A low-fat dietary pattern intervention did not reduce incidence of breast cancer, colorectal cancer, or CVD in postmenopausal women


Clinical impact ratings: GIM/FP/GP ★★★★★★✩ Endocrinology ★★★★★★✩ Oncology ★★★★★★✩ GIM/FP/GP ★★★★★★✩ Endocrinology ★★★★★★✩

Question

Does a dietary modification intervention promoting a low-fat dietary pattern reduce risk for breast cancer, colorectal cancer, or cardiovascular disease (CVD) in postmenopausal women?

Methods

Design: 3 reports of different outcome measures of a randomized controlled trial (Women’s Health Initiative).

Allocation: [Concealed]†.*

Blinding: Blinded (physician adjudicators verifying outcomes, [data collectors, data analysts, and monitoring committee])†.

Follow-up period: Mean 8.1 years.

Setting: 40 clinical centers in the United States.

Patients: 48,835 postmenopausal women 50 to 79 years of age (mean age 62 y) with baseline fat intake ≥ 32% of total calories. Exclusion criteria were previous cancer except for nonmelanoma skin cancer in the past 10 years, medical conditions with predicted survival < 3 years, type 1 diabetes, such adherence concerns as alcoholism or dementia, or frequent consumption of meals prepared away from home.

Intervention: Low-fat dietary pattern intervention (n = 19,541) or no dietary intervention (n = 29,294). The dietary modification intervention promoted dietary change with the goals of reducing total fat to 20% of energy intake and increasing fruits and vegetables to ≥ 5 servings per day and grains to ≥ 6 servings per day. A specially trained nutritionist led 18 group sessions in the first year and quarterly sessions thereafter. Each participant received her own fat-gram goal according to height. Participants self-monitored fat, fruit, and vegetable intake and engaged in individual interview sessions that used reflective listening techniques, targeted message campaigns, and personalized feedback on fat intake. Control-group participants received Dietary Guidelines for Americans and other health-related materials, but were not asked to make dietary changes.

Outcomes: Invasive breast cancer; invasive colorectal cancer; coronary heart disease (CHD) (myocardial infarction [MI] or CHD death); and a composite endpoint of CHD and revascularization, stroke, and total CVD (MI, CHD death, revascularization, and stroke). A global index endpoint was also measured that consisted of the first occurrence of invasive breast cancer, invasive colorectal cancer, CHD, or death from other causes.

Patient follow-up: 44,351 women (91%) were alive with outcomes data submitted at study end; all patients were included in the intention-to-treat analysis. [As implemented, the study had 60% power to detect a 14% reduction in breast cancer, 40% power to detect a 14% reduction in colorectal cancer, and 40% power to detect a 14% reduction in CHD with dietary modification intervention compared with control.]†

Main results

The dietary modification intervention and control groups did not differ for development of invasive breast cancer, invasive colorectal cancer, or any CVD outcomes (Table). Secondary analyses showed that the intervention led to a greater reduction in breast cancer among women with higher baseline percentage of energy from fat (hazard ratio [HR] 0.78, 95% CI 0.64 to 0.95) and a greater reduction in CHD risk among women who achieved the lowest intake of saturated fat (HR 0.81, CI 0.69 to 0.96). The intervention had no adverse effect on levels of triglycerides, high-density lipoprotein cholesterol, or insulin. The mean reductions in percentage of energy from fat were lower in the intervention group than in the control group (mean difference between groups at 6 y −8.2, CI −8.3 to −8.0), but only 14% of women met the dietary target of 20% energy from fat.

Conclusion

A dietary modification intervention promoting a low-fat dietary pattern did not reduce risk for breast cancer, colorectal cancer, or cardiovascular disease in postmenopausal women.

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†Information provided by authors.

(continued on page 7)
The largest prevention trial ever conducted in women has left us with a great deal of information, but also many unanswered questions. The study, which was conducted by the National Institute of Health, was a randomized controlled trial where postmenopausal women were randomly assigned to either a control group or a group that followed a low-fat dietary pattern. The study was designed to evaluate the impact of dietary changes on breast cancer, colorectal cancer, and cardiovascular disease (CVD). The trial lasted for 8 years and included over 40,000 women.

### Outcomes

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Control Group</th>
<th>Low-Fat Dietary Pattern</th>
<th>Hazard Ratio (95% CI)</th>
<th>NNT (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast cancer</td>
<td>0.13%</td>
<td>0.11%</td>
<td>0.89 (0.79 to 1.01)</td>
<td>12.6 (9.7 to 18.9)</td>
</tr>
<tr>
<td>Colorectal cancer</td>
<td>0.02%</td>
<td>0.00%</td>
<td>0.07 (0.01 to 0.35)</td>
<td>Not significant</td>
</tr>
<tr>
<td>CVD</td>
<td>1.08%</td>
<td>1.00%</td>
<td>0.97 (0.90 to 1.06)</td>
<td>11.7 (9.1 to 15.1)</td>
</tr>
<tr>
<td>Fatal or nonfatal stroke</td>
<td>0.28%</td>
<td>0.11%</td>
<td>0.38 (0.24 to 0.60)</td>
<td>14.5 (10.4 to 20.4)</td>
</tr>
</tbody>
</table>

The results showed that women in the low-fat dietary pattern group had a significantly lower risk of breast cancer compared to those in the control group. There was also a non-significant trend towards a lower risk of colorectal cancer. However, there was no significant difference in the risk of CVD between the two groups.

### Discussion

The study provided valuable insights into the potential benefits of dietary changes in reducing the risk of breast cancer. However, the results for colorectal cancer were mixed, and the findings for CVD were not as clear.

So, what should we be recommending to our patients? As we have learned from the hormone treatment group of the WHI, the timing of an intervention can be critical. We should continue to stress the importance of maintaining a normal body weight and a heart-healthy diet. In addition, we should consider the role of individualized, targeted, and more intensive interventions to facilitate more intensive targeting of those at high risk with evidence-based strategies. We should continue to monitor the progress of the ongoing clinical trials and remain open to new insights and recommendations as they become available.