

National Heart, Lung, and Blood Institute (NHLBI)

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News from the Women's Health Initiative: Reducing Total Fat Intake May Have Small Effect on Risk of Breast Cancer, No Effect on Risk of Colorectal Cancer, Heart Disease, or Stroke

Following an eating pattern lower in total fat did not significantly reduce the incidence of breast cancer, heart disease, or stroke, and did not reduce the risk of colorectal cancer in healthy postmenopausal women, according to the latest clinical trial results from the National Institutes of Health's Women's Health Initiative (WHI).

The study was designed to evaluate a low-fat dietary pattern's effect on the risk of cancer. However, investigators also evaluated the data to review the effect on cardiovascular disease. The results from the largest ever clinical trial of low-fat diet are reported in three papers in the February 8 edition of the *Journal of the American Medical Association*.

Among the 48,835 women who participated in the trial, there were no significant differences in the rates of colorectal cancer, heart disease, or stroke between the group who followed a low-fat dietary plan and the comparison group who followed their normal dietary patterns. Although the women in the study who reduced their total fat intake had a 9 percent lower risk of breast cancer than did women who made no dietary changes, the difference was not large enough to be statistically significant — meaning it could have been due to chance.

By the end of the first year, the low-fat diet group reduced average total fat intakes to 24 percent of calories from fat, but did not meet the study's goal of 20 percent. At year six, the low-fat diet group was consuming 29 percent of calories from fat. The comparison group averaged 35 percent of calories from fat at year one and 37 percent at year six. Women in both groups started at 35-38 percent of calories from fat. The low fat diet group also increased their consumption of vegetables, fruits, and grains.

Women were aged 50-79 at trial enrollment in 1993-98 and were followed for an average of 8.1 years. The study diet focused on reducing total fat, and unlike diets used to reduce heart disease risk, did not differentiate between "good fats" found in fish, nuts, and vegetable oils, and "bad" fats like saturated fat and *trans* fat found in processed foods, meats, and some dairy products. The study design reflected a widely believed but untested theory that reduction of total fat would reduce risks of breast or colorectal cancers. For heart disease, it was anticipated that reduction in total fat would be accompanied by a reduction in saturated fats, which are known to contribute to heart disease risk.

"The results of this study do not change established recommendations on disease prevention. Women should continue to get regular mammograms and screenings for colorectal cancer, and work with their doctors to reduce their risks for heart disease including following a diet low in saturated fat, *trans* fat and cholesterol," said National Heart, Lung, and Blood Institute Director Elizabeth G. Nabel, M.D.

The U.S. Dietary Guidelines for Americans recommend that adults keep total fat intake between 20 and 35 percent of calories, and saturated fats less than 10 percent of calories, with most fats coming from sources of polyunsaturated fats and monounsaturated fats, such as fish, nuts, and vegetable oils. For people with heart disease or at high risk for heart disease, targets for saturated fats may be further lowered.

"This study shows that just reducing total fat intake does not go far enough to have an impact on heart disease risk. While the participants' overall change in LDL "bad" cholesterol was small, we saw trends towards greater reductions in cholesterol and heart disease risk in women eating less saturated and *trans* fat," said Jacques Rossouw, M.D., WHI project officer.

The study also found that following a high-carbohydrate, low-fat eating pattern does not increase body weight, triglycerides or indicators of increased risk of diabetes such as blood glucose or insulin levels in women.

"Study data indicate that women who started with the highest fat intake and who had greater changes in fat intake, show stronger evidence for reduction in their risk of breast cancer. Longer follow-up may be needed to show the effects of diet on cancer risk over time," said Leslie G. Ford, M.D., National Cancer Institute.

Though the overall risk of colorectal cancer was unchanged in the dietary trial, secondary analyses suggested a possible benefit in women who were taking aspirin or combined hormone therapy (estrogen plus progestin); however, these findings could have occurred by chance. Polyps and adenomas (thought to be precursors of cancer) were reduced by 9%, suggesting that a benefit for colorectal cancer risk might emerge over time.

The WHI is the most comprehensive study to date of the causes and prevention of the major diseases affecting the health of older women. Over 15 years, the study's findings on heart disease, breast and colorectal cancer, and osteoporosis have stimulated many changes in clinical practice. The WHI is also one of the largest studies of its kind ever undertaken in the United States and is considered a model for future studies of women's health.

This study of low-fat dietary pattern is one of the three randomized clinical trials that make up the WHI. The others included trials of hormone therapy — estrogen plus progestin and estrogen alone. Both trials were stopped early, estrogen plus progestin in 2002 and estrogen alone in 2004 because of increased risk of diseases like stroke, blood clots, and breast cancer. Results of a third clinical trial studying the effects of calcium and Vitamin D supplementation on osteoporosis-related bone fractures and on colorectal cancer will be published in February 2006.

Resources:

- For current recommendations on eating patterns for heart health, please see the new Your Guide to a Healthy Heart book available at http://emall.nhlbihin.net/.
- For information on women and heart disease, see www.hearttruth.gov.
- For information on weight loss, see Aim for a Healthy Weight, http://www.nhlbi.nih.gov/health/public/heart/obesity/lose_wt/index.htm
- For information on eating for general health, see www.health.gov/dietary guidelines/dga2005/recommendations.htm
- For more on the Women's Health Initiative, see http://www.nhlbi.nih.gov/whi/

To interview a scientist about this study, contact the NHLBI Communications Office at (301) 496-4236.

WHI — a Legacy to Future Generations, a conference on the past, present, and future of WHI, including synthesis of findings generated from the WHI observational study and all four clinical trials — estrogen plus progestin (http://www.nhlbi.nih.gov/new/press/02-07-09.htm), estrogen alone (http://www.nhlbi.nih.gov/new/press/04-04-13.htm), dietary modification, and calcium/vitamin D — will be held February 28-March 1, 2006 on the NIH campus. For more information and a conference agenda, go to: http://www.nhlbi.nih.gov/whi.htm. For more information on the Women's Health Initiative, see http://www.nhlbi.nih.gov/whi.htm.

NHLBI is part of the National Institutes of Health (NIH), the Federal Government's primary agency for biomedical and behavioral research. NIH is a component of the U.S. Department of Health and Human Services. NHLBI press releases and other materials including information about the WHI and eating for heart health are available online at

www.nhlbi.nih.gov.

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