

# Abstract

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## Effects of B vitamins and omega 3 fatty acids on cardiovascular diseases: a randomised placebo controlled trial.

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**OBJECTIVE:** To investigate whether dietary supplementation with B vitamins or omega 3 fatty acids, or both, could prevent major cardiovascular events in patients with a history of ischaemic heart disease or stroke.

**DESIGN:** Double blind, randomised, placebo controlled trial; factorial design.

**SETTING:** Recruitment throughout France via a network of 417 cardiologists, neurologists, and other physicians.

**PARTICIPANTS:** 2501 patients with a history of myocardial infarction, unstable angina, or ischaemic stroke.

**INTERVENTION:** Daily dietary supplement containing 5-methyltetrahydrofolate (560 µg), vitamin B-6 (3 mg), and vitamin B-12 (20 µg) or placebo; and containing omega 3 fatty acids (600 mg of eicosapentanoic acid and docosahexaenoic acid at a ratio of 2:1) or placebo. Median duration of supplementation was 4.7 years.

**MAIN OUTCOME MEASURES:** Major cardiovascular events, defined as a composite of non-fatal myocardial infarction, stroke, or death from cardiovascular disease.

**RESULTS:** Allocation to B vitamins lowered plasma homocysteine concentrations by 19% compared with placebo, but had no significant effects on major vascular events (75 v 82 patients, hazard ratio, 0.90 (95% confidence interval 0.66 to 1.23, P=0.50)). Allocation to omega 3 fatty acids increased plasma concentrations of omega 3 fatty acids by 37% compared with placebo, but also had no significant effect on major vascular events (81 v 76 patients, hazard ratio 1.08 (0.79 to 1.47, P=0.64)).

**CONCLUSION:** This study does not support the routine use of dietary supplements containing B vitamins or omega 3 fatty acids for prevention of cardiovascular disease in people with a history of ischaemic heart disease or ischaemic stroke, at least when supplementation is introduced after the acute phase of the initial event.

**TRIAL REGISTRATION:** Current Controlled Trials ISRCTN41926726.

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