

ARTICLE CITATION

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Low-fat dietary pattern and long-term breast cancer incidence and mortality: The Women's Health Initiative randomized clinical trial.

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Background: Observational studies of dietary fat intake and breast cancer have inconsistent findings. To address this issue, the Women's Health Initiative (WHI) Dietary Modification (DM) clinical trial assessed a low-fat dietary pattern influence on breast cancer incidence and outcome.

Methods: The WHI DM trial is a randomized, controlled clinical trial conducted at 40 US centers, where 48,835 postmenopausal women, aged 50-79 years, with no previous breast cancer and dietary fat intake $\geq 32\%$ of total energy, were randomly assigned, from 1993-1998, to a usual diet comparison group (60%) or dietary intervention group (40%) with goals to reduce fat intake to 20% of energy and increase vegetables, fruit, and grain intake. This study is registered as: NCT00000611.

Results: The dietary intervention significantly reduced fat intake; increased fruit, vegetable and grain intake with modest weight loss (3%) (all $P < 0.001$). During 8.5 years of dietary intervention, there were 8% fewer breast cancers and deaths from breast cancer were somewhat lower in the intervention group but the rates were not significantly different. However, deaths after breast cancer (breast cancer followed by death from any cause) were significantly reduced in the intervention group, both during intervention (hazard ratio [HR] 0.65 95% confidence interval [CI] 0.45-0.95) and through 16.1 year (median) cumulative follow-up. Now, after long-term, cumulative 19.6 year (median) follow-up, with 3,374 incident breast cancers, the significant reduction in deaths after breast cancer continued (with 1,011 deaths, HR 0.85 95% CI 0.74-0.96) and a significant reduction in deaths from breast cancer (breast cancer followed by death attributed to the breast cancer) emerged (with 383 deaths, HR 0.79 95% CI 0.64-0.97).

Conclusions: Adoption of a low-fat dietary pattern associated with increased vegetable, fruit, and grain intake, demonstrably achievable by many, significantly reduced the risk of death from breast cancer in postmenopausal women. To our review, these findings provide the first randomized clinical trial evidence that a dietary change can reduce a postmenopausal woman's risk of dying from breast cancer. [Clinical trial information: NCT00000611.](#)

