

Women's Health Initiative Overview

The Women's Health Initiative (WHI) is a long-term national health study that focuses on strategies for preventing heart disease, breast and colorectal cancer and osteoporosis in postmenopausal women. These chronic diseases are the major causes of death, disability and frailty in older women of all races and socioeconomic backgrounds.

This multi-million dollar, 15-year project, sponsored by the National Institutes of Health (NIH), National Heart, Lung, and Blood Institute (NHLBI), involves over 161,000 women aged 50-79, and is one of the most definitive, far reaching clinical trials of women's health ever undertaken in the U.S. The WHI Clinical Trial and Observational Study is attempting to address many of the inequities in women's health research and provide practical information to women and their physicians about hormone replacement therapy, dietary patterns and calcium/vitamin D supplements, and their effects on the prevention of heart disease, cancer and osteoporosis.

The WHI study has three components: a randomized clinical trial, an observational study and a community prevention study.

The randomized controlled clinical trial (CT) has enrolled over 68,000 postmenopausal women between the ages of 50-79. The clinical trial has three study components. If eligible, women could choose to enroll in one, two, or all three of the components. The components are:

- **Hormone Replacement Therapy (HRT):** This component will examine the effect of HRT on the prevention of heart disease and osteoporosis, and any associated risk for breast cancer. Women participating in this component take hormone pills or a placebo (inactive pill).
- **Dietary Modification:** The Dietary Modification component will evaluate the effect of a low-fat, high fruit, vegetable and grain diet on the prevention of breast and colorectal cancer and heart disease. Study participants follow either their usual eating pattern or a low-fat eating program.
- **Calcium/Vitamin D:** This component started up to 2 years after a woman joined one or both of the other studies. It will evaluate the effect of calcium and vitamin D supplementation on the prevention of osteoporosis-related fractures and colorectal cancer. Women in this component take calcium and vitamin D pills or a placebo.

The **Observational Study (OS)** will examine the relationship between lifestyle, health and risk factors and specific disease outcomes. This component is tracking the medical history and health habits of over 93,000 women. Recruitment for the observational study was completed in 1998 and participants will be followed for 8 to 12 years.

The WHI clinical trial and observational study is being conducted at 40 clinical centers nationwide. The Fred Hutchinson Cancer Research Center in Seattle, WA serves as the WHI Clinical Coordinating Center for data collection, management, and analysis. Recruitment began in September 1993 and continued through July 1998. The OS enrolled through December 1998.

The community prevention study (CPS) is a unique collaborative venture between the Centers for Disease Control and Prevention (CDC), and the National Institutes of Health. Eight University-based Prevention Centers underwritten by CDC will conduct and evaluate health programs that encourage women of all races and socioeconomic backgrounds to adopt healthful behaviors such as improved diet, nutritional supplementation, smoking cessation, exercise and early detection of treatable health problems. The goal of the community prevention study is to develop carefully evaluated, model programs that can be implemented in a wide range of communities throughout the U.S.