



# Primary Prevention of Sexual Dysfunction With Mediterranean Diet in Type 2 Diabetes: The MÈDITA Randomized Trial

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Maria Ida Maiorino,<sup>1</sup>  
Giuseppe Bellastella,<sup>1</sup> Paolo Chiodini,<sup>2</sup>  
Ornella Romano,<sup>3</sup> Lorenzo Scappaticcio,<sup>1</sup>  
Dario Giugliano,<sup>1</sup> and Katherine Esposito<sup>3</sup>

Type 2 diabetes has been associated with sexual dysfunction in men and women (1). Erectile dysfunction (ED) is a marker of significantly increased risk of cardiovascular disease and all-cause mortality in men with diabetes and the general population; however, no data support a clear role for female sexual dysfunction (FSD) as a predictor of future cardiovascular events in women with diabetes.

There is some evidence from clinical trials that sexual dysfunction is amenable to amelioration with interventions based on diet and lifestyle modification in men and women (2). Using the data of the MEditerranean Diet and Type 2 diAbetes (MÈDITA) randomized trial (3), we investigated the long-term effect of Mediterranean diet on 1) incident ED and FSD in people with type 2 diabetes and 2) combined incidence of sexual dysfunction (men or women) with worsening of sexual function in those participants with sexual dysfunction at baseline.

Participants in the two-arm, single-center MÈDITA trial were randomly assigned to a Mediterranean diet ( $n = 108$ ) or a low-fat diet ( $n = 107$ ), with a total follow-up of 8.1 years. Sexual function was evaluated by completing the

validated self-reported questionnaires International Index of Erectile Function (IIEF) and Female Sexual Function Index (FSFI) at baseline, before randomization, and every 6 months. Survival curves were estimated by the product-limit method of Kaplan-Meier for the two groups (Mediterranean diet and low-fat diet) and compared by the log-rank statistic.

There was no difference in baseline sexual function in men ( $n = 54$  vs. 52;  $P = 0.287$ ) or women ( $n = 54$  vs. 55;  $P = 0.815$ ) randomized to Mediterranean diet or low-fat diet, respectively. Over the entire follow-up, the incidence of the primary outcome was significantly lower in the Mediterranean diet group compared with the low-fat diet group (ED: hazard ratio 0.44 [95% CI 0.19–1.00],  $P = 0.045$  [Fig. 1A]; FDS: hazard ratio 0.44 [0.19–1.00],  $P = 0.048$  [Fig. 1B]). Similarly, the incidence of the secondary outcome was also lower in the Mediterranean diet group (new ED and deterioration of preexisting ED: hazard ratio 0.41 [0.21–0.83],  $P = 0.011$  [Fig. 1C]; new FSD and deterioration of preexisting FSD: 0.50 [0.25–0.99],  $P = 0.045$  [Fig. 1D]). Compared with participants assigned to the low-fat diet, participants assigned to Mediterranean diet showed

greater reduction in weight ( $-0.98$  kg) over the entire follow-up. In the analyses that adjusted for change in body weight, HbA<sub>1c</sub>, or depressive symptoms, the hazard ratios (95% CI) were 0.48 (0.20–0.99), 0.47 (0.19–0.99), and 0.49 (0.23–0.99), respectively.

The current study is the first long-term dietary trial demonstrating that the Mediterranean diet conferred benefit on both prevention (56% relative risk reduction) and deterioration of sexual dysfunction in both men and women with newly diagnosed type 2 diabetes. In adults with type 2 diabetes, a Mediterranean-style dietary pattern may improve the inflammatory milieu and cardiovascular risk (4), both these effects being beneficial to achieving improvement of sexual dysfunction in people with diabetes (5). Although the evaluation of sexual function was not planned in the original study protocol, both primary and secondary outcomes were similar, suggesting that the results were robust.

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<sup>1</sup>Division of Endocrinology and Metabolic Diseases, Department of Medical, Surgical, Neurological, Metabolic Sciences and Aging, Second University of Naples, Naples, Italy

<sup>2</sup>Medical Statistics Unit, Second University of Naples, Naples, Italy

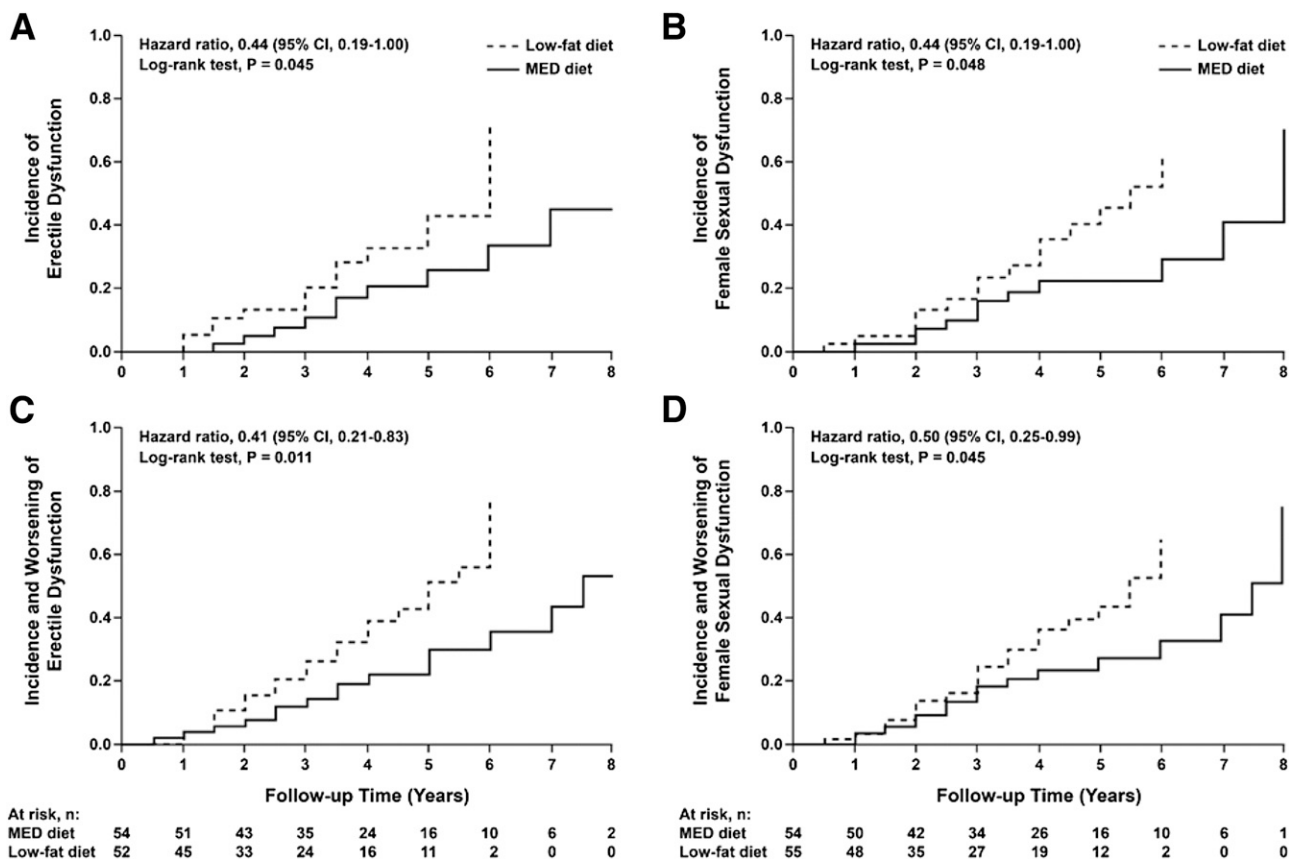
<sup>3</sup>Diabetes Unit, Department of Clinical and Experimental Medicine, Second University of Naples, Naples, Italy

Corresponding author: Maria Ida Maiorino, mariaida.maiorino@unina2.it.

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**Figure 1**—Probability of incident ED and FSD in patients with diabetes. *A*: Incident ED in patients free of ED at baseline (primary end point). *B*: Incident FSD in patients free of FSD at baseline (primary end point). *C*: Incident ED plus worsening of ED in patients with ED at baseline. *D*: Incident FSD plus worsening of FSD in patients with FSD at baseline. MED diet, Mediterranean diet.

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the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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