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## Mediterranean Diet Reduces Cardiovascular Events

### Clinical Question

Is a Mediterranean diet more effective than a low-fat diet at preventing cardiovascular events?

### Bottom Line

In a high-risk population, a Mediterranean diet, supplemented with either nuts or olive oil, reduces the likelihood of a composite outcome of cardiovascular events or death over a five-year follow-up period (number needed to treat = 70). The relative risk reduction is approximately 30%. This is the strongest evidence yet to support any particular approach to diet. Best of all, what's not to like about seafood, red wine, paella, nuts, fresh fruit, and chicken? (Level of Evidence = 1b)

### Synopsis

Most studies of diet are underpowered or are only observational. This large Spanish study identified men between 55 and 80 years of age and women between 60 and 80 years of age ( $n = 7,447$ ) who had type 2 diabetes mellitus or who had three or more of the following risk factors: hypertension, smoking, low-density lipoprotein cholesterol level greater than 160 mg per dL (4.1 mmol per L), high-density lipoprotein cholesterol level of 40 mg per dL (1.0 mmol per L) or less, body mass index (BMI) of 25 kg per  $m^2$  or greater, or a family history of premature cardiovascular disease. Patients were randomized to follow one of three diets: (1) a Mediterranean diet supplemented with olive oil, (2) a Mediterranean diet supplemented with nuts, or (3) a low-fat diet. The Mediterranean diets emphasized fresh fruit, vegetables, fish, legumes, sofrito, white meat, and wine with meals. Red meat, commercially baked goods, soda, and spreadable fats were discouraged. The olive oil group received 1 L of

oil per week, the nut group received 30 g of mixed nuts per day, and the low-fat group received a small nonfood gift. The low-fat group focused on low-fat food, lots of carbohydrates, fresh fruits, vegetables, and lean fish and seafood. Sofrito, fatty fish, spreadable fats, nuts and fried snacks, vegetable oils, commercially baked goods, and red meats were discouraged.

End points were adjudicated by a committee unaware of treatment assignment. The participants had an average age of 67 years, 97% were European whites, and 57% were women. Only 8% had a BMI of less than 25 kg per  $m^2$ , and approximately 50% had type 2 diabetes. Participants were followed for 4.8 years, and the authors assessed compliance with the diet in all three groups using self-reported intake and biomarker analysis. For 12 of the 14 items on the Mediterranean diet screener, the Mediterranean diet groups had higher scores. The primary outcome was a combined end point of myocardial infarction, stroke, and cardiovascular death. This end point was less likely for both of the Mediterranean diet groups than for the low-fat diet control group; there were approximately three fewer events per 1,000 person-years, which corresponds to a number needed to treat of approximately 70 for the 4.8-year study to prevent one adverse event. However, there was no difference in deaths due to any cause or deaths due to cardiovascular events; the only individual outcome for which there was a statistically significant benefit was strokes (4.1% for the Mediterranean diet with olive oil, 3.1% for the Mediterranean diet with nuts, and 5.9% for the low-fat diet). One limitation is that the control group received fewer counseling visits and had a higher drop-out rate than either of the intervention groups.

### Reference

Erstrich R, Ros E, Salas-Salvadó J, et al.; PREDIMED Study Investigators. Primary prevention of cardiovascular disease with a Mediterranean diet. *N Engl J Med*. 2013;368(14):1279-1290.

**Study design:** Randomized controlled trial (single-blinded)

**Funding source:** Government

**Allocation:** Concealed

**Setting:** Population-based

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