Randomised controlled trial

PREDIMED trial: Mediterranean diet may reduce the risk of type 2 diabetes

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Context

The incidence of type 2 diabetes is increasing and has been associated with the Westernisation of dietary habits. The Mediterranean dietary pattern (Med diet) may be a way to reduce the incidence of type 2 diabetes. In a trial, it was shown to reduce the need for antidiabetic drugs in diabetic patients, and an epidemiological study suggested a lower incidence of diabetes with increasing adherence to the Med diet. However, its role in the prevention of diabetes has not been investigated so far in a randomised trial.

Methods

The Prevención con Dieta Mediterránea (PREDIMED) study is a three-arm randomised trial to assess the effects of two Med diets (supplemented with either olive oil or mixed nuts) versus a low-fat control diet on cardiovascular and other chronic disease outcomes, in participants at high cardiovascular risk aged 55–80 (men) and 60–80 (women). The primary outcome was the onset of de novo diabetes diagnosed according to the criteria of the American Diabetic Association, namely a fasting plasma glucose level >7 mmol/l or a 2 h plasma glucose level >11 mmol/l after a 75 g oral glucose load. Full details of the PREDIMED protocol are available at http://www.predimed.org. The participants assigned to the Med diet groups were advised to abundantly use olive oil for cooking and dressing; increase their consumption of fruit, vegetables, legumes and fish; reduce their consumption of meat; use garlic, onion and spices; and avoid butter, cream, fast food, sweets, pastries and sugar-sweetened drinks. They were given free allotments of either virgin olive oil (1 l/week) or mixed nuts (30 g/day). The participants assigned to the low-fat control group received recommendations to reduce all types of animal and vegetable fat. Only 870 participants met the inclusion criteria of the trial, among which 452 were excluded because of a prior diagnosis of diabetes. Thus, a total of 418 non-diabetic participants were randomly assigned into the three groups. The median follow-up was 4 years.

Findings

The three diets were well tolerated. No significant difference between groups was recorded for weight, physical activity and drug treatment during the whole study. Fifty-four individuals developed de novo diabetes. The incidence rate of diabetes per 1000 person-years was 24.6 (Med diet plus olive oil), 26.8 (Med diet plus nuts) and 46.6 for the control group. After adjustment for several confounders, the risk of de novo diabetes was reduced by more than 50% in the Med diet groups as compared with the low-fat group (p<0.05).

Commentary

There are limitations to this trial. The three groups were not exactly randomised as they were subgroups of non-diabetic participants extracted from larger groups. However, there was no difference in the major risk factors at baseline. Sample size was small, and there were only 54 cases of de novo diabetes. The difference between groups for the main outcome was borderline significant. Thus, the trial should be considered exploratory and to be confirmed. However, it is the first trial to show that a Med diet can have an effect on the risk of diabetes. In addition, a previous trial found a protective effect of the Med diet on cardiovascular complications, and a meta-analysis involving 534,906 individuals reported that this diet was associated with a significant reduction of metabolic syndrome, a pre-diabetes state. These data are of considerable relevance for public health. No other dietary pattern is apparently so effective in reducing the risks of diabetes and cardiovascular complications. It is therefore surprising that, when defining dietary recommendations to prevent chronic diseases, experts forget to mention the Med diet, sometimes distort the published data to discredit the concept, and put forward treatments which increase the risk of diabetes.

Competing interests None.

References

