



Erratum

Erratum. Mediterranean Diet, Retinopathy, Nephropathy, and Microvascular Diabetes Complications: A Post Hoc Analysis of a Randomized Trial. *Diabetes Care* 2015;38:2134–2141

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Some imperfections in the randomization procedures affecting a small subset of participants in the Prevención con Dieta Mediterránea (PREDIMED) trial (at most 14%) have been reported in a recent republication of the main PREDIMED article (see Estruch et al. Primary prevention of cardiovascular disease with a Mediterranean diet supplemented with extra-virgin olive oil or nuts. *N Engl J Med* 2018;378:e34). For this reason, the authors wish to make the following corrections to their original PREDIMED substudy on the Mediterranean diet and diabetic retinopathy and nephropathy (Díaz-López et al. Mediterranean diet, retinopathy, nephropathy, and microvascular diabetes complications: a post hoc analysis of a randomized trial. *Diabetes Care* 2015;38:2134–2141).

In the original substudy, a limited number of participants ($n = 184$; 5.1% of the total sample) were directly allocated to the same arm of the trial as their relatives because a previous member of their same household (usually the spouse) was already randomized in the trial. Also, center D, one of the eleven recruiting centers, had allocated a subset of its participants (it had 360 participants [9.9% of the total sample]) by clusters (clinics) instead of using individual randomization (23 participants from center D were also second household members).

The authors have reanalyzed the effect of the intervention on the incidence of retinopathy and nephropathy adjusting for propensity scores (built with 30 predictors of allocation) and using a robust estimate of the variance to correct for intra-cluster correlation (see corrected Table 2 below). The authors show in this table the corrected estimates for these outcomes as compared with those reported in their original article. The results are basically unchanged.

Importantly, the key message from the original article does not change and the final conclusions remain the same.

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Table 2—Hazard ratios (95% CI) for diabetic retinopathy and diabetic nephropathy incidence according to intervention group in the PREDIMED trial after a median 6.0 years of follow-up

Outcomes	Control diet	MedDiet+EVOO	MedDiet+nuts	Both MedDiet groups together
Diabetic retinopathy	<i>n</i> = 1,190	<i>n</i> = 1,282	<i>n</i> = 1,142	
Original multivariable-adjusted analysis*				
Cases, <i>n</i> / person-years of follow-up	32/6,856	22/7,830	20/6,622	
Multivariable-adjusted model	1 (ref.)	0.56 (0.32–0.97)	0.63 (0.35–1.11)	0.60 (0.37–0.96)
Additionally adjusted for propensity scores, stratified by recruiting site and educational level (5 categories) and using robust estimate of the variance adjusted for intra-cluster correlation†				
Cases, <i>n</i> / person-years of follow-up	32/6,856	22/7,830	20/6,622	
Multivariable-adjusted model	1 (ref.)	0.57 (0.33–0.98)	0.62 (0.34–1.11)	0.59 (0.37–0.95)
Diabetic nephropathy	<i>n</i> = 717	<i>n</i> = 740	<i>n</i> = 672	
Original multivariable-adjusted analysis*				
Cases, <i>n</i> / person-years of follow-up	53/4,180	64/4,419	51/3,985	
Multivariable-adjusted model	1 (ref.)	1.15 (0.79–1.67)	1.06 (0.72–1.58)	1.11 (0.79–1.55)
Additionally adjusted for propensity scores, stratified by recruiting site and educational level (5 categories) and using robust estimate of the variance adjusted for intra-cluster correlation†				
Cases, <i>n</i> / person-years of follow-up	53/4,180	64/4,419	51/3,985	
Multivariable-adjusted model	1 (ref.)	1.22 (0.83–1.81)	1.15 (0.76–1.73)	1.19 (0.84–1.69)

Cox regression models with outcome of diabetic retinopathy and diabetic nephropathy incidence, and exposure to MedDiet intervention group vs. control group. MedDiet+EVOO, Mediterranean diet supplemented with extra-virgin olive oil; MedDiet+Nuts, Mediterranean diet supplemented with nuts. *Multivariable model adjusted for age, sex, baseline BMI (continuous variable), waist circumference (continuous variable), smoking (never, current, or former smoker), physical activity in MET-min/day (continuous variable), educational level (primary/secondary education or academic/graduate), hypertension (yes or no), dyslipidemia (yes or no), family history of premature coronary heart disease (yes or no), adherence to the Mediterranean diet (<10 point, low or ≥10 point, high), and stratified by recruiting site. †The authors used robust variance estimators to account for intra-cluster correlations in Cox models, considering as clusters the members of the same household and the participants in the same clinics of site D.