fatty acids (g/week)				
Baseline, median (IQR)	5 (4, 9)	5 (4, 9)		
6-month change	1.1 (0.9 to 1.2)	0.4 (0.3 to 0.6)	0.7 (0.5 to 0.8)	<0.001
12-month change	1.1 (1.0 to 1.2)	0.4 (0.3 to 0.6)	0.7 (0.5 to 0.9)	<0.001
Cholesterol (mg/week)				
Baseline, mean (SD)	2,651 (793)	2,682 (794)		
6-month change	-222 (-250 to -194)	-169 (-197 to -141)	-53 (-93 to -13)	0.009
12-month change	-218 (-247 to -189)	-206 (-235 to -178)	-12 (-52 to 29)	0.58
Sodium (g/week)				
Baseline, median (IQR)	22.2 (17.9, 27.1)	22.2 (17.9, 27.4)		
6-month change	-3.1 (-3.3 to -2.8)	-1.9 (-2.1 to -1.6)	-1.2 (-1.5 to -0.9)	<0.001
12-month change	-3.2 (-3.5 to -3.0)	-1.9 (-2.1 to -1.6)	-1.3 (-1.7 to -1.0)	<0.001

Baseline data are means (SD) or median (IQR)
E, energy; SFA, saturated fatty acids; MUFA, monounsaturated fatty acids; PUFA, polyunsaturated fatty acids;
w-3, omega-3
6-month and 12-month change are means (95% CI) calculated using mixed effect models taking into account site and intra-cluster correlations (couples) as random factors.

Supplemental eTable 6. Sensitivity analysis. Baseline and 6- and 12- month changes in quality dietary scores by randomized treatment group: All randomized participants. Replacing all missing values with baseline value.

REPLACING ALL MISSING VALUES WITH BASELINE VALUE				
Variable	**Intervention group**	**Control group**	**Between-group difference**	
	n=3,272	**n=3,311**		**p value**
17-item er-MedDiet (0 to 17)				
Baseline, mean (SD)	8.5 (2.6)	8.6 (2.7)		
6-month change	3.8 (3.7 to 3.9)	1.7 (1.6 to 1.8)	2.1 (2 to 2.3)	<0.001
12-month change	3.9 (3.8 to 4.0)	1.9 (1.8 to 2.0)	2.0 (1.9 to 2.2)	<0.001
MDS (Trichopolou 0 to 9)				
Baseline, mean (SD)	4.3 (1.7)	4.3 (1.6)		
6-month change	0.1 (0.1 to 0.2)	-0.3 (-0.4 to -0.2)	0.4 (0.3 to 0.5)	<0.001
12-month change	0.1 (0.1 to 0.2)	-0.3 (-0.4 to -0.3)	0.4 (0.4 to 0.5)	<0.001
MEDAS (0 to 14)				
Baseline, mean (SD)	7.6 (1.9)	7.6 (1.9)		
6-month change	2.3 (2.2 to 2.3)	1.3 (1.2 to 1.3)	1.0 (0.9 to 1.1)	<0.001
12-month change	2.4 (2.3 to 2.5)	1.5 (1.4 to 1.6)	0.9 (0.8 to 1.0)	<0.001
PDQS (0 to 42)				
Baseline, mean (SD)	21.0 (3.7)	21.0 (3.7)		
6-month change	4.0 (3.9 to 4.2)	2.0 (1.8 to 2.1)	2.1 (1.9 to 2.3)	<0.001
12-month change	4.0 (3.9 to 4.2)	2.1 (2.0 to 2.3)	1.9 (1.7 to 2.1)	<0.001

Baseline data are means (SD)
6-month and 12-month change are means (95% CI) calculated using mixed effect models taking into account site and intra-cluster correlations (couples) as random factors.
er-MedDiet, Energy reduced Mediterranean Diet; MDS, Mediterranean Diet Score, MEDAS, Mediterranean Diet Adherence Screener; PDQS, Prime Diet Quality Score

Supplemental eTable 7. Sensitivity analysis. Baseline values, 6-month and 12-month changes in food items by randomized treatment group: all randomized participants. Replacing all missing values with baseline value.

REPLACING ALL MISSING VALUES WITH BASELINE VALUE				
Variable	**Intervention group**	**Control group**	**Between-group difference**	
	n=3,272	**n=3,311**		**p value**
Olive oil (g/week)				
Baseline, median (IQR)	350 (175, 350)	350 (175, 350)		
6-month change	23 (18 to 27)	26 (22 to 30)	-3 (-9 to 3)	0.27
12-month change	30 (26 to 34)	38 (34 to 42)	-7 (-13 to -2)	0.01
Refined olive oil (g/week)				
Baseline, median (IQR)	0 (0, 70)	0 (0, 70)		
6-month change	-32 (-35 to -29)	-31 (-34 to -28)	-1 (-5 to 4)	0.72
12-month change	-33 (-36 to -29)	-35 (-38 to -32)	3 (-2 to 7)	0.26
EVOO (g/week)				
Baseline, median (IQR)	175 (70, 350)	175 (70, 350)		
6-month change	54 (49 to 59)	56 (51 to 61)	-3 (-9 to 4)	0.47
12-month change	63 (58 to 68)	73 (68 to 78)	-10 (-17 to -3)	0.004
Nuts (g/week)				
Baseline, median (IQR)	60 (28, 165)	60 (14, 165)		
6-month change	105 (100 to 110)	61 (56 to 67)	43 (36 to 51)	<0.001
12-month change	100 (95 to 106)	73 (68 to 78)	28 (20 to 35)	<0.001
Fruits (g/week)				
Baseline, median (IQR)	2,287 (1,523, 3,200)	2,287 (1,494, 3,281)		
6-month change	306 (256 to 356)	144 (94 to 193)	162 (92 to 233)	<0.001
12-month change	369 (319 to 419)	215 (166 to 265)	154 (83 to 224)	<0.001
Vegetables (g/week)				
Baseline, median (IQR)	2,168 (1,621, 2,814)	2,130 (1,596, 2,863)		
6-month change	287 (254 to 321)	116 (83 to 149)	171 (124 to 218)	<0.001
12-month change	295 (261 to 328)	126 (93 to 159)	169 (121 to 216)	<0.001
Cereals (g/week)				
Baseline, median (IQR)	877 (627, 1,432)	870 (645, 1,432)		
6-month change	-152 (-170 to -133)	-70 (-89 to -51)	-82 (-108 to -55)	<0.001
12-month change	-183 (-202 to -165)	-87 (-106 to -68)	-96 (-123 to -70)	<0.001

IQR, Interquartile range
Baseline data are median (IQR)
6-month and 12-month change are means (95% CI) calculated using mixed effect models taking into account site and intra-cluster correlations (couples) as random factors.

Supplemental eTable 7 cont. Sensitivity analysis. Baseline, 6-month and 12-month changes in food items by randomized treatment group: all randomized participants. Replacing all missing values with baseline value.

REPLACING ALL MISSING VALUES WITH BASELINE VALUE				
Variable	**Intervention group**	**Control group**	**Between-group difference**	
	n=3,272	**n=3,311**		**p value**
Whole grains (g/week)				
Baseline, median (IQR)	109 (0, 525)	98 (0, 525)		
6-month change	238 (221 to 255)	54 (37 to 70)	184 (160 to 208)	<0.001
12-month change	197 (180 to 214)	56 (39 to 73)	141 (117 to 165)	<0.001
Refined grains (g/week)				
Baseline, median (IQR)	779 (425, 1,475)	779 (412, 1,474)		
6-month change	-475 (-496 to -454)	-172 (-193 to -152)	-303 (-332 to -273)	<0.001
12-month change	-467 (-488 to -446)	-203 (-224 to -182)	-264 (-294 to -235)	<0.001
Legumes (g/week)				
Baseline, median (IQR)	120 (88, 180)	120 (88, 176)		
6-month change	33 (30 to 36)	14 (11 to 17)	19 (15 to 23)	<0.001
12-month change	35 (32 to 38)	17 (14 to 20)	17 (13 to 22)	<0.001
Fish (g/week)				
Baseline, median (IQR)	673 (472, 918)	682 (475, 918)		
6-month change	90 (79 to 101)	35 (23 to 46)	55 (40 to 71)	<0.001
12-month change	90 (79 to 102)	27 (16 to 38)	63 (47 to 79)	<0.001
Meat (g/week)				
Baseline, median (IQR)	993 (760, 1,263)	994 (776, 1,271)		
6-month change	-95 (-107 to -83)	-70 (-82 to -58)	-25 (-42 to -8)	0.01
12-month change	-104 (-116 to -92)	-95 (-107 to -83)	-9 (-26 to 8)	0.31
Red meat (g/week)				
Baseline, median (IQR)	290 (150, 497)	300 (150, 520)		
6-month change	-99 (-106 to -92)	-59 (-66 to -51)	-40 (-51 to -30)	<0.001
12-month change	-104 (-112 to -97)	-71 (-79 to -64)	-33 (-43 to -22)	<0.001
Processed meat (g/week)				
Baseline, median (IQR)	227 (143, 317)	227 (143, 322)		
6-month change	-55 (-60 to -50)	-38 (-43 to -33)	-17 (-24 to -10)	<0.001
12-month change	-55 (-60 to -50)	-47 (-52 to -42)	-9 (-16 to -1)	0.02
Pastries (g/week)				
Baseline, median (IQR)	121 (42, 275)	114 (42, 261)		
6-month change	-94 (-100 to -88)	-42 (-48 to -36)	-52 (-61 to -43)	<0.001
12-month change	-93 (-99 to -87)	-54 (-60 to -47)	-39 (-48 to -30)	<0.001

IQR, Interquartile range
Baseline data are median and (IQR)
6-month and 12-month change are means (95% CI) calculated using mixed effect models taking into account site and intra-cluster correlations (couples) as random factors.

Supplemental eTable 7 cont. Sensitivity analysis. Baseline values, 6-month and 12-month changes in food items by randomized treatment group: all randomized participants. Replacing all missing values with baseline value.

REPLACING ALL MISSING VALUES WITH BASELINE VALUE				
Variable	**Intervention group**	**Control group**	**Between-group difference**	
	n=3,272	**n=3,311**		**p value**
Dairy (g/week)				
Baseline, median (IQR)	2,100 (1,532, 2,959)	2,200 (1,548, 3,597)		
6-month change	19 (-24 to 63)	-125 (-168 to -82)	144 (83 to 205)	<0.001
12-month change	-29 (-72 to 14)	-166 (-209 to -123)	137 (76 to 198)	<0.001
Total yogurt (g/week)				
Baseline, median (IQR)	375 (58, 875)	375 (58, 875)		
6-month change	103 (84 to 122)	7 (-11 to 26)	95 (69 to 122)	<0.001
12-month change	77 (58 to 96)	-4 (-22 to 15)	81 (54 to 107)	<0.001
Fermented dairy (g/week)				
Baseline, median (IQR)	550 (300, 975)	575 (300, 1,025)		
6-month change	83 (64 to 103)	-6 (-25 to 14)	89 (61 to 117)	<0.001
12-month change	63 (43 to 82)	-14 (-33 to 6)	76 (49 to 104)	<0.001
Low-fat dairy (g/week)				
Baseline, median (IQR)	658 (0, 1,775)	687 (0, 1,775)		
6-month change	283 (243 to 324)	56 (15 to 96)	228 (170 to 285)	<0.001
12-month change	230 (189 to 271)	-4 (-45 to 36)	234 (177 to 292)	<0.001
Whole-fat dairy (g/week)				
Baseline, median (IQR)	0 (0, 375)	0 (0, 375)		
6-month change	-147 (-167 to -126)	-98 (-118 to -77)	-49 (-78 to -20)	0.001
12-month change	-130 (-151 to -110)	-87 (-107 to -67)	-44 (-72 to -15)	0.003
Total alcohol intake (g/week)				
Baseline, median (IQR)	32 (5, 98)	36 (5, 103)		
6-month change	-12 (-14 to -9)	-5 (-8 to -3)	-6 (-10 to -3)	0.001
12-month change	-11 (-13 to -8)	-4 (-6 to -1)	-7 (-10 to -3)	<0.001
Red wine (g/week)				
Baseline, median (IQR)	0 (0, 29)	0 (0, 29)		
6-month change	1 (-1 to 2)	2 (0 to 3)	-1 (-3 to 1)	0.36
12-month change	1 (0 to 3)	2 (1 to 4)	-1 (-3 to 1)	0.36

IQR, Interquartile range
Baseline data are median (IQR)
6-month and 12-month change are means (95% CI) calculated using mixed effect models taking into account site and intra-cluster correlations (couples) as random factors.

Supplemental eTable 8. Sensitivity analysis. Baseline values, 6-month and 12-month changes in nutrient intake by randomized treatment group: all randomized participants. Replacing all missing values with baseline value.

REPLACING ALL MISSING VALUES WITH BASELINE VALUE				
Variable	**Intervention group**	**Control group**	**Between-group difference**	
	n=3,272	**n=3,311**		**p value**
Total energy Intake (kcal/d)				
Baseline, mean (SD)	2,355 (544)	2,369 (555)		
6-month change	-151 (-168 to -135)	-67 (-83 to -50)	-85 (-108 to -61)	<0.001
12-month change	-154 (-170 to -137)	-66 (-83 to -49)	-88 (-111 to -64)	<0.001
Total protein (%E)				
Baseline, mean (SD)	16.8 (2.8)	16.8 (2.8)		
6-month change	1.0 (1.0 to 1.1)	0.1 (0 to 0.2)	0.9 (0.8 to 1)	<0.001
12-month change	0.9 (0.8 to 1.0)	0 (-0.1 to 0.1)	0.9 (0.8 to 1.1)	<0.001
Total carbohydrate (%E)				
Baseline, mean (SD)	40.7 (6.8)	40.4 (6.9)		
6-month change	-2.9 (-3.1 to -2.7)	-1.6 (-1.8 to -1.4)	-1.3 (-1.6 to -1)	<0.001
12-month change	-3.2 (-3.4 to -3.0)	-2.0 (-2.2 to -1.8)	-1.2 (-1.5 to -0.9)	<0.001
Total fat (%E)				
Baseline, mean (SD)	39.5 (6.6)	39.7 (6.5)		
6-month change	2.1 (1.9 to 2.4)	1.6 (1.4 to 1.8)	0.6 (0.3 to 0.9)	<0.001
12-month change	2.5 (2.3 to 2.7)	2.1 (1.8 to 2.3)	0.4 (0.1 to 0.8)	.006
SFA (%E)				
Baseline, mean (SD)	9.9 (2.0)	10 (2)		
6-month change	-0.9 (-0.9 to -0.8)	-0.5 (-0.6 to -0.4)	-0.4 (-0.5 to -0.3)	<0.001
12-month change	-0.8 (-0.9 to -0.7)	-0.5 (-0.6 to -0.5)	-0.3 (-0.4 to -0.2)	<0.001
MUFA (%E)				
Baseline, mean (SD)	20.5 (4.7)	20.6 (4.6)		
6-month change	3.0 (2.9 to 3.2)	2.0 (1.9 to 2.2)	1.0 (0.8 to 1.2)	<0.001
12-month change	3.4 (3.2 to 3.5)	2.6 (2.5 to 2.8)	0.7 (0.5 to 1.0)	<0.001

E, energy; SFA, saturated fatty acids; MUFA, monounsaturated fatty acids
Baseline data are means (SD)
6-month and 12-month change are means (95% CI) calculated using mixed effect models taking into account site and intra-cluster correlations (couples) as random factors.

Supplemental eTable 8 cont. Sensitivity analysis. Baseline values, 6-month and 12-month changes in nutrient intake by randomized treatment group: all randomized participants. Replacing all missing values with baseline value.

REPLACING ALL MISSING VALUES WITH BASELINE VALUE				
Variable	**Intervention group**	**Control group**	**Between-group difference**	
	n=3,272	**n=3,311**		**p value**
Ratio MUFA:SFA				
Baseline, mean (SD)	2.1 (0.5)	2.1 (0.5)		
6-month change	0.6 (0.5 to 0.6)	0.3 (0.3 to 0.4)	0.2 (0.2 to 0.3)	<0.001
12-month change	0.6 (0.6 to 0.6)	0.4 (0.4 to 0.4)	0.2 (0.1 to 0.2)	<0.001
PUFA (%E)				
Baseline, mean (SD)	6.4 (1.9)	6.4 (1.8)		
6-month change	1.1 (1.1 to 1.2)	0.7 (0.6 to 0.7)	0.5 (0.4 to 0.5)	<0.001
12-month change	1.1 (1.0 to 1.2)	0.7 (0.7 to 0.8)	0.4 (0.3 to 0.5)	<0.001
Total alcohol (%E)				
Baseline, median (IQR)	1 (0, 4)	2 (0, 4)		
6-month change	-0.3 (-0.4 to -0.2)	-0.1 (-0.2 to 0)	-0.2 (-0.3 to 0)	0.02
12-month change	-0.2 (-0.3 to -0.1)	0 (-0.1 to 0.1)	-0.2 (-0.3 to -0.1)	0.01
Fiber (g/week)				
Baseline, mean (SD)	184 (63)	182 (60)		
6-month change	35 (33 to 37)	14 (12 to 16)	21 (18 to 24)	<0.001
12-month change	32 (30 to 34)	16 (14 to 18)	16 (13 to 19)	<0.001
Long chain w-3 fatty acids (g/week)				
Baseline, median (IQR)	5 (4, 9)	5 (4, 9)		
6-month change	0.9 (0.8 to 1.1)	0.4 (0.3 to 0.5)	0.6 (0.4 to 0.7)	<0.001
12-month change	0.9 (0.8 to 1.1)	0.4 (0.3 to 0.5)	0.6 (0.4 to 0.7)	<0.001
Cholesterol (mg/week)				
Baseline, mean (SD)	2,651 (793)	2,687 (825)		
6-month change	-191 (-216 to -166)	-147 (-172 to -122)	-44 (-79 to -8)	0.02
12-month change	-187 (-213 to -162)	-182 (-207 to -157)	-6 (-41 to 30)	0.75
Sodium (g/week)				
Baseline, median (IQR)	22.2 (17.9, 27.1)	22.2 (17.9, 27.4)		
6-month change	-2.7 (-2.9 to -2.5)	-1.6 (-1.8 to -1.4)	-1.1 (-1.4 to -0.8)	<0.001
12-month change	-2.8 (-3.0 to -2.6)	-1.7 (-1.9 to -1.4)	-1.1 (-1.4 to -0.8)	<0.001

Baseline data are means (SD) or median (IQR)
E, energy; SFA, saturated fatty acids; MUFA, monounsaturated fatty acids; PUFA, polyunsaturated fatty acids; w-3, omega-3
6-month and 12-month change are means (95% CI) calculated using mixed effect models taking into account site and intra-cluster correlations (couples) as random factors.

Supplemental eTable 9. Baseline and 12- month change (95% confidence intervals) in risk factors, by treatment group: all randomized participants (multiple imputation [MI]) and completers only.

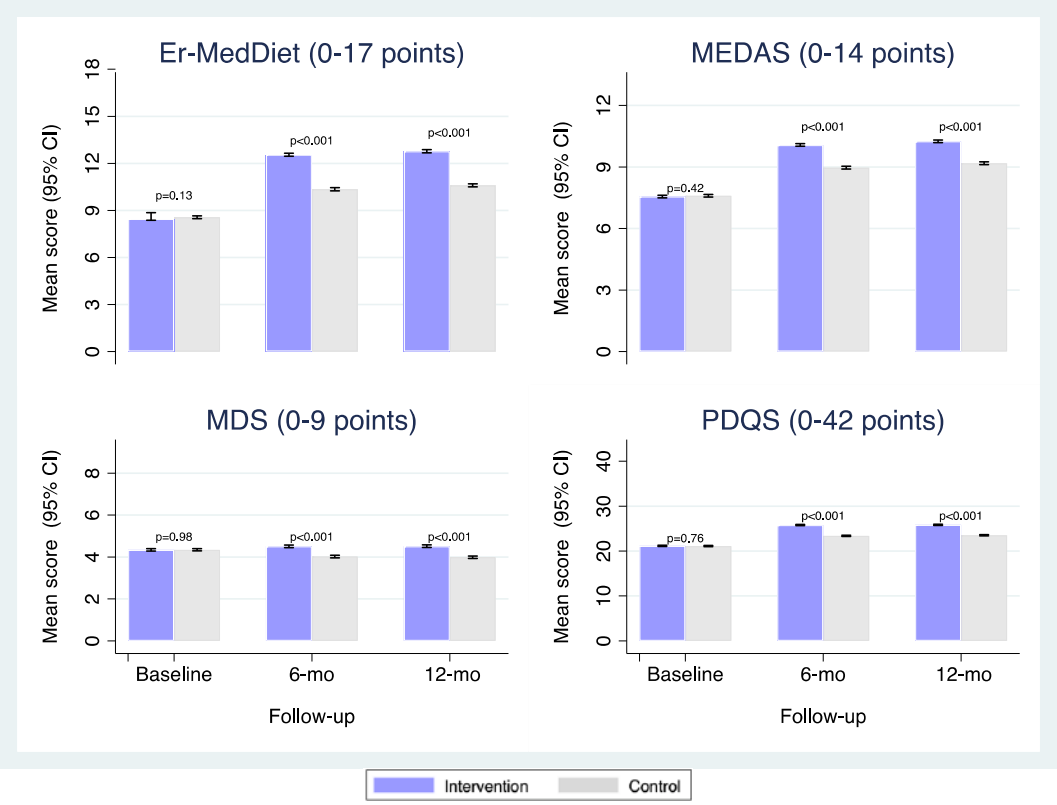
	MULTIPLE IMPUTATION: all randomized participants				COMPLETERS ONLY			
Variable	Intervention group	Control group	Between-group difference		Intervention group	Control group	Between-group difference	
	n=3,272	n=3,311		p value	n=2,840	n=2,946		p value
Weight, (kg)								
Baseline, mean (SD)	86.5 (12.9)	86.3 (13.0)			86.5 (12.9)	86.3 (13)		
12-month change	-3.6 (-3.9 to -3.4)	-0.8 (-1.0 to -0.5)	-2.9 (-3.2 to -2.6)	<0.001	-3.8 (-4.1 to -3.6)	-0.8 (-1.0 to -0.5)	-3.1 (-3.4 to -2.7)	<0.001
Waist, (cm)								
Baseline, mean (SD)	108 (9.6)	108 (9.7)			107 (9.6)	108 (9.7)		
12-month change	-4.4 (-4.6 to -4.1)	-1.1 (-1.3 to -0.9)	-3.3 (-3.6 to -2.9)	<0.001	-4.4 (-4.7 to -4.2)	-1.1 (-1.3 to -0.9)	-3.3 (-3.7 to -3.0)	<0.001
BMI, (kg/m^2)								
Baseline, mean (SD)	32.6 (3.4)	32.6 (3.5)			32.5 (3.4)	32.5 (3.5)		
12-month change	-1.4 (-1.4 to -1.3)	-0.3 (-0.3 to -0.2)	-1.1 (-1.2 to -1.0)	<0.001	-1.4 (-1.5 to -1.3)	-0.3 (-0.4 to -0.2)	-1.1 (-1.3 to -1.0)	<0.001
Serum cholesterol, (mg/dL)								
Baseline, mean (SD)	197 (37.5)	197 (37.7)			196 (37)	197 (37.6)		
12-month change	-3.0 (-4.2 to -1.7)	-1.8 (-3.1 to -0.6)	-1.1 (-2.9 to 0.7)	0.23	-2.9 (-4.2 to -1.7)	-1.9 (-3.1 to -0.6)	-1.1 (-2.8 to 0.7)	0.24
LDL-c, (mg/dL)								
Baseline, mean (SD)	121 (32.2)	121 (32.2)			120 (32)	121 (32.1)		
12-month change	-2.9 (-4.0 to -1.8)	-2.3 (-3.4 to -1.2)	-0.6 (-2.2 to 1.0)	0.48	-2.9 (-4.0 to -1.8)	-2.3 (-3.4 to -1.2)	-0.6 (-2.2 to 1.0)	0.45
HDL-c, (mg/dL)								
Baseline, mean (SD)	48 (11.8)	48 (11.7)			48 (11.9)	48 (11.7)		
12-month change	2.0 (1.7 to 2.3)	0.9 (0.6 to 1.2)	1.1 (0.7 to 1.6)	<0.001	2.2 (1.8 to 2.5)	0.9 (0.6 to 1.2)	1.3 (0.8 to 1.7)	<0.001

Supplemental eTable 9 (cont.). Baseline and 12- month change (95% confidence intervals) in risk factors, by treatment group: all randomized participants (multiple imputation [MI]) and completers only.

	MULTIPLE IMPUTATION: all randomized participants				COMPLETERS ONLY			
Variable	Intervention group	Control group	Between-group difference		Intervention group	Control group	Between-group difference	
	n=3,272	n=3,311		p value	n=2,840	n=2,946		p value
NonHDL-c, (mg/dL)								
Baseline, mean (SD)	149 (35.1)	149 (35.1)			148 (34.7)	149 (34.9)		
12-month change	-4.9 (-6.0 to -3.7)	-2.9 (-4.1 to -1.7)	-1.9 (-3.6 to -0.3)	0.02	-5.2 (-6.4 to -4.0)	-2.7 (-3.9 to -1.6)	-2.5 (-4.2 to -0.8)	0.004
Ratio Cholesterol:HDL-c								
Baseline, mean (SD)	4.3 (1.1)	4.2 (1)			4.3 (1.1)	4.2 (1)		
12-month change	-0.2 (-0.3 to -0.2)	-0.1 (-0.1 to -0.1)	-0.1 (-0.2 to -0.1)	<0.001	-0.3 (-0.3 to -0.2)	-0.1 (-0.1 to -0.1)	-0.1 (-0.2 to -0.1)	<0.001
Triglycerides, (mg/dl)								
Baseline, mean (SD)	151 (76.4)	153 (78.3)			148 (72.4)	150 (74.1)		
12-month change	-12.8 (-15.4 to -10.3)	-2.9 (-5.4 to -0.4)	-9.9 (-13.6 to -6.3)	<0.001	-14.6 (-17.2 to -12.1)	-4.2 (-6.7 to -1.7)	-10.4 (-14 to -6.9)	<0.001
SBP, (mmHg)								
Baseline, mean (SD)	140 (17.1)	139 (16.6)			139 (17.1)	139 (16.6)		
12-month change	-4.1 (-4.7 to -3.5)	-2.2 (-2.8 to -1.7)	-1.9 (-2.7 to -1.1)	<0.001	-3.9 (-4.5 to -3.3)	-2.2 (-2.7 to -1.6)	-1.7 (-2.6 to -0.9)	<0.001
DBP, (mmHg)								
Baseline, mean (SD)	81 (10)	81 (9.8)			81 (9.9)	81 (9.7)		
12-month change	-2.4 (-2.8 to -2.1)	-1.5 (-1.8 to -1.2)	-1 (-1.4 to -0.5)	<0.001	-2.5 (-2.8 to -2.2)	-1.5 (-1.8 to -1.2)	-1.0 (-1.5 to -0.6)	<0.001

MI, Multiple imputation; BMI, Body mass index; LDL-c, Low density lipoprotein cholesterol; HDL-c, High density lipoprotein cholesterol; SBP, systolic blood pressure; DBP, diastolic blood pressure.
Multiple imputation (using chained equations with the following predictors: Intervention group, sex, age at baseline, smoking status, educational level, physical activity, baseline BMI, total energy intake and the baseline value of the variable that will be imputed.)
% of imputed values: body mass index: 5%, body weight: 4.7%, waist circumference: 9.4%, serum cholesterol: 10.1%, HDL-c: 10.8%, LDL-c: 10.9%, nonHDL-c: 10.9% ratio cholesterol: HDL: 10.9%, triglycerides: 10.3%, systolic blood pressure: 6.1% and diastolic blood pressure: 6.2%
Baseline data are means (SD). 12-month change are means (95% CI) calculated using mixed effect models taking into account site and intra-cluster correlations (couples) as random factors. Conversion factors to obtain mmol/L: Cholesterol mg/dL, HDL-c and LDL-c x 0.0259; triglycerides mg/dL x 0.0113.

Supplemental eFigure 1. Mean values (95% CI) of scores capturing the 4 quality dietary patterns at baseline, at 6 months and at 12 months according to the randomized treatment group.

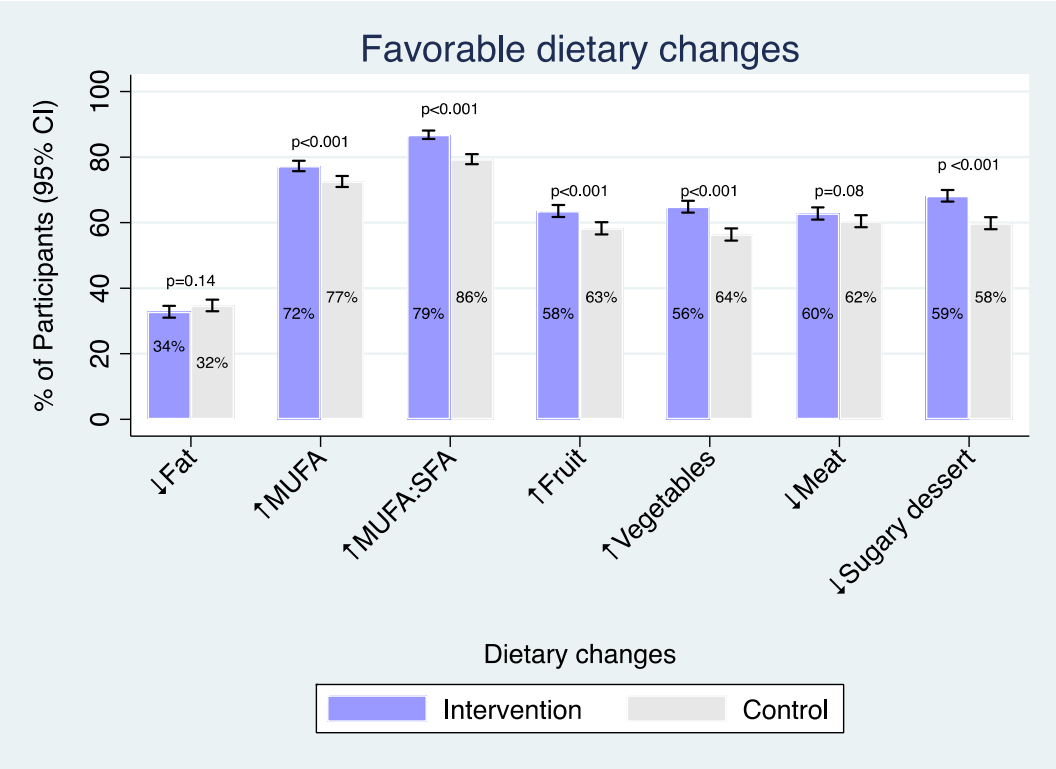


Er-MedDiet, Energy reduced Mediterranean Diet; MDS, Mediterranean Diet Score, MEDAS, Mediterranean Diet Adherence Screener; PDQS, Prime Diet Quality Score.

The direction of all 4 food patterns is the same: a higher score means a higher quality of the overall dietary pattern. The possible ranges were 0-17 for er-MedDiet, 0-9 for the MDS, 0-14 for MEDAS, and 0-42 for PDQS, Prime Diet Quality Score.

The p values shown in the graphs correspond to the comparisons of means between intervention and control groups.

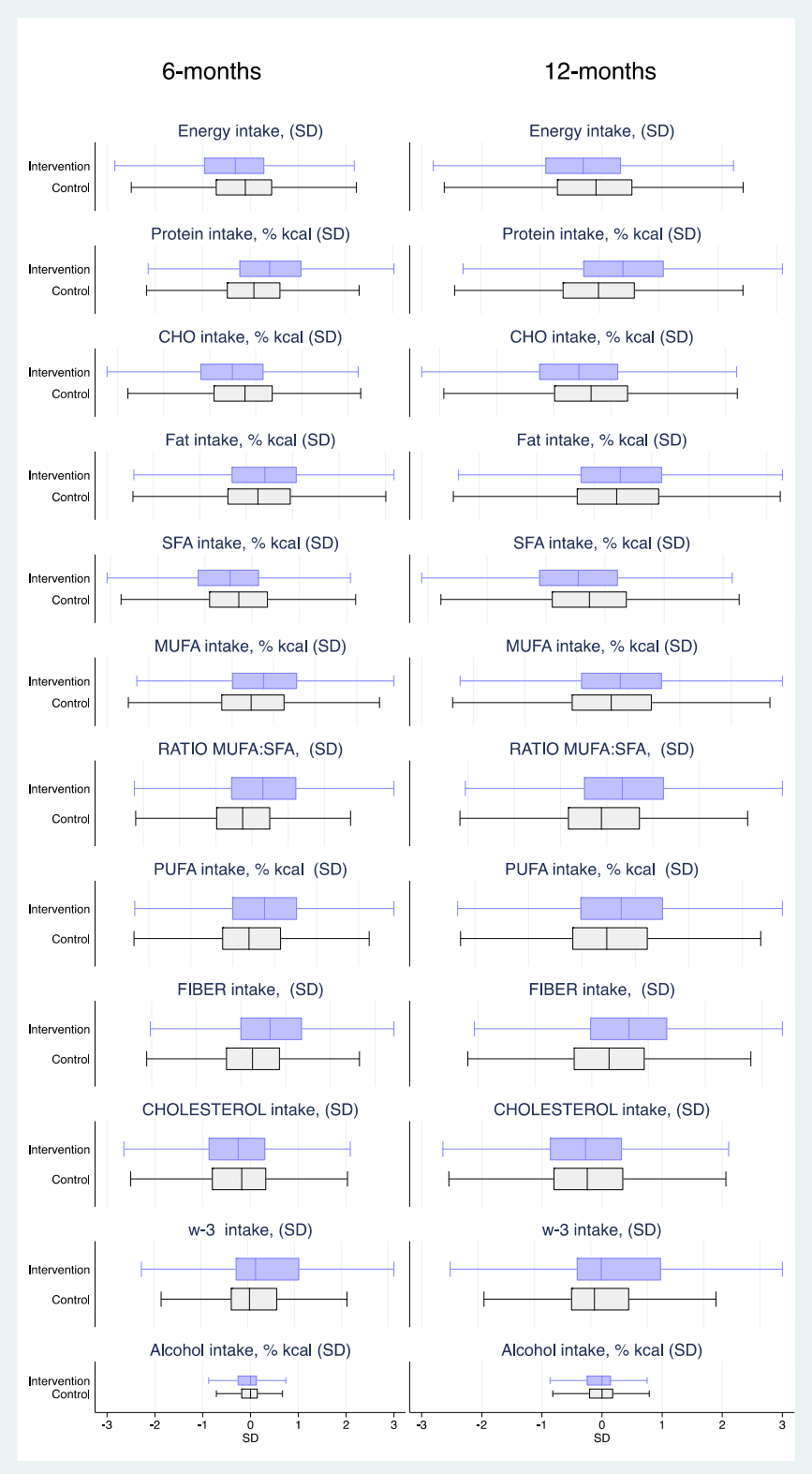
Supplemental eFigure 2. Percentage of participants complying with the intended dietary changes after 12 months by randomized treatment group.



MUFA, monounsaturated fatty acids; MUFA:SFA, ratio monounsaturated and saturated fatty acids.

The p values shown in the graphs correspond to the comparisons of proportions between intervention and control groups.

Supplemental eFigure 3 Changes in nutritional variables (expressed in common units of baseline standard deviations) after 6 and 12 months in the control and in the intervention group.



CHO, carbohydrates; SFA, Saturated fatty acid; MUFA, monounsaturated fatty acid, PUFA, polyunsaturated fatty acid; w-3, long chain omega-3 fatty acid

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