Erratum

Erratum. Reduction in the Incidence of Type 2 Diabetes With the Mediterranean Diet: Results of the PREDIMED-Reus nutrition intervention randomized trial. Diabetes Care 2011;34:14–19

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Some slight departures from the protocol of individual randomization affecting only a small subset of participants in the Prevención con Dieta Mediterránea (PREDIMED) trial (at most 14%) occurred and prompted a thorough reanalysis of data and republication of the main PREDIMED paper (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). The authors report the following clarifications and corrections on the original article (Salas-Salvadó et al. Reduction in the incidence of type 2 diabetes with the Mediterranean diet: results of the PREDIMED-Reus nutrition intervention randomized trial. Diabetes Care 2011;34: 14–19).

The fact that some participants in the overall PREDIMED trial were not individually randomized but allocated by clusters (clinics) at one of eleven recruitment sites (site D) does not affect the results because all the participants in that study came from another site (Reus is not site D). A proper randomization was conducted in the PREDIMED-Reus recruitment site.

However, a small number of participants from the Reus recruitment site were directly allocated to the same arm of the trial as their relatives because a previous member of the same household (usually the spouse) was already randomized in the trial ($n = 29$; 6.9% of the total sample).

As a sensitivity analysis, the authors reanalyzed the effect of the intervention on the incidence of diabetes after excluding the second household members, and the new multivariable-adjusted hazard ratios of diabetes were 0.47 (0.23–0.97) and 0.47 (0.23–0.98) in the Mediterranean diets supplemented with olive oil and nuts groups, respectively, compared with the control group (see corrected Table 3 below). When the two Mediterranean diet groups were merged and compared with the control group, the hazard ratio for diabetes was 0.47 (95% CI 0.26–0.87).

Importantly, the results from the original article do not change, and the final conclusions remain the same.

Table 3—Hazard ratios (95% CIs) of diabetes by intervention group*

	MedDiet with VOO vs. control diet	MedDiet with nuts vs. control diet	Both MedDiets vs. control diet
Original multivariate-adjusted model†	0.49 (0.25–0.97)	0.48 (0.24–0.96)	0.48 (0.27–0.86)
New multivariate-adjusted model†§	0.47 (0.23–0.97)	0.47 (0.23–0.98)	0.47 (0.26–0.87)
Sex‡§			
Male	0.45 (0.13–1.53)	0.75 (0.23–2.49)	0.57 (0.20–1.60)
Female	0.47 (0.18–1.20)	0.27 (0.09–0.83)	0.37 (0.16–0.87)
Age (years)‡§			
≤67	0.51 (0.18–1.41)	0.59 (0.23–1.51)	0.55 (0.24–1.26)
>67	0.25 (0.07–0.88)	0.36 (0.10–1.34)	0.29 (0.10–0.88)
BMI (kg/m^2)‡§			
≤30	0.67 (0.24–1.88)	0.53 (0.19–1.50)	0.59 (0.25–1.40)
>30	0.41 (0.14–1.25)	0.68 (0.23–1.97)	0.53 (0.21–1.32)
Fasting glucose (mmol/L)‡§			
≤6.1	0.53 (0.18–1.50)	0.61 (0.23–1.58)	0.57 (0.24–1.33)
>6.1	0.23 (0.07–0.79)	0.36 (0.10–1.29)	0.28 (0.09–0.86)

*Cox regression models to assess the relative risk of diabetes by allocation group, estimating the hazard ratios and their 95% CIs were performed. †Adjusted for baseline energy intake, BMI, waist circumference, physical activity, smoking status, fasting serum glucose, use of lipid-lowering drugs, Mediterranean diet score, and weight change during the study. ‡Adjusted for the same variables as †, except the variable of interest. §Excluding 2n nonrandomized partners. *P* for interaction (MedDiet * sex): 0.382; *P* for interaction (MedDiet * age): 0.218; *P* for interaction (MedDiet * BMI): 0.729; *P* for interaction (MedDiet * fasting glucose): 0.793. MedDiet, Mediterranean diet; VOO, virgin olive oil.