Fall Session - Year 3:

Making Sense of Health News

In this session, the participant will:

1. Identify current sources of personal health information
2. Discuss the key issues to focus on when evaluating health information
3. Practice evaluating health information

Checklist of Materials Needed

Supporting Materials

- ☐ Fat Scans
- ☐ Highlighter pens or markers to use with copies of the articles, etc.
- ☐ Nutrition/health-related articles from newspapers, magazines, (e.g., Time),
- ☐ Overhead projector, flip chart or blackboard
- ☐ Overhead:
  Overhead Fall 3-1- *What to Look for in Health Information*
  *****For groups that want more detailed information about study design (refer to Optional Materials note on next page)

Food & Paper Supplies

- ☐ Beverages of choice (coffee, tea, juice)
- ☐ Creamer, sugar, coffee stir sticks, optional
- ☐ Paper supplies: plates, napkins, cold cups, hot cups (if needed)
- ☐ Plastic spoons or forks

Food Tasting:

Note: Choice of Group Nutritionist.
Consider emphasizing foods that are low-fat and nutritious, but not "heavily" advertised (i.e., fruits, vegetables, available in the local area)

Participant Manual

Worksheets

Worksheet	**Page(s) #**
Fall 3-1	9-10

Participant Manual (continued)

Resource Section

Additional materials available in Participant Manual

Resource	Page(s) #
Evaluating Health Information	16
Resources for Reliable Nutrition Information	17

Group Nutritionist Note: The aims of this session are to:

1. Inoculate participants against sources of health information that may run counter to WHI nutrition goals.
2. Help participants develop skills to evaluate incomplete or inaccurate health claims.

The Group Nutritionist may use the health articles and advertisements included in this session, or gather their own collection of health-related articles and advertisements from newspapers or magazines. Be sure to include a mixture of articles, some based on credible scientific research and others based on coincidence or outrageous claims.

Optional Materials: For Dietary Change groups who would like more detailed information about study design and research. (See page 15 and use Option 2.).

Optional Overheads:
Overhead Fall 3-2 -- *Scientific Research: Type of Study*
Overhead Fall 3-3 -- *Scientific Research: Number of Observations*

Optional Handouts:

- Common Research Challenges
- Characteristics of Observational and Intervention Studies in Nutrition-Related Research
- Reading the Results of a Study

Fall 3 Session Outline--Key Activities

Activity Type (Time)	Activity
Pair or Small Group Discussion (20 minutes) ✍ *Notes*	**Review of Progress** ♦ Discuss summer time experiences (with or without the group support--depending on peer group meetings). Use the questions below: Q/A: - How did you handle meeting your WHI goals during the summer months? - What strategies and skills did you think helped you the most in maintaining your continued success? (Ask the group a question that addresses their last maintenance session, if appropriate): • Summer 2- Easy Cooking for One or Two; • Summer 3- Healthy Fare with an International Flair (Ask the group a question that addresses their peer group activities, if appropriate):
Individual Activity and Group Discussion (10 minutes) ✍	♦ Participants identify sources of personal health information. • Participants discuss what influences their health decisions. ♦ Key point--participants identify sources of current health information and the benefits of being a discerning consumer of health information.

Brief Overview/ Small Group Activity (20 minutes) 	♦ Use Overhead Fall 3-1: *What to Look for in Health Information* to provide a brief overview. ♦ Form small groups (3-4 people). • Provide each group with a health-related article. • Participants use **Worksheet Fall 3-1** and Resource Fall 3-1- *Evaluating Health Information* ♦ Key point--participants practice evaluating health-related information.
Large Group Discussion/ Lecture (20 minutes) 	♦ Use Overhead Fall 3-1 to help focus group discussion. • Participants share results of their evaluation with large group. • Discuss reasons behind guidelines, as appropriate. ♦ Participants discuss and identify potential resources for reliable health information. ♦ Key point--participants discuss the key issues they need to be aware of when reading health information and identify reliable resources. *Group Nutritionist Decision*: Option #1: if group just wants a quick review of study design. Option #2: if group wants more details and discussion about research methods. Use Overheads Fall 3-2 and Fall 3-3.

Summary

Large Group Discussion (15 minutes)

Discuss issues and identify participants who need more help.

- Have participants share ideas for how they can use the guidelines to help them interpret and understand health information.

Q/A:

- Where could you go for additional reliable health information, if you need help or guidance?
- Which guidelines do you think will be the most helpful for you in evaluating health information?

Home Activity

Lecture (5 minutes)

- Assign 3 Fat Scans (or other self-monitoring method).
- Suggest activities to work on during the next 3 months. Answer questions.

Food Tasting

Large Group Discussion (10 minutes)

- Group Nutritionist's choice. One suggestion would be to focus on seasonal fruits and vegetables available in local area stores.

Total Time: 100 minutes

Fall 3 Session: Making Sense of Health News

Activity Type (Time)	Activity
	REVIEW OF PROGRESS/SUCCESSES
Pair or Small Group Discussion (20 minutes)	♦ **Discuss summer time experiences (with or without the group support--depending on peer group meetings). Use the questions below:** **Q/A:** - **How did you handle meeting your WHI goals during the summer months?** - **What strategies and skills do you think helped you the most in maintaining your continued success?** **(Ask the group a question that addresses their last maintenance session, if appropriate):** • **Summer 2- Easy Cooking for One or Two;** • **Summer 3- Healthy Fare with an International Flair** **(Ask the group a question that addresses their peer group activities, if appropriate):**
	OVERVIEW OF SESSION
	• Surveys show that American consumers rely on the news media for most of their information about nutrition and food safety. However, the headlines are frequently more confusing than helpful. The purpose of today's session is to: ➢ Prepare you to evaluate and question the health information you read or hear, and ➢ Help you understand the difference between science and personal opinion.

NEW MATERIAL

Sources of Current Health Information

PURPOSE: Participants identify their current sources of health and nutrition information.

Individual Activity and Group Discussion (10 minutes)

- **Participants identify sources of personal health information.**
  - **Participants discuss what influences their health decisions.**
- **Key point--participants identify sources of current health information and the benefits of being a discerning consumer of health information.**

- Most of us use a variety of resources to help make health-related decisions. For example, when we move to a new location, we might ask neighbors, or call a medical service to ask about a good doctor or dentist. Many of us also tend to gather general health information from conversation with family, friends and co-workers (e.g., newest vitamin information, hot flash remedies, weight loss programs, etc.).

- In everyday living, we hear news on the radio, talk to family and friends, watch TV, and read newspapers and magazines. We might even look at the tabloids while waiting in the check-out line at the grocery store. Some of us even get health news from the computer.

Group Nutritionist Note: Have participants take a closer look at some of their current sources for health information. As participants share information, be aware of examples you can use later when pointing out the differences between "good science" (e.g., objective information or facts) and "science fiction" (e.g., testimonials, stories of personal experience, etc.). Use the questions on the next page to help promote discussion.

Note: If your group has access to computer information services and Internet, you might want to explore the health information sources they use (WWW sites, listservers, etc.).

- Think about some of your current sources of health information. Picture the last time you made a health-related decision. It may have been your decision to participate in the WHI study, join a health club, or try a new vitamin.

☛

Q/A:

- What information sources did you use when making your decision?
- Which information sources do you think were the most helpful?
- What influence does the media (e.g., TV, radio, newspapers, magazines) have on your health decisions?

- Consumers often complain that health news is confusing. It tosses them from headline to opposing headline. For example, one study may proclaim that "coffee increases your risk of heart disease," then a month later the headlines read: "new study finds coffee drinking is not related to the risk of heart disease."

- Scientific research is slow and time consuming. It's like putting together a large jigsaw puzzle. Most of those "well-publicized" headline studies that you see or hear about are just one piece of the puzzle. Researchers need many pieces before they can figure out what the whole picture looks like.

- Why is it important for you to become skilled at reading and evaluating health information? Well, two potential reasons are:
  - It can help you identify more reliable information, and;
  - It can help you apply the best available information to your own personal health decisions.

Fact or Fiction

PURPOSE: Provide an opportunity for participants to practice evaluating health-related information.

Brief Overview/ Small Group Activity (20 minutes)

- **Use Overhead Fall 3-1: *What to Look for in Health Information* to provide a brief overview.**
- **Form small groups (3-4 people).**
  - **Provide each group with a health-related article.**
  - **Participants use Worksheet Fall 3-1 and Resource Fall 3-1- *Evaluating Health Information***
- **Key point--participants practice evaluating health-related information.**

- You can evaluate the health information you read even without special training in science. As you review health-related articles or ads, look for answers that address two questions:
  - What's the source of the information?
  - How was the study designed?

Group Nutritionist Note: Use Overhead Fall 3-1: *What to Look for in Health Information* to provide a quick overview of the areas addressed by **Worksheet Fall 3-1** and Resource Fall 3 - *Evaluating Health Information.*

Let the participants know **Worksheet Fall 3-1** questions will help them know what to look for when they evaluate their assigned health material. They will have a chance to discuss the details and reasons behind each of these questions after they have completed the **Worksheet Fall 3-1** evaluation.

- Let's use this overhead to take a quick look at some of the areas that you will be evaluating when you use **Worksheet Fall 3-1**. First, look at the source of the information:
  - Is the information is based on personal experience or objective data?
  - Are there any hidden motives?
  - Where are the study results or information published (e.g., scientific journal, magazine, book, etc.)?
  - Do dramatic headlines match what the article says?
  - Are qualifying words are used when describing the study results (e.g., "may help" or "possibly works", etc.)?

- Second, look at the design of the study, using the questions on **Worksheet Fall 3-1**:
  - Can you tell what type of a study was done? (One that observes a group of people, or one that tests a way to treat or prevent a disease)
  - Who took part in the study?
  - How many people were involved?
  - How long did the study last?

Group Nutritionist Note: Break the participants into small groups (or pairs) and give each group a health article or advertisement to evaluate. The groups will use **Worksheet Fall 3-1** and the information provided in Resource Fall 3-1- *Evaluating Health Information* to help them review and discuss their health article/materials.

Provide each group with a colored highligher pen. Have each group identify a person to record the group's responses to the questions on **Worksheet Fall 3-1**. Allow them about 15 minutes to review their health article/materials. Then use the questions and information provided in the next section (Evaluating Health Information) to review and discuss their impressions and questions.

- For this next activity, I'd like you to break into groups of 3-4 people (or pairs). You will be using **Worksheet Fall 3-1** and the information in the Resource Fall 3-1 *Evaluating Health Information* to review and discuss a health-related article.

- When you get in your groups, identify a person who will serve as your group recorder. This person will be responsible for recording your group's responses and impressions to the article. As you review your health article, don't be surprised if you can't find all the answers to the questions on **Worksheet Fall 3-1**.

- Consider using a highlighter pen, to identify and highlight the answers you can find. Based on your answers to the questions on **Worksheet Fall 3-1**, decide whether or not you would believe the message provided in your health article. Then identify any additional questions your group had after reviewing the article.

- Now, is everyone excited to give this a try? You'll have about 15 minutes. I'll let you know about two minutes before you need to wrap up your group discussion. This will let your group use the last few minutes to complete **Worksheet Fall 3-1** and identify your additional questions.

Evaluating Health Information

PURPOSE: Participants discuss guidelines for evaluating health information.

Large Group Discussion/ Lecture (20 minutes)

- **Use Overhead Fall 3-1 to help focus group discussion.**
  - **Participants share results of their evaluation with large group.**
  - **Discuss reasons behind guidelines, as appropriate.**
- **Participants discuss and identify potential resources for reliable health information.**
- **Key point--participants discuss the key issues they need to be aware of when reading health information and identify reliable resources.**

***Group Nutritionist Decision*:**
Option #1: if group just wants a quick review of study design.
Option #2: if group wants more details and discussion about research methods. Use Overheads Fall 3-2 and Fall 3-3.

Group Nutritionist Note: Use Overhead Fall 3-1: *What to Look for in Health Information* to help focus the group discussion.

Use the discussion questions listed below (or similar open-ended questions). Allow participants the opportunity to make their own discoveries. Focus on how the source of the information and the study design can influence a health message and its generalizablity to their own personal lives.

Source of Information

- There are many different ways that scientists search for new health information. However, to be considered worthwhile, health information needs to be:
  - Not influenced by any personal beliefs or values, and
  - The results of many studies, not just one.

Q/A:

What were some of the sources of information in the health articles or materials you reviewed (testimonials, personal experience, objective studies, etc.)?

- What factors could influence the health information reported (experience of researchers, hidden motives)?

- Personal Experience Be careful of reports of personal experience or testimonials especially when the researcher or author is trying to sell a product, procedure or book. Testimonials and reports of personal experience can make the news, but they happen to very few people and thus may be due to chance.

- For example, earlier this year (1996) a TV station announced that a research team had found that there was an association between wearing bras and an increased risk of women developing breast cysts and potentially breast cancer. The reporter commented that the research team's findings were based on personal observation and experience.

- Unfortunately, it's impossible to know from a few personal experiences if there is a relationship between two factors. In other words, breast cysts occur in women who don't wear bras, and bras are commonly worn by women who never develop breast cysts.

- Thus in individual cases, researchers cannot always see the difference between relationship and chance.

- Hidden Motives Search for possible hidden motives when you look at a news article or an advertisement. See if you can identify who paid for the study and who reported it (reputable institutions or researchers. Decide if any special interest group would gain or lose by showing particular results.

- For example, what thoughts would you have if a meat group reported the results of a study showing that people should eat a side of beef each day? Or, what concerns would you have if an anti-meat group did a study showing that meat was poisonous. These examples are both potential conflicts of interest and should trigger an alarm to make you stop and think about the results.

Q/A:

- Why do you think it might help to know if the study or research project had been published in a scientific journal (e.g., *Lancet, Am. Medical Assoc., New England Journal of Medicine, etc.*)?

- Where the Information is Published Look at the article and see if you can identify the scientific journal where the study was published. Articles in scientific journals have been approved by panels of medical professionals, so they have undergone review by fellow scientists. On the other hand, a study released at a medical meeting may be on the cutting edge of science, and so results are much more uncertain; more research may be necessary.

☛ Q/A:

- How did the impression you received from the headline or title compare to the actual content of the article?

- Dramatic Headlines or Promises of Easy Answers Look past headlines. News headlines, TV news reports and advertisements are designed to catch your attention. However, they often provide only part of the story. Question headlines that make bold or extreme statements, promise easy answers, or quick fixes, or sound too good to be true. In addition, be careful of headlines and articles that tell you that a particular procedure or food is "bad" or "good". Many of these articles are probably false, incomplete or misleading.

☛ Q/A:

- Did you find any qualifying words or terms in your article, such as "may" or "probably", etc.?
- What were some of the qualifying words you found?
- How did these qualifying words influence the way you looked at the health information or results of the study?

- Qualifying Words Reports that use words such as "may", "seem", "possibly", or "in some cases" are usually more reliable. The researchers want you to interpret the study results with caution. So, they use these words to indicate to readers that the study results are not definite or may not apply to everyone. Remember--the results of one study alone, rarely prove anything.

☛ Q/A:

- How could the design of the study influence the way you interpret (or evaluate) the study results?
- How could you tell what type of study was done?

GROUP NUTRITIONIST DECISION POINT

Group Nutritionist Decision:

A. <u>Option 1:</u>
Continue on with a brief overview of study design. Use the information on <u>pages 16-20</u>.

B. <u>Option 2:</u>
If you feel that your group would like more detailed information about study design and potential research challenges, use the supplemental information on <u>pages 21-28</u> and **Overheads Fall 3-2 and Fall 3-3** *Scientific Research* -- to explain the two major types of studies used with people.

OPTION #1:

Study Design

Type of Study

- The two types of research studies most commonly used with people are:
  - Studies that follow and observe groups of people (Observational studies), and
  - Studies that test ways to prevent or treat a disease. (Intervention studies)

- Observational studies follow a population or group of people to see if they can identify any factors (associations) that are connected with a disease.

- This type of study creates a lot of media attention because it is usually very large. For example, the WHI Observational Study will have 100,000 women participating.

- The benefit of observational studies is that they help to provide some clues and direction for future research. However, they cannot usually prove the cause of a disease because it's difficult for them to separate one potential risk factor from another. What does this mean?

- Well, look at the following example: In the 1970s and 1980s some observational studies associated coffee drinking with the risk of developing heart disease. Yet, other observational studies could not match these results. Coffee drinking could not be separated from all the other characteristics or risk factors that were also common to coffee drinkers (e.g., smoking, high-fat foods, less exercise, etc.).

- Intervention studies test ways to treat or prevent disease. They are considered to be the "gold standard" of all studies because they are carefully designed to avoid chance results. Intervention studies, like the WHI Dietary Study can provide much stronger evidence about the cause and treatment of a disease.

- In intervention studies, random assignment is important to keep researchers fair and neutral. This is why the WHI Dietary Study randomly assigns participants to either the Dietary Change or the Comparison group. Women are willing to make the effort to change their eating patterns and other women are willing to continue eating as usual. Both randomization assignments are difficult and demand some dedication.

- The WHI Clinical Trials (Dietary Modification, Hormone Replacement Trial and the Calcium/Vitamin D Trial) provide good examples of randomized, controlled intervention studies.

☛ Q/A:

- How important do you think it is to know who participated in the study (kind of people)?

- Type of Participants In addition to the type of study, it's important to look at who participated. Were the people like you (age, sex, etc.)? Remember the type of participants involved in a study affects how well the information relates to you and should influence any health decisions you make (generalizability of information).

- For example, previous intervention studies about heart disease only included men. This was done because middle-aged men were more likely to have heart disease than middle-aged women. When study results were published, researchers assumed that many of the study results could be applied to women, as well as men. However, it is now known that many of the results do not apply to women of a similar age. This was one of the reasons that WHI was funded.

☛ Q/A:

- What affect do you think the number of participants has on the results of a study?
- How could the length of a study influence the final results?

- Number of Participants It is important to find out how many people took part in the study because the smaller the number of participants the greater the chance that the findings lead to the wrong conclusions.

- Length of Study It is also important to know how long the study lasted. The length of a study is particularly important when the disease being followed is cancer or heart disease. Both of these diseases take a long time to develop, so a study needs to allow enough time to see a difference between the groups. This is why the WHI study will last an average of 9 years.

Group Nutritionist Note: Use the questions in the Summary section to allow participant's time to identify reliable resources the could use if they needed additional information. In addition, have participants identify how they can use these guidelines when they read health information.

Summary

Large Group Discussion (15 minutes)

Discuss issues and identify participants who need more help.

- **Have participants share ideas for sources of reliable health information and ways that they can use the guidelines to help them evaluate health information.**

Group Nutritionist Note: Ask the group members to identify additional sources of reliable health information. Ask participants to share ideas. Refer them to Resource Fall 3-2, *Resources for Reliable Health Information* at the back of their Fall 3 Participant materials.

If they need help, suggest some of the following resources: WHI nutritionist, local consumer office, Better Business Bureau, National Cancer Information Service (1-800-4-CANCER), personal physician, National Council Against Health Fraud/Consumer Health Information Institute.

Q/A:

- Where could you go for reliable health information, if you needed help or guidance?
- Which guidelines do you think will be the most helpful for you in evaluating health information?

- Don't jump to conclusions when you read or hear the "latest research findings." Remember, a single study is not enough reason to change your health habits.

- Keep up your good work and participation in the WHI. You are an important partner in advancing the scientific knowledge about women's health issues and the role of diet in the prevention of cancer and heart disease. Your contributions are greatly appreciated.

Home Activity

Lecture
(5 minutes)

- ♦ **Assign 3 Fat Scans (or other self-monitoring method).**
- ♦ **Suggest activities to work on during the next 3 months. Answer questions.**

- During the next three months, use your Fat Scan (or other self-monitoring method) to monitor your intake of fat, fruits/vegetables and grains. Please keep at least one Fat Scan (or other tool) each month.

- If possible, evaluate a newspaper or magazine article on health using the checklist provided in **Worksheet Fall 3-1** and the guidelines provided in the Resource Fall 3-1 - *Evaluating Health Information* at the end of your Fall Year 3 Participant materials.

Food Tasting

Large Group
Discussion
(10 minutes)

- ♦ **Group Nutritionist's choice. One suggestion would be to focus on seasonal fruits and vegetables available in local area stores.**

Overhead Fall 3-1

What to Look for in Health Information

Source of Information

- **Based on personal experiences or objective research?**
- **Hidden motives?**
- **Published in a scientific journal, magazine, book?**
- **Dramatic headlines, misleading titles or promises of easy answers?**
- **Uses qualifying words?**

Study Design

- **Type of study used?**
- **Type of participants?**
- **Number of participants?**
- **Length of study?**

OPTION # 2:

Study Design

Type of Study

- The two types of research studies most commonly used with people are:
  - Studies that follow and observe groups of people (Observational studies), and
  - Studies that test ways to prevent or treat a disease. (Intervention studies)

Group Nutritionist Note: Use **Overheads Fall 3-2 and 3-3** *Scientific Research: Type of Study and Number of Observations* to explain the two major decisions that researchers make:

- Type of Study--observational vs. intervention
- Number of Observations--cross-sectional vs. longitudinal

The main point is that an intervention study, such as the WHI is the 'gold standard' and the only way to truly show cause-and-effect.

- There are many different ways that scientists search for new information. However, we are going focus on two types of research. These are:
  - Observational (studies of people)
  - Intervention (treatment/prevention studies)

- I am going to briefly describe both of these types of research and point out some of their characteristics. During this overview, keep in mind how these characteristics may influence the final results of a study.

- **Overhead Fall 3-2** shows you the first decision that needs to occur in scientific research: What type of study will be done? The researcher needs to decide whether to change the events being studied, or just observe them.

Use Overheads Fall 3-2 and Fall 3-3

Observational Studies (Studies of People):

- In an observational study, the researcher observes the events without changing them. For example, an observational study could compare the eating pattern history of post-menopausal women who have breast cancer with the history of those who do not.

- Observational studies are an important type of research. The studies look at the distribution of a disease and risk factors in people. They attempt to identify the factors that are connected with the disease. These studies create a lot of media attention because some of them are very large. For example, the WHI Observational Study will have 100,000 women.

- **Overhead Fall 3-3** represents the second decision researchers make when they are doing an observational study: How many observations or measurements should they make?

- One choice is to take one measurement or observation. This is called a cross-sectional study. The national census survey or the NHANES nutrition survey would be examples of cross-sectional observational studies.

- A second choice would be to make multiple observations on more than one occasion. This is called a longitudinal study. Longitudinal studies can follow people forward (prospective) or backward (retrospective) in time.

- In a prospective (cohort) study, researchers start with an identified group of people and follow them forward in time to see who and who does not get a disease. Information about each person's background and lifestyle is used to reach conclusions about the factors linked with disease.

- The WHI Observational Study is an example of a longitudinal study. It is collecting information on 100,000 women throughout the U.S. and then following these women for the next 9-12 years. Another follow-up study that is often featured in the media is called the Nurses Health Study. It is following about 120,000 nurses.

- In a retrospective (case-control) study, researchers start with individuals who have a certain disease and similar people who do not have the disease. They study past lifestyles and experiences of both groups to see if any particular factor or factors are more common in the people with the disease.

Advantages and Disadvantages of Observational Studies

- An advantage of observational studies is that they help to provide some clues and direction for future research. These clues are provided when the studies show associations or connections between certain risk factors and a disease.

- One of the major disadvantages of observational studies is that they usually cannot prove the cause of a disease. This is because this type of study cannot easily separate one potential risk factor from another. Thus, even if a media article reports the study found that X was "associated with" or "contributed to" Y, the consumer needs to remember that this does not mean that X caused Y.

- Why does this matter? Well, look at the following example: In the 1970s and 80s some follow-up studies associated coffee drinking (X) with the risk of developing heart disease (Y). Yet, other follow-up studies could not match these results. Coffee drinking as a risk factor for people with heart disease could not be separated from all the other characteristics or risk factors also common to coffee drinkers (e.g., smoking, high-fat foods, less exercise, etc.).

Group Nutritionist Note: Other common challenges for observational studies can be pointed out, if appropriate. (Optional handout *Common Research Challenges* provides a definition and example for each of these challenges.)

- **Confounding variables** (hidden) may cloud the results. Cannot tell what part of a person's eating patterns might be causing the disease--or it might be some other unknown factor about people with the disease.
- **Bias, recall:** People may not reliably report their eating and exercise habits. Do you know how many citrus fruits you ate when you were in your early 20's? Few of us could say. People who are aware of the benefits of eating vegetables may unconsciously exaggerate their fruit or vegetable consumption on a questionnaire.
- **Misclassification:** The questionnaire or tool used in the study may not be able to accurately determine the variable of interest (nutrient, etc.).
- **Study too short:** The study wasn't long enough or should have started when people were younger.

Use Overhead Fall 3-2

Intervention Studies (Prevention/Treatment studies)

- If the researcher decides to change the events being studied and then observe the effects, this is called an intervention study.

- Intervention studies test ways to treat or prevent disease. They are considered to be the "gold standard" of all studies because they are carefully designed to avoid chance results. Intervention studies, like the WHI Dietary Study can provide much stronger evidence about the cause and treatment of a disease.

- In intervention studies, random assignment is important to keep researchers fair and neutral. This is why the WHI Dietary Study randomly assigns participants to either the Dietary Change or the Comparison group. Women are willing to make the effort to change their eating patterns and other women are willing to continue eating as usual. Both randomization assignments are difficult and demand some dedication.

- Whenever possible, intervention studies also maintain what is called a "double-blind." This means that both the study participants and the clinical staff involved in the study do not know the group assignments. This type of "double-blind" is possible with the WHI Hormone and Calcium/Vitamin D studies.

- However, in the Dietary Study women need to be aware of their dietary changes, so only a single blind is possible. A single blind is when the participant knows her own group assignment, but some of the clinic staff are unaware (e.g., nurses, dietary assessment staff, etc.). That is why we ask you not to talk about your group assignment when you are come in for your annual clinic visits. Random assignment and blinding are important to keep researchers objective and unbiased.

- The WHI Clinical Trials (Dietary Modification, Hormone Replacement Trial and the Calcium/Vitamin D Trial) provide good examples of randomized, controlled intervention studies.

<u>Advantages and Disadvantages of Intervention Studies</u>

- One of the major advantages of intervention studies is that they can help prove cause and effect. Intervention studies, unlike observational studies, control most of the outside factors by randomly assigning participants to either treatment or comparison groups. This means that, except for the intervention being studied, any other factors linked with the disease should occur equally between both groups.

Q/A:

- How important do you think it is to know who participated in the study (kind of people)?

- Type of Participants In addition to the type of study, it's important to look at who participated. Were the people like you (age, sex, etc.)? Remember the type of participants involved in a study affects how well the information relates to you and should influence any health decisions you make.

- One potential disadvantage of intervention studies is called "generalizability." This means how well the results of a study can be applied to other population groups.

- For example, previous intervention studies about heart disease only included men. This was done because middle-aged men were more likely to have heart disease than middle-aged women. When study results were published, researchers assumed that many of the study results could be applied to women, as well as men. However, it is now known that many of the results do not apply to women of a similar age. This was one of the reasons that WHI was funded.

Group Nutritionist Note: If appropriate, point out other common challenges for intervention studies.

- **Making and maintaining changes:** People do not change, or maintain their eating changes. So there is no difference in the nutrient intake or eating patterns between the two groups.
- **Participants who are not asked to change, make large changes.** Women in the Comparison group significantly change their eating patterns.
- **Study too short:** The study wasn't long enough or should have started when people were younger.

Q/A:

- What affect do you think the number of participants has on the results of a study?
- How could the length of a study influence the final results?

- Number of Participants It is important to find out how many people took part in the study because the smaller the number of participants the greater the chance that the findings lead to the wrong conclusions.

- Length of Study It is also important to know how long the study lasted. The length of a study is particularly important when the disease being followed is cancer or heart disease. Both of these diseases take a long time to develop. So, a study needs to allow enough time to see a difference between the groups. This is why the WHI study will last an average of 9 years.

Group Nutritionist Note: Use the questions in the Summary section to allow participants time to identify reliable resources the could use if they needed additional information. In addition, have participants identify how they can use these guidelines when they read health information.

Summary

Large Group Discussion (15 minutes)

Discuss issues and identify participants who need more help.

- **Have participants share ideas for sources of reliable health information and ways that they can use the guidelines to help them evaluate health information.**

Group Nutritionist Note: Ask the group members to identify additional sources of reliable health information. Ask participants to share ideas. Refer them to Resource Fall 3-2, *Resources for Reliable Health Information* at the back of their Fall 3 Participant materials.

If they need help, suggest some of the following resources: WHI nutritionist, local consumer office, Better Business Bureau, National Cancer Information Service (1-800-4-CANCER), personal physician, National Council Against Health Fraud/Consumer Health Information Institute.

Q/A:

- Where could you go for reliable health information, if you needed help or guidance?
- Which guidelines do you think will be the most helpful for you in evaluating health information?

- Don't jump to conclusions when you read or hear the "latest research findings." Remember, a single study is not enough reason to change your health habits.

- Keep up your good work and participation in the WHI. You are an important partner in advancing the scientific knowledge about women's health issues and the role of diet in the prevention of cancer and heart disease. Your contributions are greatly appreciated.

Home Activity

Lecture
(5 minutes)

- ♦ **Assign 3 Fat Scans (or other self-monitoring method).**
- ♦ **Suggest activities to work on during the next 3 months. Answer questions.**

- During the next three months, use your Fat Scan (or other self-monitoring method) to monitor your intake of fat, fruits/vegetables and grains. Please keep at least one Fat Scan (or other tool) each month.

- If possible, evaluate a newspaper or magazine article on health using the checklist provided in **Worksheet Fall 3-1** and the guidelines provided in the Resource Fall 3-1 - *Evaluating Health Information* at the end of your Fall Year 3 Participant materials.

Food Tasting

Large Group
Discussion
(10 minutes)

- ♦ **Group Nutritionist's choice. One suggestion would be to focus on seasonal fruits and vegetables available in local area stores.**

Overhead Fall 3-1

What to Look for in Health Information

Source of Information

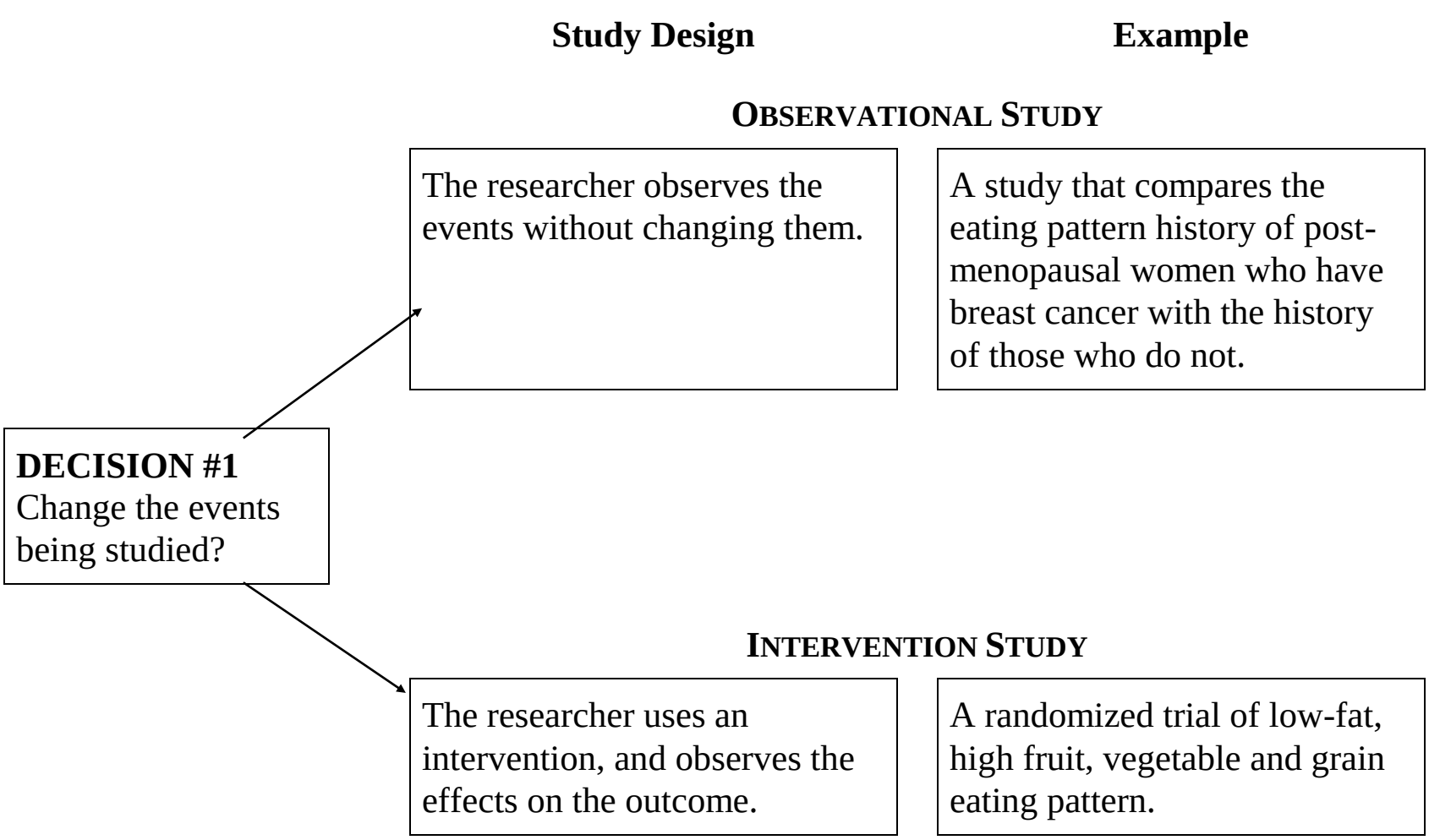
- **Based on personal experiences or objective research?**
- **Hidden motives?**
- **Published in a scientific journal, magazine, book?**
- **Dramatic headlines, misleading titles or promises of easy answers?**
- **Uses qualifying words?**

Study Design

- **Type of study used?**
- **Type of participants?**
- **Number of participants?**
- **Length of study?**

Overhead Fall 3-2

SCIENTIFIC RESEARCH: TYPE OF STUDY



Overhead Fall 3-3

SCIENTIFIC RESEARCH: NUMBER OF OBSERVATIONS

(Applies to Observational Studies Only)