

Long-term follow-up reports key findings and clinical messages from largest study of women's health in the US

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Researchers from the Brigham and colleagues report on the long-term follow-up of the largest study of women's health in the U.S., shedding



light on the role of menopausal hormone therapy, calcium and vitamin D supplementation, and a low-fat dietary pattern among postmenopausal women

More than 1.1 billion women worldwide are postmenopausal. A review paper by authors from Brigham and Women's Hospital and other leading experts from across the country helps to answer some of the most pressing questions in <u>postmenopausal women</u>'s health and to fill key knowledge gaps to improve health after menopause.

Leveraging data from The Women's Health Initiative (WHI), the authors present guidance about <u>menopausal hormone therapy</u> (HT), calcium and vitamin D supplementation, and low-fat dietary pattern. The review paper is <u>published</u> in *JAMA*.

Based on long-term WHI follow-up (up to 20 years), the researchers report that younger women (below age 60) had lower rates of adverse events and a more favorable benefit-to-risk ratio of HT than women in later menopause. Although HT should not be used to prevent <u>heart</u> <u>disease</u>, stroke, dementia, or other chronic diseases, the WHI findings support its use in early menopause for treatment of moderate-to-severe hot flashes, night sweats, and other menopausal symptoms, which is an FDA-approved indication.

"The WHI findings should never be used as a reason to deny hormone therapy to women in early menopause with bothersome menopausal symptoms. Many women are good candidates for treatment and, in shared decision making with their clinicians, should be able to receive appropriate and personalized health care for their needs," said JoAnn Manson, MD, Chief of Preventive Medicine at Brigham and Women's Hospital and first author of the new report in *JAMA*.

Manson added, "Women also have more options for treatment now,



including estrogen in lower doses and delivered through the skin as a patch or gel, which may further reduce risks; non-hormonal treatments are also available."

Regarding calcium and vitamin D supplements, WHI results do not support routinely recommending these supplements for fracture prevention in all postmenopausal women. However, calcium and vitamin D supplements are appropriate to fill nutritional gaps for women who do not meet national guidelines for intakes of these nutrients through diet.

Finally, a low-fat dietary pattern with increased fruit, vegetable, and grain intake did not reduce the risk of breast or colorectal cancer but was associated with a lower risk of breast cancer mortality more than a decade after the trial ended.

"A dietary pattern low in fat and high in fruits, vegetables, and grains showed benefits for reducing deaths from breast cancer in long-term follow-up, offering an option for women seeking to reduce these risks," said Manson.

The Brigham's Division of Preventive Medicine was one of the vanguard centers for the WHI, which included multi-center, randomized trials initiated by the National Institutes of Health. The WHI, the largest study of women's health in the U.S., enrolled more than 160,000 postmenopausal women aged 50–79 in studies to prevent heart disease, cancer (especially breast and colorectal cancer), and hip fractures.

More than 68,000 women enrolled in randomized <u>clinical trials</u> to test the health effects of menopausal HT, calcium plus vitamin D supplementation, and low-fat dietary modification. The WHI observational study addressed a wide range of questions related to healthy aging and chronic disease prevention.



When the WHI began recruitment in 1993, observational studies had reported that postmenopausal women who took HT had lower risks of heart disease, stroke, dementia, other chronic diseases, and all-cause mortality than women not taking HT.

"In the early 1990s, nearly 15 million U.S. women received HT prescriptions each year and HT was often (and increasingly) prescribed to try to prevent cardiovascular disease and other chronic diseases among women in both early and late menopause, whether or not the patient had hot flashes or other menopausal symptoms," said Manson.

"However, no randomized trials had been done in postmenopausal women to evaluate the benefits and risks of HT for chronic disease prevention. Ironically, the only randomized trial of estrogen had been done in men."

The WHI tested the most used formulations of HT at the time. The study was not designed to evaluate HT for treatment of hot flashes or other <u>menopausal symptoms</u> because those benefits of HT were already well-established; and this was an FDA-approved indication for use.

Calcium and vitamin D supplements were studied in the WHI because they had been previously tested primarily in populations with osteoporosis or low bone mineral density, and no prior clinical trial had evaluated their benefits and risks among postmenopausal women with typical fracture risk.

A low-fat dietary pattern was tested because observational studies suggested that people with higher intake of dietary fat and fewer fruits and vegetables had higher rates of breast and <u>colorectal cancer</u>.

"This new WHI report, for the first time, provides clinical messages for health care providers and for the general public from the long-term



follow-up of all of the trials," said Manson.

More information: JoAnn Manson et al, The Women's Health Initiative randomized trials and clinical practice: A review. *JAMA* (2024). <u>DOI: 10.1001/jama.2024.6542</u>.

Provided by Brigham and Women's Hospital

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