WHI — The Results Are In!

After 12 years, 7.5 million forms, and 1 million clinic visits, we've reached the most exciting phase of the Women's Health Initiative - the results! For the next several years, scientists will be carefully analyzing the information you have so generously provided over the years. As you may recall, the WHI Hormone Study has been in the news since 2002, when initial findings for that study were released. Now it's time to release the findings of the other two trial components: the Dietary Study and the Calcium and Vitamin D Study. In this newsletter we review the findings from these two important studies, as well as provide updates on findings from the Hormone Study and the Observational Study.

The study results we report here are just the beginning. For years to come, WHI scientists will continue to analyze the data you have already provided, as well as new data collected in the WHI Extension Study. Scientists around the world will be carefully reviewing the findings from WHI, and thinking of new ideas for research on women's health. You are a part of a research program that will continue for many years and impact future generations of women worldwide.

Thank You!

We extend a big thank you to each and every woman who has participated in WHI. Whichever study component you were in, and whatever the level of your contribution, WHI would not have been possible without your ongoing, generous support. You have played a historic role in women's health, and because of your unselfish gift, we are learning more about the major causes of death and disability in older women of all races and backgrounds.

The WHI Extension Study

The Women's Health Initiative (WHI) Extension Study has been funded through the year 2010. All WHI participants, regardless of which study component they were in, are welcome to join the WHI Extension Study. Many of you -- over 110,000 -- have already joined! If you have not joined the Extension Study, and are interested, please contact your clinical center at the phone number listed on the back of this newsletter. It's not too late to join! Keep in mind that there are no clinic visits in the WHI Extension Study, only mail and phone contacts.

We thank you for all you've done over the years and hope you decide to continue with the Women's Health Initiative.

For those of you who are continuing in the WHI Extension Study, you will receive a WHI Matters newsletter each year. For those of you not continuing in WHI, this will be your final study newsletter.

We hope all of you will visit the WHI participant website (www.whi.org) periodically for the latest news and findings on WHI. Thank you again for being part of the answer!
The Diet / Health Connection: 
Results from the WHI Dietary Study

Beginning in 1993, 48,835 women came together to answer a health question important to their lives and to future generations of women: Does a low-fat eating pattern with lots of fruits/vegetables, and grains lower the risk of breast cancer, colorectal cancer, and heart disease in postmenopausal women? Finally, after 12 years of clinic visits, filling out forms, and — for some — making dietary changes, the main findings of the WHI Dietary Study are here!

When the study was designed, international data suggested that a low-fat diet might reduce the risk of breast and colorectal cancers. Fruits, vegetables, and grains might also have a role, but this had not been tested in a randomized trial. The effect of a low-fat diet on heart disease was also unclear. “Diet and disease is a particularly difficult subject to investigate, and there are very few formal experiments that look at this question,” said Ross Prentice, Principal Investigator of the WHI Clinical Coordinating Center.

WHI Dietary Study participants were randomized (assigned by chance) to either the Dietary Change or the Comparison group. Women in the Comparison group were not asked to make any dietary changes. Women assigned to the Dietary Change group were asked to lower their fat intake to 20% of total calories and eat five or more fruit/vegetable and six or more grain servings daily.

These were not trivial changes to make! Starting from an average 34% energy from fat, women in the Dietary Change group reduced their fat intake to 24% of total calories by the end of the first year. By the end of the study, with an average intake of 29% energy from fat, they had maintained much of their initial change. “I’m proud that I stuck to it,” said Jeanette Schwertfeger, a Dietary Change participant at the Nevada Clinical Center.

Women in the Dietary Change group also increased their fruit/vegetable intake, but had a more challenging time with increasing grains.

Referring to all women in the Dietary Study, Dr. Shirley Beresford, Principal Investigator of the Seattle Clinical Center, says, “We are really in awe of everything the women did. The women in the Dietary Change group made major changes in their patterns. The women in the Comparison group did not have the benefit of regular meetings, and yet they also continued to provide us the information we kept asking them for, to fill out questionnaires about what they were eating, and so on.”

What were the findings?

- Breast cancer

The Dietary Study ended in March 2005 after an average of 8.1 years of follow-up. Breast cancer rates were 9% lower in women in the Dietary Change group compared to women in the Comparison group. This means that, out of 10,000 women, 42 women in the Dietary Change group and 45 in the Comparison group on average developed breast cancer each year. There is only about a 7% probability that a difference between groups of this size would occur by chance alone. That’s pretty low, but scientists prefer the probability to be less than 5%.

However, there are reasons to think that the 9% lower breast cancer occurrence in the Dietary Change group may be real. For example, Dietary

We are really in awe of everything the women did.
— Dr. Shirley Beresford, Principal Investigator of the Seattle Clinical Center
Change group women with a higher fat intake at the start of the study had a greater reduction in breast cancer than did those with a lower fat intake. Also, breast cancer risk differed according to whether the breast tumor cells had receptors for estrogen or progesterone. Because diet can have long-lasting effects, the continued follow-up of Dietary Study women in the WHI Extension Study is expected to provide the information needed for a more conclusive test of the low-fat eating pattern.

- **Colorectal cancer**

  The WHI low-fat eating pattern did not reduce the risk of colorectal cancer. The results were similar when looking at where the cancer occurred—the entire colon, upper or lower colon, or rectum. The results were also similar when different levels of dietary adherence among Dietary Change participants were taken into consideration.

- **Heart disease**

  To study the effect of the WHI low-fat eating pattern on heart disease, researchers looked at how many participants had a heart attack, heart bypass surgery, or other heart procedures (stent or balloon angioplasty). They found that the low-fat eating pattern did not reduce the risk of heart disease, although the intervention was not designed specifically to study heart disease. There were, however, small favorable effects of the low-fat eating pattern on some risk factors. LDL-cholesterol and diastolic blood pressure were lower, as was factor VIIa, a blood clotting protein that is sometimes higher in people who have had heart attacks. Scientists will continue to study these promising findings to further explore the link between diet and heart disease.

- **Body weight changes**

  The low-fat eating pattern was not designed for weight loss, but, nonetheless, many women in the Dietary Change group maintained or lost weight on the low-fat eating pattern. This is good news, since obesity is on the rise in the United States.

![Graph showing disease rates for women in the Dietary Study](image)

**What now — how should you eat?**

Your health care providers, including your doctor or a registered dietitian, can offer guidance about an eating pattern that is right for you. Contacting your health care providers for dietary guidance is particularly important if you have a diet-related health condition such as diabetes or heart disease, or are above or below a healthy weight. The American Dietetic Association (ADA) offers a Consumer Hotline (1-800-366-1655) where you can listen to brief pre-recorded nutrition messages or get help finding a dietitian in your area. You can also find food and nutrition information at the ADA website (www.eatright.org).

A low-fat eating pattern, full of fruits, vegetables, and grains, is consistent with current national dietary guidelines and remains an option for generally healthy postmenopausal women. The Dietary Guidelines for Americans 2005 suggest consuming 20-35% energy from fat with most coming from polyunsaturated and monounsaturated sources, such as vegetables and nuts. The Guidelines further recommend five to nine one-half-cup servings of fruits and vegetables daily, and three or more servings of whole grains daily (www.healthierus.gov/dietaryguidelines).

If you were a participant in the Dietary Study, thank you very much for your important contribution to these findings!
To Supplement or Not? That is the Question
Results from the Calcium and Vitamin D Study

It's hard to believe that it's been 10 years since the first participant joined the WHI Calcium and Vitamin D (CaD) Study! You may remember that women joined the CaD Study about a year after they joined the Hormone and/or Dietary studies. If you were a CaD participant, you contributed to at least two WHI studies. Because of your dedication to the WHI, we now have some answers to questions about the effects of calcium and vitamin D on women's health.

What were the goals of the CaD study?
The goals of the CaD Study were to see if calcium and vitamin D supplements prevent hip fractures and colorectal cancer. Although scientists have known for some time that calcium and vitamin D are important for bone health and may help to slow bone loss in older adults, it was not clear if this meant they would have fewer hip fractures. This was an important question to answer, because broken bones from osteoporosis often cause serious and long-term health problems for older women. In addition to these possible benefits, other research had shown that calcium and vitamin D may prevent certain types of colon polyps, but it was not certain that these supplements would prevent colorectal cancer.

How was the study carried out?
The CaD Study was a randomized clinical trial. This means that when women joined the study, a computer program assigned them at random (by chance) to take either an active calcium and vitamin D pill or an inactive placebo pill. Participants were asked to take these study pills two times a day. This means that women in the active CaD group got a total of 1000 mg of calcium and 400 IU of vitamin D from their study pills every day, while women in the placebo group took a study pill with no calcium or vitamin D.

Some nutrition guidelines suggest that postmenopausal women should get a total of 1200 mg of calcium and 400 to 800 IU of vitamin D every day in their diet or as supplements. CaD participants in both groups were able to take their own supplements as well. Because participants were asked about the amount of their own supplements, WHI scientists were able to take this information into account when they analyzed the study data.

Who are the CaD participants?
Between 1995 and 2000, a total of 36,282 women in the Hormone and/or Dietary studies, or both, joined the CaD Study — 18,176 were assigned at random to the active calcium and vitamin D supplement group and 18,106 to the placebo group. Like all other WHI participants, women in the CaD Study were 50 to 79 years old when they first joined the WHI, with an average age of 62 years. The CaD Study included 17% racial and ethnic minority women.

CaD participants were generally healthy when they joined the WHI, but 15% had already had a fracture in their postmenopausal years (broken bone after age 55). Up to 61% of participants were taking less than the recommended 1200 mg of calcium each day from diet and supplements combined. When they joined the CaD Study, over half of the women were taking hormone therapy, either on their own or because they were randomized to active hormones in the WHI Hormone Study.
Special Supplement
FOR COMPARISON PARTICIPANTS OF THE WHI DIETARY STUDY

Thanks to you, the WHI Dietary Study has added to the knowledge of diet and health in postmenopausal women. Without your participation, we would not have been able to complete the study and learn about the effects of dietary changes on cancer and heart disease in postmenopausal women.

Some of you have asked what the women in the Dietary Change group did. This special newsletter for you — women in the Comparison group — provides a snapshot of the Dietary Change program.

WHI Dietary Study
A LOOK BACK AT THE DIETARY CHANGE PROGRAM

What were the goals of the WHI Dietary Study?

Women in the Dietary Change group were asked to lower their fat intake to 20% of calories and to increase their servings of fruits, vegetables and grains. Each woman received an individualized fat gram goal to help her reach the 20% goal. The average fat gram goal was 25 grams of fat per day. Women were not given an individualized saturated fat gram goal because saturated fat intake usually decreases when total fat goes down. The women were free to make their own food choices based on the WHI Dietary Study goals, as well as their personal preferences.

WHI Dietary Study Goals

✓ Reduce total fat intake to 20% of total calories.
7% or less of total calories as saturated fat
✓ Increase intake of fruits and/or vegetables to five or more servings daily.
✓ Increase intake of grains to six or more servings daily.
How did women in the Dietary Change group learn how to make these changes?

Women in the Dietary Change group attended a series of small group meetings (8-15 women), led by a trained nutritionist. Women were encouraged to work together, share ideas, and support each other in making and maintaining dietary changes. During the first year, there were a total of 18 group meetings and one individual counseling session. After the first year, the groups of women met together with a nutritionist every three months to help them maintain their eating pattern changes.

Some types of information and activities provided during Dietary Change meetings may apply to any type of eating changes you might make:

✓ **Self-awareness skills**

Women in the Dietary Change group increased their awareness in a variety of ways. They learned about the sources of fat in their diets — some of it visible and some of it hidden in foods. Keeping track of the amount and type of foods eaten helped them become aware of their eating patterns and potential behaviors they could change. This was an eye-opening experience for many!

✓ **Self-management skills**

Women in the Dietary Change group learned a number of different self-management skills, such as how to be assertive when eating away from home, how to problem-solve challenging situations, and how to set specific, realistic and measurable goals. They discovered that changing eating patterns took time and patience. Setting goals provided an opportunity for them to identify behaviors they wanted to change and explore ways to accomplish these changes.

🤔 **How aware are you about your own eating patterns?**

🤔 **When do you find it helpful to set goals?**
Social support skills

Women in the Dietary Change group explored ways to involve family and friends for support and to ask for help when needed. The group meetings provided many opportunities for the women to use their social support skills by sharing ideas, offering encouragement, and providing companionship for one another.

Dietary change skills

Women in the Dietary Change group updated current skills and learned new ones, such as reading and understanding nutrition labels, selecting lower-fat choices, modifying recipes, and eating less fat when dining away from home. They also learned the importance of paying attention to portion sizes and discovered that their portions were sometimes larger than “standard” serving sizes. A large bagel can be equal to four slices of bread — four servings! But, it’s easy to think that it’s only one serving because it’s only one bagel.

Where do you look for support when you’re trying to make a change?

Food groups to change

Women in the Dietary Change group learned how to make changes in their eating patterns. They explored ways to add fruits, vegetables and grains into their meals and snacks. They learned about the food groups that provide the majority of fat in most people’s diets: added fats, meats, baked goods, salty snacks, and dairy foods. Some of the fat was easy to see, such as margarine on bread. But, about 85% of the fat was hidden in food, such as the fat in pie crust or oil used to sauté!

What do your portions look like? Consider taking a minute to compare your portions to the examples below.

What are some of the eating pattern changes you’ve made during your lifetime?

What does a serving look like?

Here are some examples:

A fist or a tennis ball = about 1 cup

A cupcake wrapper = about 1/2 cup

A deck of cards = about 3 ounce serving of meat, poultry, or fish

1 fingertip = about 1 teaspoon

1 thumb = about 1 tablespoon
Interested in making a dietary change?
Here are some tips:

✓ Keep track of what you eat; it may help you stay aware of your eating habits.

✓ Set realistic and measurable goals; it may help you identify areas to change and provide a way to track your progress over time.

✓ Welcome the support of family and friends.

✓ Support yourself with positive thoughts and a “can do” attitude.

✓ Measure your portion sizes. You may be eating more than you think.
What were the findings?

- **Fracture findings**
  Over an average of 7 years, 378 CaD participants had hip fractures. Although women taking active CaD study pills had 12% fewer hip fractures than those taking placebo pills, this difference was smaller than expected and could have happened by chance. Women taking active CaD pills had 4% fewer fractures when scientists analyzed data on all fractures combined. When the analysis focused just on the data obtained while participants were taking most of their study pills, women taking the active supplements had 30% fewer hip fractures than those taking placebo.

During the study, participants at three of the WHI clinical centers had regular bone density scans, which showed that women taking active CaD study pills did have higher hip bone density. These analyses included all CaD participants, even those who were not taking all (or any) of their study pills.

- **Colorectal cancer findings**
  Over an average of 7 years, 322 women were diagnosed with invasive colorectal cancer. When the WHI scientists looked at colorectal cancers in women who took active CaD study pills compared with those who took placebo pills, there were no differences. There were also no differences between the two groups in the colorectal tumors themselves. For example, the tumors were not more advanced in one group over the other. In addition, there were no differences in the number of colon polyps reported by participants in the two groups. When the analysis focused just on the data obtained from participants who were taking most of their study pills, the findings about colorectal cancer did not change.

- **Other findings**
  Additional analyses showed that the findings about hip fractures and colorectal cancer were similar even when women's calcium and vitamin D intake and blood levels of vitamin D at enrollment were taken into account. There were also no differences in the symptoms that participants reported during the study—symptoms like bloating and constipation were similar for women taking active CaD study pills and those taking placebo. However, women in the active supplement group did report more kidney stones during follow-up.

What do these findings mean?

We now have some very valuable answers to questions about the effects of calcium and vitamin D on postmenopausal women's health. We know that the use of these supplements for seven years slows loss of bone density and may help prevent some hip fractures. We also know that these supplements, in the dosage used for this study over seven years, do not prevent colorectal cancer in healthy postmenopausal women.

Given there were few health problems linked to the use of calcium and vitamin D, these findings suggest there may be a role for these supplements in preventing hip fracture in generally healthy postmenopausal women.

If you were a participant in the Calcium and Vitamin D Study, thank you very much for your important contribution to these findings!
More Findings from the Hormone Study!

When the Hormone Study findings were released, people around the world learned that WHI participants were making women’s health history! You have already received updates about the main findings from the Estrogen plus Progestin (E+P) and Estrogen Alone (E-Alone) studies. WHI scientists have continued to analyze the data from E+P participants, who did not have a hysterectomy before they joined WHI, and E-Alone participants, who had a prior hysterectomy. Findings from these analyses are described below.

Quality of life describes how a woman’s health affects her sense of well-being in many ways, such as physical function, relationships, and mental health. Taking hormone therapy in either the E+P or E-Alone studies did not affect participants’ quality of life. Although there were small improvements in sleep in the first year after starting hormone therapy, these effects were not seen after three years.

Cognitive function is a concern as women grow older, and scientists thought that taking hormone therapy might help with memory and thinking and might even prevent dementia or Alzheimer’s. The WHI Memory Study (WHIMS) enrolled women who were 65 years or older when they joined the E+P or E-Alone studies. No cognitive benefits of hormone therapy were found. In fact, memory and thinking were worse among WHIMS participants taking active hormones.

Symptoms in postmenopausal women may have many different causes—hormone changes with menopause, aging in general, or certain health problems. Hot flashes, night sweats, achiness and stiffness symptoms, and vaginal dryness were improved among women taking combined hormones in the E+P study. However, some of these women also had problems with breast tenderness, headaches, and vaginal spotting or bleeding. WHI scientists found that in the E+P and E-Alone studies, taking hormone therapy increased risk of urinary incontinence (leaking of urine) in women who did not have this problem and made it worse in women who already had the problem.

Diabetes, a problem with how the body processes sugar, was analyzed in the E+P study. Women taking the combined hormones had a decreased risk for diabetes.

Gallbladder disease, including problems with gallstones, was evaluated in both the E+P and E-Alone studies. Women taking hormone therapy had increased gallbladder problems and were more likely to have surgery to remove their gallbladders.

What do the Hormone Study findings mean overall?
The use of hormone therapy has been debated a great deal since the main WHI Hormone Study findings were released, and the findings described above suggest other risks and benefits. Currently, hormone therapy is recommended for postmenopausal women who have moderate to severe hot flashes or night sweats. Instead of hormone pills, topical hormones like vaginal creams are recommended for women who have problems with vaginal dryness. Women should talk about these issues with their doctors, who also may prescribe hormones to prevent osteoporosis (brittle bones) if other kinds of medicines cannot be taken. Thanks to the dedication of all the women in the WHI Hormone Study, we now know that postmenopausal women should not take hormone therapy as they grow older to prevent problems like heart disease.
Findings from the Observational Study

The Observational Study (OS) is the largest component of WHI, with nearly 94,000 participants. A number of findings based on information provided by OS participants have been published over the past several years, and many have been summarized in previous issues of WHI Matters. These findings have covered a wide variety of health topics, including physical activity, high blood pressure, cancer screening, sleep habits, and mammogram use, just to mention a few. Described below are the results of some of the most recently published scientific papers on OS participants.

- Fracture risk following breast cancer
  WHI investigators studied data from OS breast cancer survivors to see if breast cancer and its treatment increase the risk for fractures (broken bones). They found that postmenopausal survivors of breast cancer are at increased risk for fractures, when compared with women who have no cancer history. The increased risk for total fractures was found in all ages of breast cancer survivors, regardless of the time of the breast cancer diagnosis. More research is needed to develop strategies to reduce the number of fractures in these cancer survivors. These findings were published in the March 2005 issue of the Archives of Internal Medicine.

- Abuse and postmenopausal women
  Because physical and psychological abuse can be a serious problem for women, WHI researchers looked at the rate of abuse reported by women in the OS. At the time they joined the study, 11.1% reported they had been the victim of some type of abuse (physical, verbal, or both) during the prior year. At the 3-year follow-up, 5% of women reported some type of new abuse. Prior to this research, the rate of abuse for healthy, non-frail women over 50 was not known. This type of information is very helpful to public health scientists who design programs to screen for and help victims of domestic violence. This research was published in the American Journal of Public Health in April 2004.

- Depression and cardiovascular disease
  Data from women in the OS were analyzed to understand more about depression and cardiovascular diseases like heart attack, stroke, and high blood pressure. When they joined the study, about 16% of the women were depressed and had a higher risk for cardiovascular disease than those who were not depressed. Women are encouraged to recognize their depression early, since depression can usually be treated with medications and counseling. These findings were published in the Archives of Internal Medicine on February 9, 2005.

- Social support increases breast cancer screening
  Past research suggests that women who have close friends and family (social support) are more likely to have mammograms and breast exams. Data from OS participants were analyzed to learn more about breast cancer screening and different kinds of social support (such as having people in your life who support you emotionally or help in other ways). The researchers found that women who have emotional support are more likely to have repeat mammograms and breast exams, but having help with daily routines does not increase breast cancer screening. These findings were published in the June 2005 issue of Health Psychology.

Letters
We'd love to hear feedback on the newsletter. We regret that we cannot answer questions about individual medical conditions.
Send a letter to:
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