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Original Contribution

Low-Fat Dietary Pattern and Risk of Invasive Breast Cancer

The Women's Health Initiative Randomized Controlled Dietary Modification Trial

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Context The hypothesis that a **low-fat** dietary pattern can reduce breast cancer risk has existed for decades but has never been tested in a controlled intervention trial.

Objective To assess the effects of undertaking a **low-fat** dietary pattern on breast cancer incidence.

Design and Setting A randomized, controlled, primary prevention trial conducted at 40 US clinical centers from 1993 to 2005.

Participants A total of 48 835 postmenopausal women, aged 50 to 79 years, without prior breast cancer, including 18.6% of minority race/ethnicity, were enrolled.

Interventions Women were randomly assigned to the dietary modification intervention group (40% [n = 19 541]) or the comparison group (60% [n = 29 294]). The intervention was designed to promote dietary change with the goals of reducing intake of total **fat** to 20% of energy and increasing consumption of vegetables and fruit to at least 5 servings daily and grains to at least 6 servings daily. Comparison group participants were not asked to make dietary changes.

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Main Outcome Measure Invasive breast cancer incidence.

Results Dietary **fat** intake was significantly **lower** in the dietary modification intervention group compared with the comparison group. The difference between groups in change from baseline for percentage of energy from **fat** varied from 10.7% at year 1 to 8.1% at year 6. Vegetable and fruit consumption was higher in the intervention group by at least 1 serving per day and a smaller, more transient difference was found for grain consumption. The number of women who developed invasive breast cancer (annualized incidence rate) over the 8.1-year average follow-up period was 655 (0.42%) in the intervention group and 1072 (0.45%) in the comparison group (hazard ratio, 0.91; 95% confidence interval, 0.83-1.01 for the comparison between the 2 groups). Secondary analyses suggest a **lower** hazard ratio among adherent women, provide greater evidence of risk reduction among women having a high-**fat** diet at baseline, and suggest a dietary effect that varies by hormone receptor characteristics of the tumor.

Conclusions Among postmenopausal women, a **low-fat** dietary pattern did not result in a statistically significant reduction in invasive breast cancer risk over an 8.1-year average follow-up period. However, the nonsignificant trends observed suggesting reduced risk associated with a **low-fat** dietary pattern indicate that longer, planned, nonintervention follow-up may yield a more definitive comparison.

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

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