Mediterranean-style diet for the primary and secondary prevention of cardiovascular disease: Cochrane systematic review and meta-analysis of randomised clinical trials

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Background: Observational studies have confirmed the benefits of adherence to a Mediterranean dietary pattern on cardiovascular disease (CVD) but the randomised controlled trial (RCT) evidence is limited.

Objective: To determine the effectiveness of a Mediterranean-style diet for the primary and secondary prevention of CVD.

Methods: We searched the Cochrane Central Register of Controlled Trials, MEDLINE, EMBASE, Web of Science, DARE, HTA, NHS EED and trial registers (September 2018). We selected RCTs in healthy adults and adults at high risk of CVD (primary prevention) and those with established CVD (secondary prevention). Both of the following key components were required for our definition of a Mediterranean-style diet: high monounsaturated/saturated fat ratio and a high intake of plant based foods, including fruits, vegetables, and legumes. The intervention could be dietary advice, provision of relevant foods or both. The comparison group received either no intervention, minimal intervention, usual care or another dietary intervention. Outcomes included clinical events and CVD risk factors. We included only studies with follow-up periods of 3 months or more.

Results: Overall, 30 RCTs (12,461 participants randomised) and 7 ongoing trials met our inclusion criteria, whereas 22 primary prevention trials and 6 secondary prevention trials were analysed. Low quality evidence shows little or no effect of the PREDIMED (7747 randomised) intervention (advice to follow a Mediterranean diet plus supplemental extra virgin olive oil or tree nuts) compared to a low fat diet on CVD mortality (HR 0.81 (95% CI 0.5, 1.32)) or total mortality (HR 1.0 (95% CI 0.81, 1.24)) over 4.8 years. There was however a reduction in the number of strokes with the PREDIMED intervention (HR 0.6 (95% CI 0.45, 0.8), moderate quality evidence). For secondary prevention, in the Lyon Diet Heart Study (605 CVD patients), there was moderate quality evidence of a reduction in CVD mortality (HR 0.35 (95% CI 0.15, 0.82)) and total mortality (HR 0.44 (95% CI 0.21, 0.92)) with the intervention, over 46 months. For CVD risk factors, in primary prevention trials, there was low quality evidence for a possible small reduction in total cholesterol (−0.16 mmol/L (95% CI −0.32, 0.00), and moderate quality evidence for a reduction in SBP (−2.99 mmHg (95% CI −3.45, −2.53)) and DBP (−2.0 mmHg (95% CI −2.29, −1.71)). In secondary prevention trials, there was moderate quality evidence of no effect of a Mediterranean-style diet on lipid levels and low or very low quality evidence for blood pressure.

Conclusions: Despite the relatively large number of studies included in this review, there is still some uncertainty regarding the effects of a Mediterranean-style diet on clinical endpoints and CVD risk factors for both primary and secondary prevention. The ongoing studies may provide more certainty in the future.