

The WHI Study: Why So Much Confusion About Hormone Therapy?

Women's Wellness Center | Columbia Hormone Health

Background

- By the late 1990s, hormone therapy was widely recommended after menopause because of proven benefits for the heart, brain, bones, and relief of a wide range of menopausal symptoms.
 - Then, in 2002, a large government study — the **Women's Health Initiative (WHI)** — made global headlines claiming that hormone therapy increased **breast cancer, heart attacks, and dementia**.
 - In response, the FDA in 2003 required a “black box” warning on all menopausal hormone therapy products, cautioning of serious risks. This decision—**based on flawed and misinterpreted data**—created over two decades of fear and confusion among patients and clinicians.
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What We Later Learned

WHI's conclusions were **misleading and poorly reported**. Here's what the data really showed:

Breast Cancer

- The WHI claimed a “26% increase” in breast cancer — but that meant an absolute incidence of **less than 1 extra case per 1,000 women per year**, a difference that *is not statistically significant*.
- Later analysis found, of the subjects in the “non-hormone” group who had been using hormone therapy before the study, there were **fewer cancers** than expected, meaning **prior hormone use may have been protective**. This correction received little media coverage.
- As subjects have continued to be monitored, data revealed that for those who used hormone therapy during the study, there were **fewer cancers and lower mortality** during the next 20 years of follow up.

Heart Disease

- The reported increase in heart attack and stroke occurred only in **older women (ages 60–79)** who already had pre-existing heart disease.
- Women who started hormone therapy **around menopause (ages 50–59)** had **lower rates of heart attack and stroke** than non-users.

Dementia

- The WHI's claim of increased dementia was also misleading.
 - The increase was only in women **age 75 and older**, many with early cognitive decline before the study.
 - Women who began hormone therapy **in their 50s** had up to **50% lower risk** of neurodegenerative disease (Dementia, Parkinson's, Multiple Sclerosis, etc).
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The Real Story

- The WHI's flawed design and inaccurate reporting of the data caused many years of confusion and fear about hormone therapy, resulting in millions to be denied access.
 - In reality, evidence shows that **starting hormone therapy near menopause** provides major health benefits, and is safe to begin even long after menopause, when appropriately prescribed and monitored.
 - Now, after extensive review and testimony from leading experts, the FDA has announced it will **remove the black box warning**, acknowledging that the original claims were **inaccurate and misleading**. This long-overdue correction represents an important step toward restoring confidence in the safety and benefits of hormone therapy for women.
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At Women's Wellness Center, we are dedicated to helping women make informed, confident decisions about their health. Our team specializes in safe, individualized hormone therapy that supports long-term wellness, vitality, and quality of life.
