



Background and Overview of the Women's Health Initiative

The Women's Health Initiative (WHI) represents:

- A landmark in women's health research, which was mandated by Congress in 1991 and was launched operationally in 1992.
- The largest, most definitive long-term study of postmenopausal women's health ever undertaken in the United States.
- A multi-million dollar, 15-year project, sponsored by the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH).
- Over 161,000 postmenopausal women enrolled at 40 clinical centers across the nation.
- A Clinical Trial and Observational Study that addresses inequities in women's health research and focuses on major causes of death and disability in postmenopausal women.
- Participation of women from racial/ethnic minority groups in proportion to their representation in the general population.
- Findings that provide practical information to women and their physicians about the effects of hormone therapy, dietary patterns, and calcium/vitamin D supplementation in the prevention of chronic diseases.





Women's Health Initiative Enrollment

Hormone Therapy (HT)	27,347
Dietary Modification (DM)	48,835
Calcium/Vitamin D (CaD)	36,282
Clinical Trial (CT) Total*	68,132
Observational Study (OS)	93,676
WHI TOTAL	161,808

*Reflects total HT/DM overlap of 8050; HT and DM participants are invited to join the CaD at their first annual visit.

Age Distribution by WHI Study Component

Age (years)	Hormone Therapy	Dietary Modification	Calcium and Vitamin D	Clinical Trial	Observational Study
50-54	3,425	6,961	5,153	9,188	12,381
55-59	5,413	11,037	8,269	14,661	17,329
60-69	12,360	22,715	16,519	31,389	41,200
70-79	6,154	8,122	6,341	12,894	22,766



Race/Ethnicity by WHI Study Component

Racial/Ethnic Group	Hormone Therapy	Dietary Modification	Calcium and Vitamin D	Clinical Trial	Observational Study
American Indian/ Alaska Native	130	202	149	292	421
Asian/Pacific Islander	527	1,105	721	1,519	2,671
Black/African American	2,738	5,262	3,315	6,983	7,635
Hispanic/Latina	1,537	1,845	1,502	2,875	3,609
White	22,030	39,762	30,155	55,525	78,016
Unknown	385	659	440	938	1,324





A New Era in Women's Health: The Women's Health Initiative

Historically, research on women's health lagged far behind health studies in men. In response to the crucial need for the involvement of women in medical research, the NIH in 1990 established the Office of Research on Women's Health (ORWH). The earliest undertakings of the ORWH included the development of a research agenda to identify and address gaps in scientific knowledge of women's health and to strengthen and revitalize already existing NIH guidelines and policies for the inclusion of women and minorities in clinical studies.

At the same time, research on the major causes of morbidity and mortality in postmenopausal women was identified as an important gap in health research. Many of the largest studies of heart disease did not include women, despite the fact that heart disease is the number one cause of death in women overall. These studies were aimed at prevention of early heart attacks and were thus focused on men, in whom heart disease manifests approximately ten years earlier than women. With the growing scientific interest in research on women's health, Dr. Bernadine Healy, then director of the NIH, launched the WHI in April 1991.





How was the WHI conducted?

The WHI had two study components: a randomized, controlled clinical trial and an observational study.

The **Clinical Trial (CT)** enrolled 68,132 postmenopausal women between the ages of 50-79. The CT has three separate components, and eligible women could join one, two, or all three of these components:

- **Dietary Modification Trial (DM):** The DM component evaluated the effect of a low-fat, high fruit, vegetable and grain diet on the prevention of breast and colorectal cancer and heart disease. DM participants followed either their usual dietary pattern or a low-fat dietary program. 48,835 women enrolled in this component.
- **Calcium and Vitamin D Supplementation Trial (CaD):** Women who were already enrolled in the Clinical Trial could join the CaD component 1 to 2 years later. The CaD evaluated the effect of calcium and vitamin D supplementation on the prevention of osteoporosis-related fractures and colorectal cancer. The 36,282 women in this component took calcium and vitamin D pills or a placebo.
- **Hormone Therapy Trials (HT):** This component involved two separate trials of hormone therapy for women who had an intact uterus (Estrogen plus Progestin Trial) or a previous hysterectomy (Estrogen Alone Trial) when they joined the WHI. The HT examined the effects of hormone therapy on the prevention of heart disease and osteoporosis and any associated risk for breast cancer. Women participating in this component took hormone pills or a placebo (inactive pill). A total of 27,347 women enrolled in this component. The interventions in both trials were stopped early, although participants continued to provide information about their health. The 2002 findings from the Estrogen plus Progestin Trial and the 2004 findings from the Estrogen Alone Trial reverberated throughout the world and changed health care practice for postmenopausal women.

The **Observational Study (OS)** tracked the medical history and health habits of 93,676 women who were not receiving a WHI intervention. The OS examined the relationship between lifestyle, health and risk factors and specific disease outcomes.

Recruitment for the WHI was carried out at 40 clinical centers across the United States between 1993 and 1998. The WHI Clinical Coordinating Center was at Fred Hutchinson Cancer Research Center in Seattle, WA. Women who chose to “be part of the answer” and join the WHI were followed for 8 to 12 years. Study participants had the personal satisfaction of knowing that they contributed to knowledge benefiting the health of women for generations to come.

All WHI study components ended March 31, 2005, although most participants have agreed to be followed for an additional 5 years, through 2010, in the WHI Extension Study.



Why WHI?

The WHI is focusing on the major causes of death and disability in postmenopausal women. The overall goal of WHI is to reduce coronary heart disease, breast and colorectal cancer, and osteoporotic fractures among postmenopausal women via prevention strategies and risk factor identification.

Scientific knowledge about preventing and treating of heart disease, breast and colorectal cancer, and fractures from osteoporosis in postmenopausal women has been insufficient. Research findings about successful prevention strategies for these conditions, the primary outcomes of the WHI, have major public health implications when one considers the following health statistics:

HEART DISEASE:

- Leading cause of death in postmenopausal women.
- Over 240,000 women die of heart attacks each year.
- Approximately half of all coronary deaths each year occur in women.
- Occurs 10 years later in women, but once heart disease develops, the prognosis may be worse for women than for men
- Long-term clinical trials on hormone replacement therapy and risk of coronary heart disease among women have been lacking.

BREAST CANCER:

- Most common cancer in U.S. women; 1 in 8 women will develop breast cancer in their lifetime
- 2nd leading cause of cancer deaths in U.S. women; over 46,000 women die of breast cancer each year.
- Cause is still unknown, and about two-thirds of breast cancers are not associated with a known risk factor
- Inconclusive data on dietary fat intake and breast cancer.
- Inconsistent data on hormones and breast cancer risk.

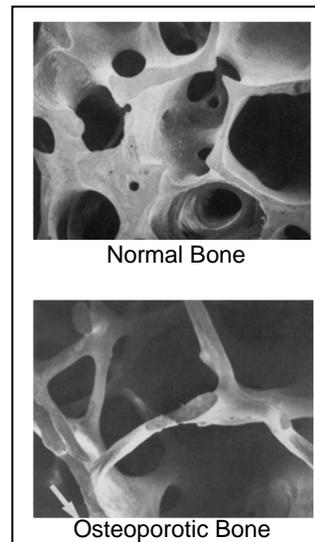


COLORECTAL CANCER:

- Third most common cancer in U.S. women with over 70,000 cases diagnosed each year.
- Third leading cause of cancer deaths in U.S. women; over 28,000 women die of colorectal cancer each year.
- Observational studies have suggested higher calcium and Vitamin D intake may decrease risk of colorectal cancer, however limited trial data are available.
- Mortality rates increase with age
- Prevention relies primarily on early detection

OSTEOPOROSIS:

- One-sixth of all women will have a hip fracture during their lifetime.
- Hospitalized hip fracture has up to a 30% mortality rate
- Osteoporotic fractures contribute to increased disability and lessen the quality of life in older women.
- Hip fractures are more common than the combined risk of breast, uterine, and ovarian cancer.
- Fractures occur more frequently in women than men (3-4 times more) in those over 50 years of age.
- Limited trial data have been available for women on effect of calcium and Vitamin D on fracture risk.



STROKE:

- About 3 million women in the U.S. today are stroke survivors; over 100,000 women die each year of stroke.
- Because women live longer than men, more women than men die of stroke each year – of every 5 deaths from stroke, 2 are in men and 3 are in women.
- One-fourth of women who have an initial stroke die within a year.
- Risk factors for stroke are similar to those for heart disease, including high blood pressure, smoking, and diabetes.



WHI Recruitment Brochures

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ANSWER



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WHI Timeline

October 1992

WHI Clinical Coordinating Center named

March 1993

Vanguard Clinical Centers (1st 16 study centers) named

December 1993

First Clinical Trial (Dietary Modification/Hormone Therapy Trials) participant randomized

September 1994

New Clinical Centers (2nd 24 study centers) named
First Observational Study participant enrolled

June 1995

First Calcium and Vitamin D Trial participant randomized

August 1998

Last Dietary Modification Trial participant randomized

September 1998

Last Hormone Therapy Trials participant randomized

December 1998

Last Observational Study participant enrolled

September 2000

Last Calcium and Vitamin D Trial participant randomized

July 2002

Estrogen plus Progestin Trial study pills stopped

March 2004

Estrogen Alone Trial study pills stopped

March 2005

Close-Out visits ended

April 2005

WHI Extension Study began

February 2006

Primary findings from the Dietary and Calcium and Vitamin D Trials to be released



WHI Dietary Modification Trial



WHAT WAS THE PURPOSE OF THE DIETARY MODIFICATION TRIAL (DM)?

The DM researched the effect of a low-fat, high fruit, vegetable and grain diet on breast cancer, colorectal cancer and heart disease in postmenopausal women.

WHO PARTICIPATED IN THE DM?

48,835 postmenopausal women of multiple races and ethnicities and varying ages participated in the DM.

HOW WAS THE DM CONDUCTED

The DM was a randomized controlled clinical trial, the most rigorous of research designs and often referred to as the gold standard.

Participants were randomly assigned to one of two treatment groups for follow-up:

- Comparison
- Dietary change

WHAT WAS REQUIRED OF THE COMPARISON GROUP?

Comparison group participants maintained their usual eating habits and received standard nutrition information (US Dietary Guidelines).

Why have a comparison group?

- To compare the number of cases of breast cancer, colorectal cancer, heart disease against the number in the Dietary Change group (the intervention group).
- To account for gradual diet changes that women may make for reasons not related to the DM intervention.

WHAT WAS REQUIRED OF THE DIETARY CHANGE GROUP?

Women in the dietary change group were asked to decrease their fat intake to 20 percent of their total daily calories; increase fruits and vegetables combined to five or more servings per day; and increase grains to six or more servings per day.



Dietary Change participants learned how to change their eating habits by:

- Attending group sessions. They met in groups of 8-15 women 18 times during the first year and four times annually thereafter. These groups were led by registered dietitians or nutritionists.
- Self-monitoring their intake of fat, fruits, vegetables, and grains. Self-monitoring is a well documented aid in changing behaviors and maintaining the changes.



HOW WERE DM PARTICIPANTS FOLLOWED UP?

Participants in both the Comparison and Dietary Change groups were followed for 8 years on average.

- Physical exams were conducted annually and health information updates collected every six months.
- Blood samples were collected from everyone at the start of the study (baseline) and the first year. At the 3rd, 6th, and 9th years, blood samples were collected from a subsample that included the same women each year (a cohort).
- Dietary intake information was collected from all participants at the start of the trial (baseline) and at year 1. After year 1, each woman's dietary intake was assessed every three years. (Dietary information was collected mostly by a food frequency questionnaire that had questions about a woman's eating habits for the previous three months. Some women also completed a four-day food record or 24-hour telephone recall.)
- Staff and investigators were uninformed about (blinded to) treatment assignment when follow-up information was being collected.

WHAT HAVE WE LEARNED ABOUT HOW THE WOMEN CHANGED THEIR EATING HABITS?

Sources of Dietary Fat

At the start of the DM, the major sources of fat intake in both the Comparison and Dietary Change groups were added fats (23% of fat intake), meats (19% of fat intake), desserts (10% of fat intake), milk and cheese (8% of fat intake), mixed dishes (8% of fat intake), and high-fat breads and salty snacks (5% of fat intake) [Patterson et al. J Am Diet Assoc. 2003;103:454-460.].



After the first year:

Sources of fat in the Comparison Group did not change.

The major sources of fat changed in the Dietary Change group. At the start of the trial, added fats were the major source of fat intake. After the first year, added fats the second major source (tied with mixed dishes). Fat on meats became the highest source of fat.

- Added fats decreased the most, by 78% (new total: 5%). Women ate less butter, margarine, oil, mayonnaise, salad dressing, peanut butter and nuts, and guacamole
- Fat on meats decreased by 49% (new total, the highest source of fat intake: 10%). Women ate leaner cuts of meat, less fatty types of meats, trimmed fats, or removed skin from poultry
- Fat from desserts decreased by 86% (new total: 1%). Women ate fewer cakes, cookies, pastries, and pies, and less ice cream and chocolate, or chose lower fat versions.
- Fat from milk and cheese decreased by 61% (new total: 3%). Women consumed less milk or dairy or chose lower fat milks and cheeses.
- Fat from mixed dishes decreased by 38% (new total: 5%). Women consumed fewer mixed dishes or chose lower fat mixed dishes.
- Fat from high-fat breads and salty snacks by 70% (new total: 1%). Women ate fewer crackers, chips, popcorn, biscuits, fried potatoes, and waffles and pancakes, or chose lower fat versions.





Adherence to the Low-Fat Dietary Pattern

Dietary change can be achieved and maintained [WHI Study Group. J Am Diet Assoc. 2004;104:654-658.].

- At the end of the first year, women in the Dietary Change group compared to those in the Comparison group reported consuming on average:
 - 10.9% less energy from fat per day
 - 1.2 more fruit/vegetable servings per day
 - 0.8 more grain/servings per day
- At the end of the fifth year, mid-way through the DM, women in the Dietary Change group compared to those in the Comparison group reported consuming on average:
 - 9.0% less energy from fat per day
 - 1.3 more fruit/vegetable servings per day
 - 0.5 more grain/servings per day

Factors associated with adherence for the Dietary Change Group

Dietary change and maintaining change was most strongly associated with attending group sessions and self-monitoring food intake. [WHI Study Group. J Am Diet Assoc. 2004;104:654-658.]

- 74% monitored their own intake of fat, fruit, vegetable, and grain servings during the first year of intervention, and many continued to use a variety of monitoring aids throughout the DM. [Mossavar-Rahmani, et al. J Am Diet Assoc. 2004;104:76-85.]
- Women who reported better physical functioning, general health, and mental health (e.g., better psychological well-being and less anxiety), at the beginning of the trial followed the low-fat diet more closely during the first year. They also attended more sessions and self-monitored more. [Tinker, et. al. J Am Diet Assoc. 2002;102:789-794,799-800.]
- Having additional contacts with a nutritionist helped some women further lower their fat intake. [Bowen, et al. J Am Diet Assoc. 2002;102:1631-1637.]

WHAT ARE THE FINDINGS FROM THE DM?

The results will be published in February 2006.



WHERE CAN PEOPLE FIND INFORMATION ON NUTRITION AND CURRENT DIETARY RECOMMENDATIONS?

Individual

An individual's personal health care provider, including a registered dietitian, can offer guidance about a dietary pattern that is right for the individual.

- The American Dietetic Association (<http://www.eatright.org>) is the nation's largest organization of food and nutrition professionals.

Consumer Hotline: 1-800-366-1655 offers brief pre-recorded nutrition messages or help finding a registered dietitian in one's local area.

- Additional food and nutrition information. The U.S. government has many health-related resources. For example, the www.healthierus.gov website offers information about a variety of nutrition topics such as healthy eating, food label reading, the USDA Dietary Guidelines for Americans 2005, and the 5 A Day for Better Health program.
- Information on achieving and maintaining a healthy weight, the DASH Eating Plan to reduce blood pressure, and cholesterol lowering can be found on the NHLBI Website at www.nhlbi.nih.gov.



WHI Calcium/Vitamin D Supplementation Trial



WHAT WAS THE PURPOSE OF THE CALCIUM AND VITAMIN D TRIAL (CaD)?

The CaD tested whether calcium and vitamin D supplements reduce the risk of hip and other bone fractures and colorectal cancer in postmenopausal women.

Previous research on calcium and vitamin D and its effect on bone fractures is limited. Past research in this area is observational or focused primarily on bone mass or bone density. The WHI CaD studied osteoporosis-related hip fractures, because hip fractures are the major cause of disability from osteoporosis.

Observational studies also suggest that increased calcium and vitamin D intake may decrease the risk of colorectal cancer, however limited trial data exists.

HOW WAS THE CaD CONDUCTED?

Eligible women in the hormone replacement therapy and/or the dietary modification clinical trials were invited to also join the CaD at their first and second annual visits.

A total of 36,282 postmenopausal women between the ages of 50 and 79 years were randomized to receive calcium and vitamin D supplements or inactive placebos each day.

Two study pills were taken each day—one in the morning and one in the evening, with meals. Participants could choose to take their study pills as either chewable, peppermint-flavored tablets or pills that could be swallowed.

Women who were already taking calcium supplements were able to continue taking them.

Women were followed for 7 to 10 years for this part of the WHI. Participants had clinic contacts every six months, and an independent Data and Safety Monitoring Board reviewed WHI study data for all parts of WHI, including the CaD, every 6 months to ensure participants' safety.

WHY WAS VITAMIN D COMBINED WITH CALCIUM?

Vitamin D has been shown to increase the availability and absorption of calcium in the body.

WHAT ARE THE FINDINGS FROM THE CaD?

The results will be published in February 2006.



WHAT ARE THE CURRENT RECOMMENDATIONS FOR CALCIUM AND VITAMIN D INTAKE?

For postmenopausal women, the Institute of Medicine, Food and Nutrition Board currently recommends a calcium intake of 1200 mg each day and a vitamin D intake of 400 to 600 International Units (IUs) each day. If this recommended intake cannot be obtained in the diet, then calcium and vitamin D supplementation should be considered.



Hormone Therapy Trials



WHAT WAS THE PURPOSE OF THE HORMONE TRIALS (HT)?

The HT component of the Women's Health Initiative (WHI) tested whether long-term hormone therapy reduced coronary heart disease and osteoporosis-related fractures without increasing breast cancer risk. The effects of hormone therapy on other cardiovascular disease and endometrial cancer were also evaluated. These trials enabled scientists to assess the balance of benefits and risks of hormone therapy so that health care providers and women could make informed decisions about the use of postmenopausal hormones.

HOW WAS THE HT CONDUCTED?

A total of 27,347 women between the ages of 50 and 79 years joined the HT, which included two separate trials:

- Estrogen plus Progestin Trial: Women with an intact uterus were randomized to receive either estrogen plus progestin or a placebo (inactive pill). Progestin is added to protect women with a uterus from endometrial cancer.
- Estrogen-Alone Trial: Women who had a hysterectomy before they joined were randomized to receive either estrogen alone or a placebo.

The plan for the HT involved following participants for 8 to 12 years while they were taking their study pills. Participants had clinic contacts every six months, and an independent Data and Safety Monitoring Board reviewed the HT data every 6 months to ensure participants' safety. Based on this review, the NHLBI halted the trial interventions early—the Estrogen plus Progestin in 2002 and the Estrogen Alone in 2004. The semi-annual reviews of the HT data indicated that for safety and scientific reasons, participants should no longer receive the HT interventions. Participants in both trials continued to be followed every 6 months, even after the interventions were halted, to learn more about how women's health changes after they stop hormone therapy.

WHY DID THE TWO HORMONE THERAPY TRIALS STOP EARLY?

In July 2002, the Estrogen plus Progestin intervention was halted early, after an average of 5.6 years of follow-up, because of an increased risk of heart disease and breast cancer and more harm than benefit overall in the active hormone group. These historic findings have changed health care practice for postmenopausal women throughout the world.

In March 2004, the Estrogen Alone intervention was halted early, after an average of 7.1 years of follow-up, because an increased risk of stroke was found with no benefit for coronary heart



disease. The NHLBI felt that sufficient information was obtained to provide an overall assessment of the risks and benefits of treatment with estrogen alone.

WHERE CAN I LEARN MORE ABOUT THE FINDINGS FROM THE HT?

The primary findings from the WHI Estrogen plus Progestin Trial and Estrogen Alone Trial are available at <http://www.whi.org/findings/>.

WHY WERE THE HT FINDINGS DIFFERENT FROM EARLIER STUDIES SHOWING POSTMENOPAUSAL HORMONE THERAPY DECREASED HEART DISEASE?

No study had proven that hormone therapy reduces heart attacks. Numerous observational studies were conducted on the effects of hormone therapy on heart disease, suggesting a decreased risk for heart disease or decreased heart disease risk factors, such as LDL cholesterol (the “bad” cholesterol). However, these studies were mostly observational studies where women themselves (or their physicians) chose hormone therapy and were followed over time. Such studies are not considered the gold standard for providing evidence for health care practice. They were not controlled enough to offer definitive answers.

WHY DON'T PEOPLE TALK ABOUT HORMONE *REPLACEMENT* THERAPY ANYMORE?

Menopausal or postmenopausal hormone therapy are now generally accepted as more accurate terms for what has been described in the past as hormone *replacement* therapy. This clarification reflects the fact that menopause is a natural event, not a disease of hormone absence requiring replacement. In addition, the doses of female hormones used during hormone therapy are generally lower than those produced naturally in premenopausal women, and the WHI has shown that *replacement* of these hormones may not be *therapeutic* for all women.



WHI Observational Study Facts

WHAT WAS THE PURPOSE OF THE OBSERVATIONAL STUDY?

The WHI observational study (OS) had several goals, including:

- To give estimates of the extent to which risk factors, known primarily from studies of men, predict heart disease, cancers and fractures in women;
- To identify "new" factors associated with these and other diseases in women;
- To compare risk factors, presence of disease at the start of the study, and new occurrence of disease during the WHI across all study components; and
- To create a future resource to identify biological indicators of disease, especially substances and factors found in blood.



HOW WAS THE OBSERVATIONAL STUDY CONDUCTED?

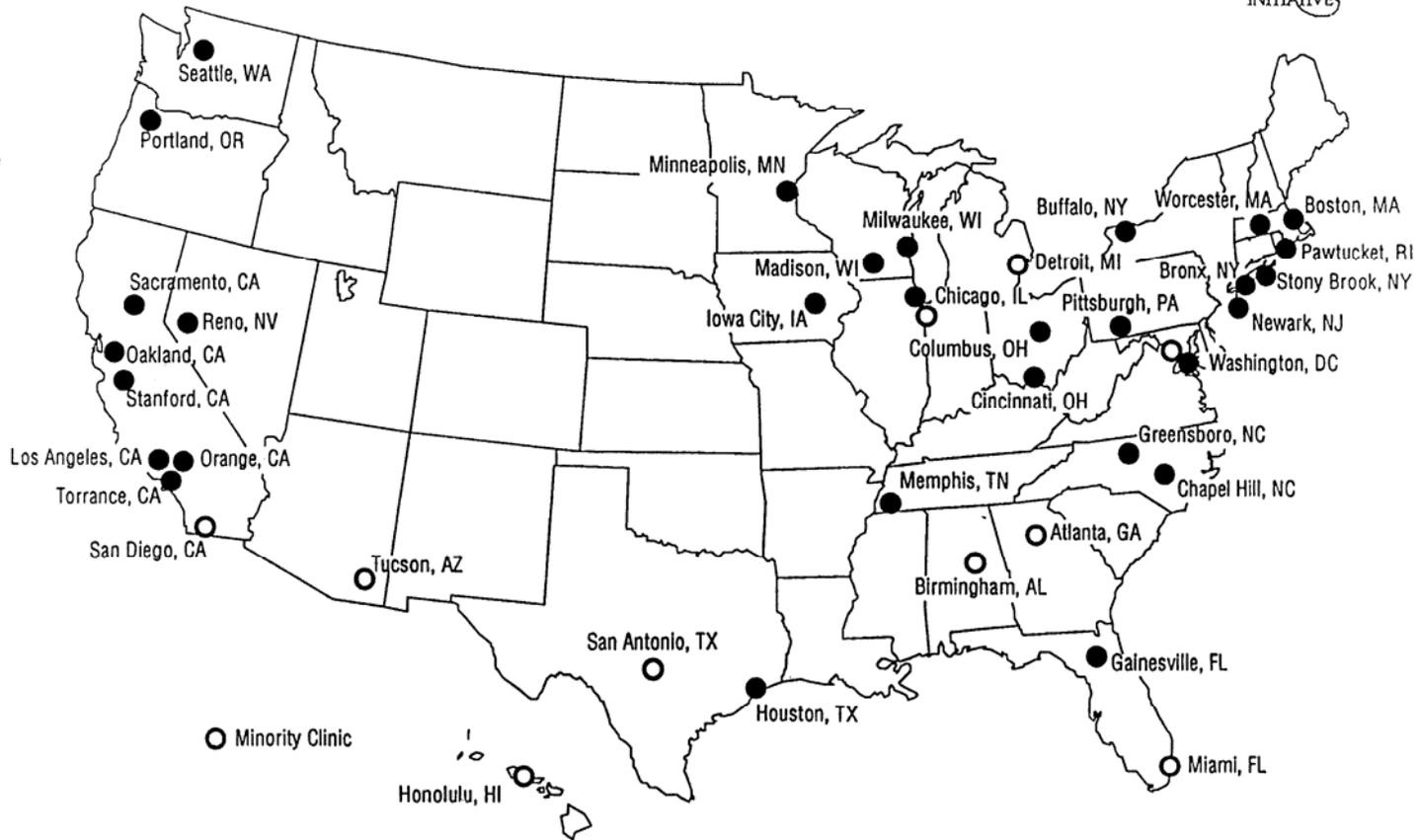
The observational study enlisted 93,676 postmenopausal women between the ages of 50 and 79 years. The health of OS participants was tracked for 8 to 12 years.

Women who joined this study filled out periodic health forms and also visited the clinic three years after they enrolled in the study. OS participants were not asked to take any medication or change their health habits. The WHI OS did, however, follow a woman's health over a long period of time.

The OS continues to provide information that complements the findings from the Clinical Trial.



Women's Health Initiative Clinical Centers National Institutes of Health





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