

A diet low in fat and high in vegetables, fruit, and fiber following breast cancer treatment did not reduce new breast cancer events

Pierce JP, Natarajan L, Caan BJ, et al. Influence of a diet very high in vegetables, fruit, and fiber and low in fat on prognosis following treatment for breast cancer: the Women's Healthy Eating and Living (WHEL) randomized trial. *JAMA*. 2007;298:289-98. 17635889

Clinical impact ratings: GIM/FP/GP ★★★★★☆☆

QUESTION

In women previously treated for early-stage breast cancer, does a diet low in fat and high in vegetables, fruit, and fiber reduce risk for recurrent or new primary breast cancer and all-cause mortality?

METHODS

Design: Randomized controlled trial (The Women's Healthy Eating and Living [WHEL] Study).

Allocation: {Concealed}†.*

Blinding: Blinded {participants, clinicians, data collectors, outcome assessors, data safety monitoring committee, and manuscript writers}†.*

Follow-up period: Mean 7.3 years.

Setting: 7 clinical sites {in the United States}†.

Patients: 3088 women 18 to 70 years of age (mean age 53 y, 85% white) who were diagnosed with primary operable invasive breast cancer in the past 4 years, had axillary dissection and total mastectomy or lumpectomy following primary breast radiation, no current or planned chemotherapy, no recurrent or new breast cancer since completing initial treatment, and no other cancer in the past 10 years.

Intervention: Dietary ($n = 1537$) or comparison ($n = 1551$) intervention. The dietary intervention consisted of telephone counsel-

ing, 12 cooking classes, and monthly newsletters. Telephone counseling comprised 3 phases: phase 1 (3 to 8 calls in 4 to 6 wk) focused on building self-efficacy to reach daily targets of 5 vegetable servings, vegetable juice (16 oz), 3 fruit servings, fiber (30 g), and 15% to 20% of energy intake from fat; phase 2 (to 5 mo) focused on self-monitoring and dealing with barriers to adherence; phase 3 (to end of study) focused on keeping motivated and preventing setbacks. The comparison group was given printed guidelines for the 5-A-Day diet (5 servings of vegetables and fruit, > 20 g fiber, and < 30% energy intake from fat), was offered cooking classes, and received newsletters.

Outcomes: A composite endpoint of recurrent (local, regional, or distant metastasis but not carcinoma in situ) or new primary breast cancer and all-cause mortality. The study had 82% power to detect a 19% reduction in additional breast cancer events in the dietary

group and a 24% reduction in all-cause mortality.

Patient follow-up: 99% (intention-to-treat analysis).

MAIN RESULTS

At a mean 7.3 years, groups did not differ for the composite endpoint or all-cause mortality (Table).

CONCLUSION

A diet low in fat and high in vegetables, fruit, and fiber did not reduce risk for recurrent or new primary breast cancer and all-cause mortality in women previously treated for early-stage breast cancer.

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*See Glossary.

†Information provided by author.

A dietary (low-fat; high in vegetables, fruit, and fiber) vs comparison intervention in women previously treated for early-stage breast cancer‡

Outcomes at a mean 7.3 years	Dietary	Comparison	RRR (95% CI)	NNT
Composite endpoint [§]	17%	17%	3.7% (-13 to 18)	Not significant
All-cause mortality	10%	10%	8.6% (-14 to 27)	Not significant

‡Abbreviations defined in Glossary. RRR, NNT, and CI calculated from control event rates and adjusted hazard ratios in article.

§Local (dietary vs comparison = 2.3% vs 1.8%), regional (0.7% vs 0.6%), distal (11% vs 12%), or new primary (2.8% vs 2.3%) breast cancer.

COMMENTARY

Unlike the Women's Intervention Nutrition Study (WINS), which reported improved relapse-free survival (RFS) in the low-fat diet group (1), the WHEL study found no benefit of a dietary intervention. WINS included women within the first year of breast cancer diagnosis, and improvement in RFS was more pronounced in the hormone receptor–negative group, a group that is at increased risk for early relapse (1). Interactions between the dietary group and estrogen receptor status and time from diagnosis to randomization were not statistically significant in the WHEL study. However, WHEL study participants could be enrolled up to 4 years from diagnosis (median 23.5 mo); therefore, some women who might have benefited from an intervention would have been excluded because they had already relapsed.

A dietary intervention might be more beneficial in decreasing risk for incident breast cancer. Modifying diet in women who have already been diagnosed with cancer and received optimal local and systemic treatment (e.g., long-term endocrine manipulations) might not provide additional benefits. To better evaluate the effect of a healthy diet on breast cancer risk, women would need to be given this intervention earlier in life. Indeed, epidemiologic data suggest that a healthy diet during puberty and pregnancy might decrease risk for breast cancer (2).

Women enrolled in the WHEL study already consumed a reasonable diet compared with the general population. Therefore, a stricter diet resulting in weight loss (as observed in WINS) combined with other lifestyle modifications, such as exercise, might have been needed to reduce breast cancer events. Women should be encouraged to include a balanced diet and regular exercise as part of an overall healthy lifestyle, regardless of whether they have had breast cancer (3).

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