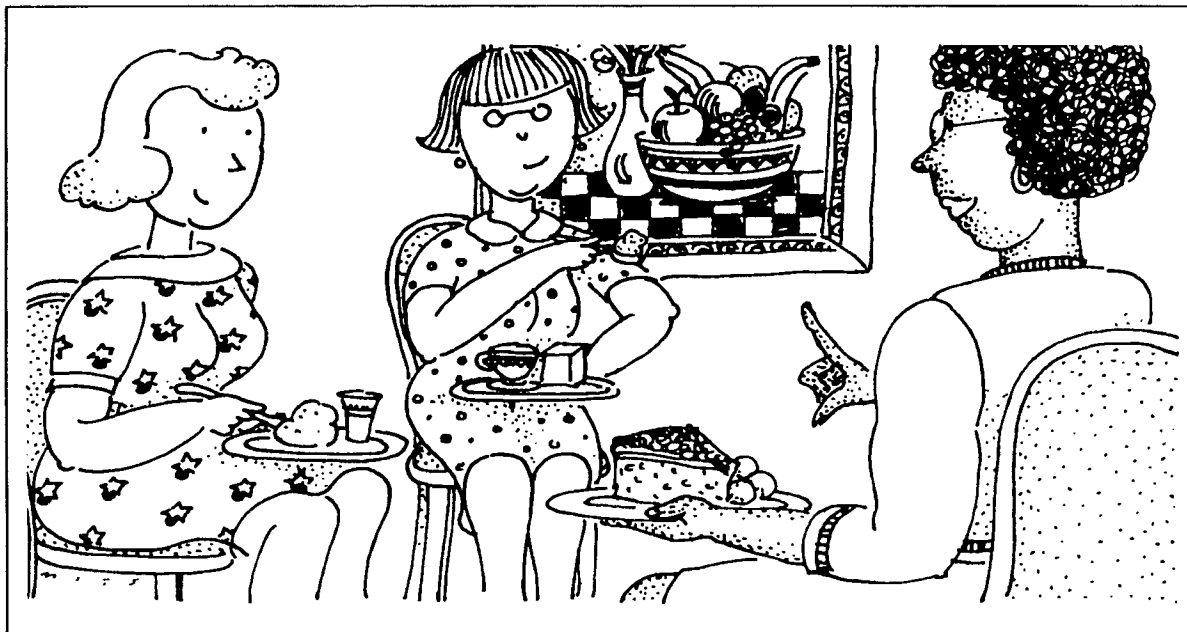


Fall 2001

Women Helping Women: A Celebration

During this session you will:

- ◆ *Review the WHI's critical importance in the lives of women.*
- ◆ *Share what it is like to be a part of WHI.*
- ◆ *Explore ways that a significant person in your life might continue to share and support your involvement in WHI.*



Next Steps Follow-Up

- ◆ At the Summer session, we talked about eating a variety of foods and selecting nutrient-rich choices. What of that discussion was most interesting or important to you?
- ◆ In what ways have you added variety and/or nutrient-rich food choices to what you eat?

Let's Celebrate

This session is about women helping women. It provides a time to share and celebrate WHI with someone important in your life. This person can be anyone important to you – a woman or a man. This session celebrates your monumental contribution to the lives of women everywhere. For the special person you choose to share this session with, it celebrates the very important support they give you in WHI.

The celebration includes:

- ◆ A brief overview of the purpose and importance of the WHI study.

- ◆ Some questions that may help you and your special person learn more about how WHI fits into each of your lives.
- ◆ A menu and recipes for an Autumn Tea.

Who would you like to share and celebrate WHI with (name)?

This person is important to you because:



Purpose & Importance of WHI



Below you will find an overview of a few key points about WHI. Take some time to talk about these points with the person with whom you've chosen to share this session. You might start by asking what they already know about WHI. After that, you might ask what else they would like to know. Help this special person know more about WHI's purpose and importance.

Why is WHI a landmark study?

Public health

WHI is designed to address some of the major causes of disease and death in post-menopausal women.

- ◆ Breast cancer is the most common cancer for US women. It is the second leading cause of cancer death (after lung cancer) for US women.
- ◆ Colon cancer is the third most common cancer and cause of cancer death (after lung and breast cancer) for US women.
- ◆ Coronary heart disease is the leading specific cause of death for US women.
- ◆ Bone fractures are common at older ages and are a major cause of disability and loss of mobility. Deaths from complications of hip fractures approximate those for breast and colorectal cancer.

Population

WHI includes ethnically diverse post-menopausal women who were at least 50 years of age at the beginning of the study. This is a population that has previously received little scientific attention.

Complexity

WHI is complex. It includes a clinical trial that has three separate parts: the hormone replacement study, the calcium and Vitamin D study, and the Dietary Modification (DM) study. WHI also includes an observational study.

Size

WHI is a very large study. It includes 161,809 women:

- ◆ The clinical trial has 68,133 women. Of these women, 48,836 are in the DM study and 19,542 of them are in the Dietary Change part of the study.
- ◆ The observational study includes 93,676 women.

Duration

WHI is a long study. Participants will be followed for an average of 8.5 years.

What is the purpose of the WHI DM study?

The purpose of the DM study is to test whether a low-fat dietary pattern high in fruits/vegetables and grains reduces the risk of breast and colorectal cancers and heart disease in post-menopausal women.

Why do we need the WHI DM study?

Most previous research on dietary intake and disease has used observational study designs. In these types of studies, investigators simply observe disease occurrence among women who choose a healthy eating pattern compared to women who have less healthy eating patterns. However, we know that women who choose eating patterns low in fat and high in fruits and vegetables are also more likely to choose other healthy behavior, such as more exercise, less smoking, and more disease screening. Therefore, scientists can never be sure in these types of studies which of these healthy lifestyle choices are affecting disease risk.

What is the WHI DM study design?

WHI uses a very rigorous study design called a randomized, controlled clinical trial. Briefly, the main points are:

- ◆ Most randomized, controlled clinical trials test treatments for patients with disease and the results only apply to patients. WHI is different. WHI is testing prevention of disease in healthy women, and therefore, the findings about diet and risk of cancer and heart disease will apply to all healthy postmenopausal women.
- ◆ The DM study has two groups that will be compared to each other: the Dietary Change group and the Comparison group. Women in the Dietary Change group eat a low-fat dietary pattern high in fruits/

vegetables and grains. Women in the Comparison group eat as usual.

- ◆ At the beginning of the study, the Dietary Change and Comparison groups had the same personal characteristics (such as age) and other behavior (such as exercise) because women were randomly assigned to one of the two groups. Random assignment to a group is done with a coin toss (except scientists use a computer to “toss the coin”).
- ◆ The two groups will be followed for disease occurrence for the duration of the study.
- ◆ At the end of the study, we will compare disease occurrence in the two study groups. We will look to see if low-fat eating helped women in the Dietary Change group have less breast and colorectal cancers and heart disease than women in the Comparison group.

WHI's randomized, controlled clinical trial design is the “gold standard” of scientific study design.

Why is the WHI DM study so important?

WHI has the potential to give strong evidence about the role that low-fat eating plays in breast and colorectal cancers and heart disease in postmenopausal women.



The evidence from WHI is especially strong because the computer coin toss means that the Dietary Change and Comparison groups are exactly equal, except for their dietary pattern. Therefore, scientists can feel confident that differences in disease occurrence between these two groups is the result of the differences in eating patterns.

What role do participant volunteers play in the WHI DM study?

Participants make the study possible. WHI could not be done without participant volunteers. We could not test the study question without:

- ◆ women randomly assigned to the two study groups for comparison.
- ◆ women in the Dietary Change group eating a low-fat dietary pattern high in fruits/vegetables and grains.

Each participant is irreplaceable. No one in the study can be replaced by another person. Each participant's information will be included in study analyses. The data are always confidential. Including all participants in analyses is another reason that evidence from WHI is especially strong.

Each participant makes a huge contribution of time and effort. In order to compare disease occurrence between the Dietary Change and Comparison group at the end of the study:

- ◆ Each participant completes clinic visit exams and many forms at least once a year for the duration of the study.
- ◆ Each participant in the Dietary Change group eats a low-fat dietary pattern for the duration of the study. She also attends Dietary Change group sessions and closely monitors what she eats.

How does the study protect participant safety?

Participant safety is paramount. WHI has a Data Safety and Monitoring Board (DSMB) that meets every six months. This group reviews WHI data and relevant non-WHI study results. They recommend WHI protocol changes if needed, and even whether it is appropriate to continue WHI. WHI staff are available to talk with participants about safety concerns.

Resource 1 – The Woman's Health Initiative (WHI) (pages 11-14) briefly summarizes these points. Feel free to give this resource to the person with whom you've chosen to share this session.

After the two of you have talked about the purpose and importance of WHI, ask yourselves these questions:

- What are your thoughts about WHI?
- How are you feeling about WHI?



Sharing WHI

How often do you have the chance to really talk with someone about WHI? If it isn't as often as you would like, this session may give you a jump start on talking with someone important to you.

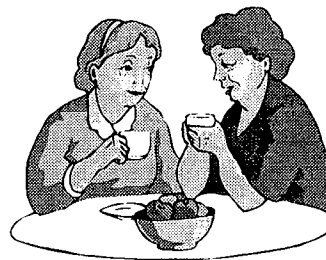
Sharing WHI with people who are important to you is a good thing.

Sharing can:

- ◆ help you think about the many reasons you joined the study.
- ◆ give you a good feeling about all the time and effort you are giving to WHI.
- ◆ give you the chance to sit back and feel proud that what you are doing in WHI is very important and that your contributions will make a difference in the lives of women for the rest of time.

Sharing WHI with someone close to you can bring WHI and your life outside WHI a little closer together. This is also a good thing. The more others really know about what you do in WHI, the more they'll be able to support your efforts. All of these things can make it easier for you to strengthen and maintain your connection to WHI.

Sharing WHI with someone important to you can be good for the other person, too. It can help them learn more about you and what you're doing in WHI. It can also give them ideas for ways to make WHI easier for you.



Most people feel good knowing that they're doing something to help another.

Worksheet Fall 1 (a and b) – Sharing WHI (pages 9-10) has some questions that may help you and someone important to you share WHI.

The “You Ask” questions are for you to ask the person with whom you’ve chosen to share the session. These questions are meant to help this person share what they know about WHI, what new things they might want to learn about WHI, and how your being a part of WHI impacts their life. These questions may help you learn more about your special someone.

The “They Ask” questions are for your special person to ask you. These questions are meant to help you share what it is like to be a part of WHI and the kinds of support you might be seeking for your efforts in the study. These questions may help your special someone learn more about you.

Don't feel limited to the questions on the worksheet. Ask whatever questions you want to ask each other about WHI. Have some fun with this! If you think it would be helpful, you can jot down each other's answers in the space provided on the worksheet.

Next Steps

Think about the wonderful contribution you are making to the lives of women. Think about the special person with whom you've shared and celebrated WHI.



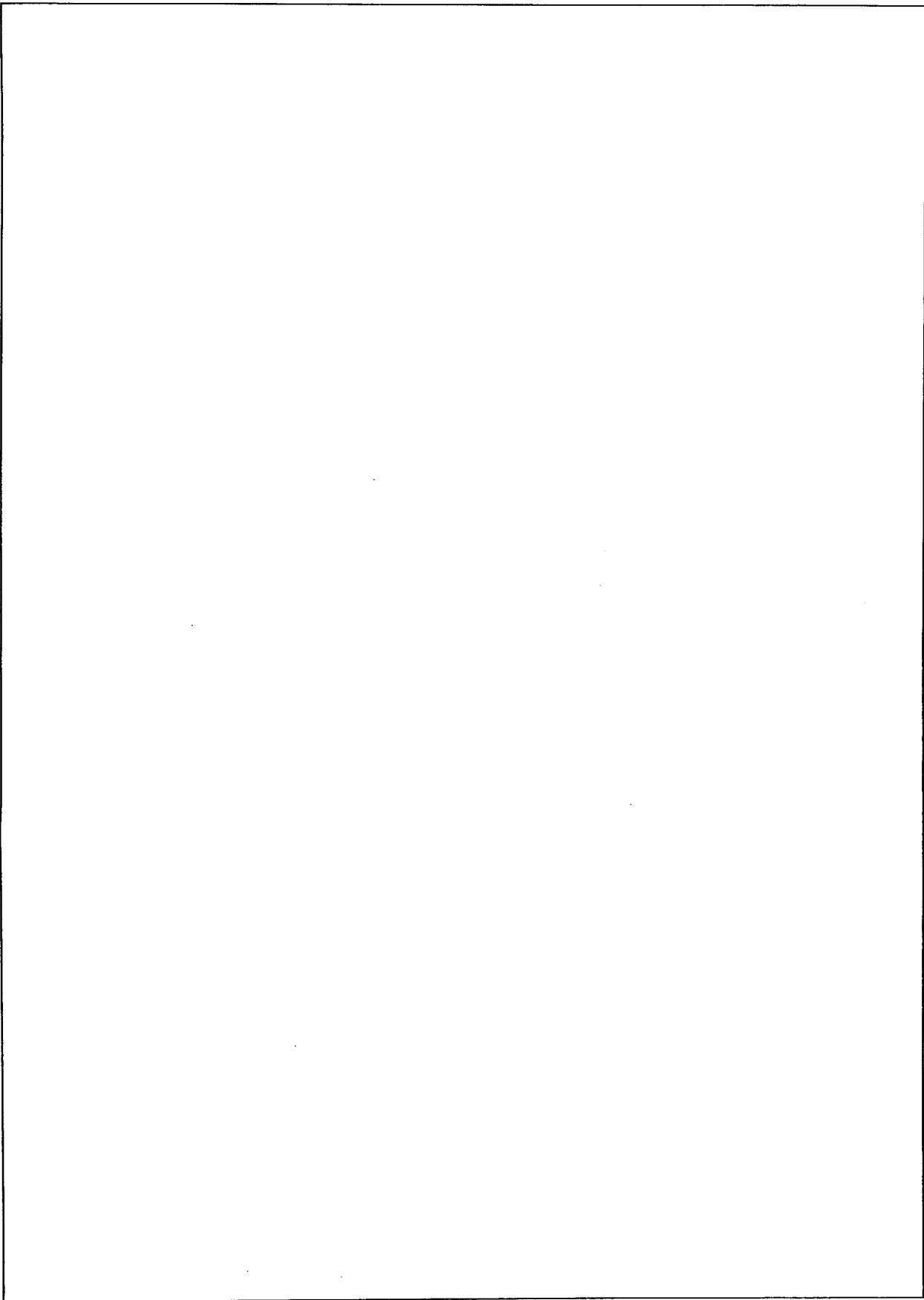
Questions for Thought

For you:

- ◆ What is the most important thing you learned about yourself and WHI from this celebration and sharing?
- ◆ How might this celebration and sharing help you seek support for what you're doing in WHI?

For your special person:

- ◆ How might this celebration and sharing help you support the person who brought you here today?



Sharing WHI

You Ask

These questions are for you to ask someone important to you. They are meant to help this person share what they know about WHI, what new things they might want to learn about WHI, and how your being a part of WHI impacts their life.

Question	Answer
How does the WHI study matter to you?	
How does my personal involvement in WHI impact you?	
What additional things about the WHI would you like to know about?	
What aspects of my WHI eating plan appeal to you?	
What parts of my WHI eating plan seem difficult to you?	
Are you considering any dietary changes of your own in the next 3 months?	
How could I support your efforts to make dietary changes?	
Sometimes it is difficult for me to talk about the WHI with others; would you be willing to share conversations with me about my WHI efforts?	
How can I show you that I appreciate your support of my WHI work?	
Tell me about the ways you make the world a better place for women.	
Your personal question:	

Sharing WHI

They Ask

These questions are for your special person to ask you. They are meant to help you share what it is like to be a part of WHI and the kinds of support you might be seeking for your efforts in the study.

Question	Answer
What were some of the reasons you joined the WHI?	
What have you gained by being a part of the WHI ?	
What do you want others (or me) to know about your involvement in WHI?	
What are you most proud of accomplishing in WHI?	
I understand that WHI runs until 2005; what are you planning to do to stay active in the WHI?	
What are some changes you've made in your daily life while in WHI?	
What do you find most challenging about eating the WHI way?	
What new dietary changes do you still plan to work on?	
How can others (or I) support your continuing efforts in the study?	
How can others (or I) show appreciation to you for your participation?	
Your personal question:	

The Women's Health Initiative (WHI)

Resource 1

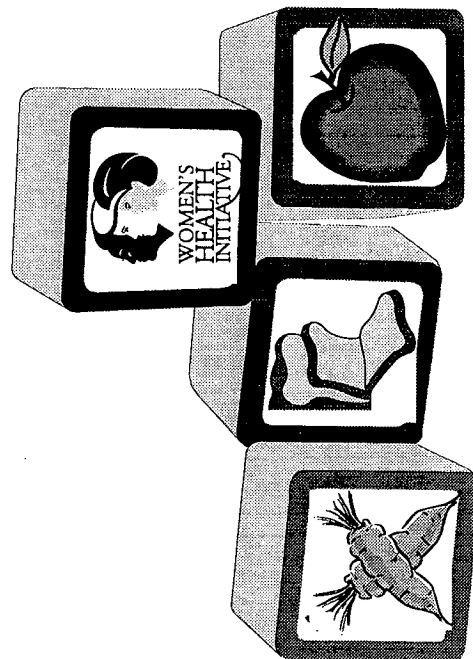
<p>Why is WHI a landmark study?</p>	<p><u>Public health</u> WHI is designed to address some of the major causes of disease and death in post-menopausal women.</p> <ul style="list-style-type: none"> ◆ Breast cancer is the most common cancer for US women. It is the second leading cause of cancer death (after lung cancer) for US women. ◆ <u>Colon cancer</u> is the third most common cancer and cause of cancer death (after lung and breast cancer) for US women. ◆ <u>Coronary heart disease</u> is the leading specific cause of death for US women. ◆ <u>Bone fractures</u> are common at older ages and are a major cause of disability and loss of mobility. Deaths from complications of hip fractures approximate those for breast and colorectal cancer. <p><u>Population</u> WHI includes ethnically diverse post-menopausal women who were at least 50 years of age at the beginning of the study. This is a population that has previously received little scientific attention.</p> <p><u>Complexity</u> WHI is complex. It includes a clinical trial that has three separate parts: the hormone replacement study, the calcium and Vitamin D study, and the Dietary Modification (DM) study. WHI also includes an observational study.</p> <p><u>Size</u> WHI is a very large study. It includes 161,809 women:</p> <ul style="list-style-type: none"> ◆ The clinical trial has 68,133 women. Of these women, 48,836 are in the DM study and 19,542 of them are in the Dietary Change part of the study. ◆ The observational study includes 93,676 women. <p><u>Duration</u> WHI is a long study. Participants will be followed for an average of 8.5 years.</p>
--	---

What is the purpose of the WHI DM study?

The purpose of the DM study is to test whether a low-fat dietary pattern high in fruits/vegetables and grains reduces the risk of breast and colorectal cancers and heart disease in post-menopausal women.

Why do we need the WHI DM study?

Most previous research on dietary intake and disease has used observational study designs. In these types of studies, investigators simply observe disease occurrence among women who choose a healthy eating pattern compared to women who have less healthy eating patterns. However, we know that women who choose eating patterns low in fat and high in fruits and vegetables are also more likely to choose other healthy behavior, such as more exercise, less smoking, and more disease screening. Therefore, scientists can never be sure in these types of studies which of these healthy lifestyle choices are affecting disease risk.



What is the WHI DM study design?

WHI uses a very rigorous study design called a randomized, controlled clinical trial. Briefly, the main points are:

- ◆ Most randomized, controlled clinical trials test treatments for patients with disease and the results only apply to patients. WHI is different. WHI is testing prevention of disease in healthy women, and therefore, the findings about diet and risk of cancer and heart disease will apply to all healthy post-menopausal women.
- ◆ The DM study has two groups that will be compared to each other: the Dietary Change group and the Comparison group. Women in the Dietary Change group eat a low-fat dietary pattern high in fruits/vegetables and grains. Women in the Comparison group eat as usual.
- ◆ At the beginning of the study, the Dietary Change and Comparison groups had the same personal characteristics (such as age) and other behavior (such as exercise) because women were randomly assigned to one of the two groups. Random assignment to a group is done with a coin toss (except scientists use a computer to “toss the coin”).
- ◆ The two groups will be followed for disease occurrence for the duration of the study.
- ◆ At the end of the study, we will compare disease occurrence in the two study groups to see if low-fat eating helped women in the Dietary Change group have less breast and colorectal cancers and heart disease.

WHI's randomized controlled clinical trial design is the "gold standard" of scientific study design.

WHI has the potential to give strong evidence about the role that low-fat eating plays in breast and colorectal cancers and heart disease in post-menopausal women.

The evidence from WHI is especially strong because the computer coin toss means that the Dietary Change and Comparison groups are exactly equal, except for their dietary pattern. Therefore, scientists can feel confident that differences in disease occurrence between these two groups is the result of the differences in eating patterns.

Why is the WHI DM study so important?

What role do participant volunteers play in the WHI DM study?

Participants make the study possible.

WHI could not be done without participant volunteers. We could not test the study question without:

- ◆ Women randomly assigned to the two study groups for comparison.
- ◆ Women in the Dietary Change group eating a low-fat dietary pattern high in fruits/vegetables and grains.

Each participant is irreplaceable.

No one in the study can be replaced by another person. Each participant's information will be included in study analyses. The data are always confidential. Including all participants in analyses is another reason that evidence from WHI is especially strong.

Each participant makes a huge contribution of time and effort.

In order to compare disease occurrence between the Dietary Change and Comparison group at the end of the study:

- ◆ Each participant completes clinic visit exams and many forms at least once a year for the duration of the study.
- ◆ Each participant in the Dietary Change group eats a low-fat dietary pattern for the duration of the study. She also attends Dietary Change group sessions and closely monitors what she eats.

How does the study protect participant safety?

Participant safety is paramount.

WHI has a Data Safety and Monitoring Board (DSMB) that meets every six months. This group reviews WHI data and relevant non-WHI study results. They recommend WHI protocol changes if needed, and even whether it is appropriate to continue WHI. WHI staff are available to talk with participants about safety concerns.

Autumn Tea

- ♦ *Ham Tea Sandwiches*
- ♦ *Garden Frittata*
- ♦ *Grape Clusters*
- ♦ *Pumpkin Orange Poppy Seed Cake*
- ♦ *Earl Grey Tea*



Ham Tea Sandwiches

4 slices bread, thin but firm
apricot jam
2 ounces very thinly sliced lean smoked ham
Dijon mustard
parsley or watercress (garnish)

1. Spread 2 bread slices with apricot jam to taste. Arrange 1 ounce of sliced ham on top.
2. Spread remaining bread slices with Dijon mustard to taste and place on top of ham.
3. Neatly cut off all crusts.
4. Cut each sandwich into 4 triangles or squares.
5. Arrange on a doily-lined plate, garnish with parsley or watercress leaves.

Makes 2 servings (4 triangles/squares per serving).

Fat: 4 grams

Grain Servings: 2 per serving

Additional Tea Sandwich Ideas

Cucumber & Watercress

4 slices bread, thin but firm
1 cup (about 1/2 a medium) thinly sliced cucumber
1 small bunch watercress (washed, dried, stems removed)
2 tablespoons low-fat mayonnaise
salt & pepper to taste

Makes 2 servings (4 triangles/squares per serving).

Fat: 6 grams

Fruit/Vegetable Servings: 1 per serving

Grain Servings: 2 per serving

Tomato & Cream Cheese

4 slices bread, thin but firm
1 cup (about 1 large) thinly sliced tomato
2 tablespoons low-fat cream cheese
salt & pepper to taste

Makes 2 servings (4 triangles/squares per serving).

Fat: 5 grams

Fruit/Vegetable Servings: 1 per serving

Grain Servings: 2 per serving

Tuna Salad

4 slices bread, thin but firm
1 cup tuna salad (made with water packed tuna and fat-free mayo)

Makes 2 servings (4 triangles/squares per serving).

Fat: 3 grams

Grain Servings: 2 per serving

Garden Frittata

1 clove garlic, minced
1 small onion, chopped
1 teaspoon oil
1 1/2 cups chopped vegetables (bell peppers, mushrooms, potatoes, zucchini, etc.)
1/2 teaspoon (each): dried thyme, dried basil, dried rosemary
1/4 teaspoon salt
1/8 teaspoon pepper
3/4 cup egg substitute
2 egg whites
2 tablespoons grated Parmesan cheese

1. Preheat oven to 375°F.
2. In a medium non-stick skillet, sauté garlic and onion in oil on low heat until softened.
3. Add vegetables and seasonings. Cook until vegetables are tender (about 3 minutes). Remove from heat.
4. Beat egg substitute and egg whites together. Stir in Parmesan cheese and cooked vegetables.
5. Pour mixture into a pie plate coated with non-stick spray. Bake for about 30 minutes, until eggs are solid and the top is golden.
6. Serve immediately or at room temperature.

Makes 2 servings.

Fat: 4 grams

Fruit/Vegetable Servings: 2 per serving

Recipe adapted from The New American Diet. Connor & Connor, 1986.

Pumpkin Orange Poppy Seed Cake

Cake:

1 package (18 1/2 ounce) yellow cake mix
1 can (15 ounces) pumpkin puree (not pumpkin pie filling)
3 large eggs
2/3 cup orange juice
1/4 cup poppy seeds

Glaze:

1 1/2 cups sifted powdered sugar
2 to 3 tablespoons orange juice

1. Preheat oven to 350°F. Grease and flour 12-cup bundt or tube pan.
2. Combine cake mix, pumpkin, eggs and orange juice in large mixing bowl. Beat on low speed until moistened. Beat on medium speed for 2 minutes. Add poppy seeds; mix until blended. Pour into bundt pan.
3. Bake 50 minutes, until wooden pick inserted in cake comes out clean. Cool in pan on wire rack for 10 minutes; remove to wire rack to cool completely.
4. Prepare glaze: Combine powdered sugar and orange juice until smooth.
5. Drizzle cooled cake with glaze.

Makes 16 servings.

Fat: 4 grams

Fruit/Vegetable Servings: .25 per serving

Grain Servings: .75 per serving

Recipe from Libby's submitted by the
Pawtucket/Fall River WHI Clinical
Center