

Low–Total-Fat Diet Did Not Reduce the Risk of Cardiovascular Events

Reviewed by Michael Pignone, MD, MPH

STUDY

Howard BV, Van Horn L, Hsia J, Manson JE, Stefanick ML, Wassertheil-Smoller S, Kuller LH, LaCroix AZ, Langer RD, Lasser NL, Lewis CE, Limacher MC, Margolis KL, Mysiw WJ, Ockene JK, Parker LM, Perri MG, Phillips L, Prentice RL, Robbins J, Rossouw JE, Sarto GE, Schatz IJ, Snetelaar LG, Stevens VJ, Tinker LF, Trevisan M, Vitolins MZ, Anderson GL, Assaf AR, Bassford T, Beresford SA, Black HR, Brunner RL, Brzyski RG, Caan B, Chlebowski RT, Gass M, Granek I, Greenland P, Hays J, Heber D, Heiss G, Hendrix SL, Hubbell FA, Johnson KC, Kotchen JM: Low-fat dietary pattern and risk of cardiovascular disease: the Women's Health Initiative Randomized Controlled Dietary Modification Trial. *JAMA* 295:655–666, 2006

SUMMARY

Design. The Women's Health Initiative Dietary Modification Trial (WHI DMT) was the largest single randomized trial to date examining the effects of a low-fat diet on health outcomes, including the incidence of cardiovascular events over 8 years in 48,835 women. WHI DMT compared the effect of intensive dietary counseling designed to reduce the intake of total fat to < 20% of daily caloric intake against conventional diet.

Subjects. Women aged 50–79 years were eligible to participate. Participants had to have a daily dietary fat intake of $\geq 32\%$ for entry, based on a food frequency questionnaire. The mean age of the participants was 62 years; 82% were

white, and 11% were African American. Only 26% had a BMI < 25 kg/m²; 38% had a BMI > 30 kg/m². Approximately 4% had previous cardiovascular disease, and 4% were receiving treatment for diabetes. More than 35% had metabolic syndrome as defined by the National Cholesterol Education Program Adult Treatment Panel III criteria, based on a 6% subsample of participants.

Methods. The intervention included 18 nutritionist-led group sessions in the 1st year and quarterly meetings thereafter. The group visits were supplemented by individual contacts by telephone or mail. The intervention focused on reductions in dietary fat and increases in consumption of fruits, vegetables, and grains. No specific attempts were made to change the types of fats consumed. The control group received a dietary advice booklet. Patients were followed for a mean of 8.1 years. The occurrence of cardiovascular events was monitored with regular (every 6 months) contacts. Records of any hospitalization or cardiac procedure were reviewed by blinded central adjudication physicians, using standardized criteria. Electrocardiograms were performed every 3 years as well. Follow-up was high, particularly for a rather long trial, and most (> 85%) of the women in the intervention continued their participation throughout the study.

Results. The WHI DMT found no reduction in the risk of coronary heart disease events (hazard ratio 0.97, 95% CI 0.90–1.06), stroke (1.02, 0.90–1.15), or a composite of both (0.98, 0.92–1.05). The total fat intake as

assessed by food frequency questionnaire at year 6 was reduced by 8.2% in intervention patients compared with control subjects. Saturated fat was reduced by 2.9%, and consumption of fruits or vegetables (1.1 servings per day) and grains (0.5 servings per day) also increased.

Conclusions. Intensive dietary counseling to promote a low–total-fat diet did not reduce cardiovascular events in healthy adults.

COMMENTARY

Associations between dietary patterns and risk of cardiovascular events have been an important topic for epidemiological and behavioral research, health policy, and clinical practice for the past 30 years. Ecological and observational studies have suggested that the intake of saturated fat and *trans* fats is associated with increased risk of cardiovascular events. Total dietary fat has been linked with an increased risk of certain cancers, although its relationship with cardiovascular risk is less strong than for saturated or *trans* fats.¹

Several previous randomized trials, most conducted in secondary prevention settings, have attempted to study whether interventions designed to reduce the intake of dietary fat reduce the risk of subsequent cardiovascular events.² They have reached mixed conclusions and are limited in the generalizability to the current U.S. adult population because of secular changes in dietary patterns and because several of the previous studies were conducted in very controlled settings (e.g., Veteran's Administration

nursing homes, psychiatric hospitals) where dietary choices were restricted.³

What then can we learn from the WHI DMT? First, it is difficult to reduce total fat intake. Even a very intensive, well-developed intervention applied to a volunteer population could only reduce dietary fat intake by 8%. These results are similar to other intensive counseling trials.³ Less-intensive interventions delivered in primary care settings produce even smaller changes on average. Whether other interventions to change dietary patterns through counseling, such as attempts to change the type of fat or carbohydrate intake or encourage fish consumption, are more effective remains unclear.

Secondly, the WHI DMT suggests that intensive dietary counseling to reduce total fat intake does not reduce the risk of cardiovascular events during a mean follow-up time of 8 years. In addition to the lack of benefit for cardiovascular events, the low-total-fat diet did not reduce the incidence of cancer, although the results for breast cancer did not rule out the possibility of a modest benefit.^{4,5} Weight decreased modestly (− 1.29 kg), as did diastolic blood pressure (− 0.31 mmHg). Whether other changes in dietary patterns could reduce cardiovascular events in primary prevention remains unclear. In secondary prevention, diets that change the ratio of saturated to unsaturated fats, such as the so-called Mediterranean Diet, appear to be effective in reducing cardiovascular events.⁶

A recent Cochrane review examined the evidence for different types of diet in patients with type 2 diabetes. It found

insufficient evidence to strongly recommend any single dietary pattern for weight loss or glycemic control in patients with diabetes.⁷ Current American Diabetes Association (ADA) recommendations support a diet low in saturated fats (< 7% of daily caloric intake) and *trans* fats, but they do not recommend a low-carbohydrate diet and do not recommend lowering total fat content to < 20–35%.⁸

How should this new study affect dietary recommendations for patients with diabetes? Patients with diabetes accounted for only 4.5% of participants in this trial, making it difficult to reach any firm conclusions. Given that limitation, the WHI DMT supports the current ADA recommendation of 20–35% of daily caloric intake from total fat. Efforts to change dietary behavior should focus on weight loss or maintenance and limiting the consumption of saturated or *trans* fats but should not focus on reducing total fat consumption. Further studies are needed to determine whether low-carbohydrate diets should be encouraged or discouraged.

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