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Randomized Controlled Trial [JAMA](#). 2006 Feb 8;295(6):655-66.

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Low-fat Dietary Pattern and Risk of Cardiovascular Disease: The Women's Health Initiative Randomized Controlled Dietary Modification Trial

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Abstract

Context: Multiple epidemiologic studies and some trials have linked diet with cardiovascular disease (CVD) prevention, but long-term intervention data are needed.

Objective: To test the hypothesis that a dietary intervention, intended to be low in fat and high in vegetables, fruits, and grains to reduce cancer, would reduce CVD risk.

Design, setting, and participants: Randomized controlled trial of 48,835 postmenopausal women aged 50 to 79 years, of diverse backgrounds and ethnicities, who participated in the Women's Health Initiative Dietary Modification Trial. Women were randomly assigned to an intervention (19,541 [40%]) or comparison group (29,294 [60%]) in a free-living setting. Study enrollment occurred between 1993 and 1998 in 40 US clinical centers; mean follow-up in this analysis was 8.1 years.

Intervention: Intensive behavior modification in group and individual sessions designed to reduce total fat intake to 20% of calories and increase intakes of vegetables/fruits to 5 servings/d and grains to at least 6 servings/d. The comparison group received diet-related education materials.

Main outcome measures: Fatal and nonfatal coronary heart disease (CHD), fatal and nonfatal stroke, and CVD (composite of CHD and stroke).

Results: By year 6, mean fat intake decreased by 8.2% of energy intake in the intervention vs the comparison group, with small decreases in saturated (2.9%), monounsaturated (3.3%), and polyunsaturated (1.5%) fat; increases occurred in intakes of vegetables/fruits (1.1 servings/d) and grains (0.5 serving/d). Low-density lipoprotein cholesterol levels, diastolic blood pressure, and

factor VIIc levels were significantly reduced by 3.55 mg/dL, 0.31 mm Hg, and 4.29%, respectively; levels of high-density lipoprotein cholesterol, triglycerides, glucose, and insulin did not significantly differ in the intervention vs comparison groups. The numbers who developed CHD, stroke, and CVD (annualized incidence rates) were 1000 (0.63%), 434 (0.28%), and 1357 (0.86%) in the intervention and 1549 (0.65%), 642 (0.27%), and 2088 (0.88%) in the comparison group. The diet had no significant effects on incidence of CHD (hazard ratio [HR], 0.97; 95% confidence interval [CI], 0.90-1.06), stroke (HR, 1.02; 95% CI, 0.90-1.15), or CVD (HR, 0.98; 95% CI, 0.92-1.05). Excluding participants with baseline CVD (3.4%), the HRs (95% CIs) for CHD and stroke were 0.94 (0.86-1.02) and 1.02 (0.90-1.17), respectively. Trends toward greater reductions in CHD risk were observed in those with lower intakes of saturated fat or trans fat or higher intakes of vegetables/fruits.

Conclusions: Over a mean of 8.1 years, a dietary intervention that reduced total fat intake and increased intakes of vegetables, fruits, and grains did not significantly reduce the risk of CHD, stroke, or CVD in postmenopausal women and achieved only modest effects on CVD risk factors, suggesting that more focused diet and lifestyle interventions may be needed to improve risk factors and reduce CVD risk.

Clinical trials registration: ClinicalTrials.gov Identifier: [NCT00000611](https://clinicaltrials.gov/ct2/show/study/NCT00000611).

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