

SECTION 1

GENERAL INFORMATION

INTRODUCTION

The goals of the Dietary Modification (DM) Intervention are to:

- Reduce dietary fat to 20% of total daily energy.
- Decrease intake of saturated fat to less than 7% of total daily energy.
- Increase intake of fruits and vegetables to five or more servings per day.
- Increase intake of grains and grain products to six or more servings per day.

The key principles underlying the DM Intervention are:

- **It is a self-control, not a prescriptive model.**

Each participant receives a daily fat gram intake goal. She makes her own personal choices; there is no dietary prescription provided. This allows flexibility and reinforces the ability of the woman to evaluate her own progress through self-monitoring.

- **It is a low-fat dietary pattern (15-20% of baseline calories; 20% in-trial calories).**

Research suggests that a significant reduction in fat gram intakes is required to see a difference in the long-term health of this population. A woman's fat gram goal is based on her height. The fat gram goal is not related to weight or age in this protocol. All women receive fat gram goals within a range of 23-27 grams per day based on expected caloric intake after one year in the intervention. The ultimate goal for each woman is to meet her fat gram goal, although any reductions in fat should be encouraged. Women may reduce their fat intake below their assigned goal.

- **It focuses on decreases in total fat to accomplish decreases in saturated fats.**

The focus on total fat allows the message to be simplified and focused. It also increases the participant's success and streamlines self-monitoring requirements. The original Women's Health Trial (WHT) found that participants lowered their average intakes of saturated fat to 7% when total fat intake was decreased to 20% or less of baseline calories.

- **It focuses on increasing consumption of fruits, vegetables and grains.**

The WHI fruit/vegetable and grain goals are based on the recommendations from the Committee on Diet and Health (Committee on Diet and Health, Food and Nutrition Board, Commission on Life Sciences, National Research Council. Diet and Health. Implications for Reducing Chronic Disease Risk. Washington, DC 20418: National Academy Press, 1989). The recommendations are incorporated into national nutrition policy, i.e., Dietary Guidelines for Americans (Dietary Guidelines for Americans, Third Edition. U.S. Department of Agriculture, U.S. Department of Health and Human Services, 1990. Home and Garden Bulletin Number 232.) and its companion translation piece, The Food Guide Pyramid (The Food Guide Pyramid. U.S. Department of Agriculture, Human Nutrition Information Service. 1992. Home and Garden Bulletin Number 252.)

Fruits, vegetables, and grains are generally low in fat, high in complex carbohydrates (i.e., dietary fiber and starch), and good sources of several micronutrients. High intakes of fruits and vegetables have been

related to lower risk of colon cancer. The data are less striking for grains, although somewhat supportive of lower cancer risk with high intakes of grains.

Increasing consumption of fruits, vegetables and grains will help the woman meet her fat gram goal and will serve a scientific end as well. Practically, the increased consumption of fruits, vegetables, and grains can provide additional energy to replace the energy lost from the decreased fat intake. Scientifically, the original WHT feasibility study found a modest increase in daily servings of fruit. The current intervention contains behavioral suggestions in most sessions for increasing servings of these foods. Self-monitoring of fruits, vegetables and grains will begin in Session 7 with the use of the Fat Scan as a self-monitoring tool.

1.1 Guidelines for DM Group Nutritionists

The Group Nutritionist communicates with the participants' usual health care providers and works with participants to incorporate pre-existing dietary plans into the WHI dietary change program. She/he must continue to encourage participants to see their usual health care providers.

Health care providers are notified by letter (sent by the CC designated staff or participant) of their patient's participation in WHI. At the end of Session 1, the Group Nutritionist should ask participants who are on physician-prescribed diet plans to stay a few minutes longer to discuss their diet plans.

The Group Nutritionist should avoid spending a great deal of WHI group meeting time discussing clinical diets advised from outside medical sources. The following guidelines are provided to WHI nutritionists to assist incorporating pre-existing meal plans for WHI participants who have been randomized into DM Intervention (20% fat dietary change program). Examples of pre-existing meal plans include the Step I or II Diets from AHA or NCEP, sodium restricted plans, and diabetic plans. The nutrients addressed include cholesterol, saturated fat, sodium, and carbohydrate. The existing recommendations for the therapeutic meal plan are listed with literature references. Suggested actions and responses for the Group Nutritionists are provided.

1.1.1 Incorporating Pre-Existing Diets Into WHI DM Intervention

The DM Intervention is modeled after the WHT (average 20% fat/day) with increased use of fruits, vegetables and grains. It is compatible with many therapeutic meal plans. Data from WHT indicate that saturated fat accounts for an average of 7% of total energy, and average dietary cholesterol is less than 300 mg/day with a 20% fat eating pattern. Reference information is available in *Vol. 4, Section 3.1. - Suggested Readings*.

1.1.2 American Heart Association (AHA) and National Cholesterol Education Program (NCEP) - Step I or Step II Diets

1.1.2.1 Fat

Total fat should be less than 30% of energy in the Step I Diet, saturated fat less than 10% of energy, polyunsaturated fat up to 10% of energy and dietary cholesterol less than 300 mg/day. Step II Diet recommendations are the same as Step I except saturated fat should be less than 7% of energy and dietary cholesterol should be less than 200 mg/day. Reference information is available in *Vol. 4, Section 3.1. - Suggested Readings*.

- **Suggested WHI Actions:**

- Group Nutritionists can reinforce that the DM Intervention has a lower fat intake goal than NCEP Step I and II Diets.
- Group Nutritionists can also reinforce that previous experience with WHT has shown dietary cholesterol and saturated fat intakes are within NCEP Step I guidelines.
- Group Nutritionists can suggest optional WHI recipe modifications such as using polyunsaturated oil, margarine, egg whites, or commercial egg substitutes. Be sure to let participants know that most of the recipes have been tested only as written.

1.1.2.2 Carbohydrate

- **NCEP Recommendation:** Carbohydrate should contribute 50% to 60% of total energy, including simple, complex, and fiber-containing complex carbohydrates.

- **Suggested WHI Actions:**

- Group Nutritionists should note that there is a good chance that carbohydrate intake may increase to 60% energy with the 20% fat DM Intervention goal.

- Group Nutritionists can also reinforce that the DM Intervention goals include five vegetable/fruit servings and six grain servings per day.

1.1.3 AHA - Recommended Sodium Intake

1.1.3.1 Moderate and Low Sodium

- **AHA Recommendation:** The American Heart Association (1988) recommends that sodium intake should not exceed 3 g/day for healthy American adults. However, there will be participants who, for medical reasons, have been prescribed diets that contain sodium levels of 2 grams or less per day. Reference information is available in *Vol. 4, Section 3.1. - Suggested Readings*.

- **Suggested WHI Actions:**

- Group Nutritionists can suggest optional WHI recipe modifications such as omitting salt from recipes and using sodium-reduced foods whenever possible ("sodium reduced" sandwich meats, canned soups, canned vegetables, canned beans). Be sure to let participants know that most of the recipes have been tested only as written.

1.1.4 American Diabetes Association (ADA) - Nutritional Recommendations

Type II diabetes mellitus (non-insulin dependent diabetes mellitus, NIDDM) may be treated with insulin, oral hypoglycemic agents, diet, or various combinations of the three. An individual's blood glucose levels may change in response to a change in diet leading to changes in insulin or oral hypoglycemic dose requirements. Thus it is critical for participants with diabetes mellitus to maintain active contact with their health care providers. Reference information is available in *Vol. 4, Section 3.1. - Suggested Readings*.

- **Suggested WHI Actions:**

- Group Nutritionists should encourage women with diabetes to continue their pre-existing routines for self-monitoring blood glucose and to keep actively involved with their diabetes health care providers.

1.1.4.1 Carbohydrate Amount - Percent of Energy

- **ADA Recommendation:** Recommended intakes vary based on individual eating habits and nutrition assessment (e.g., blood glucose, triglyceride, and cholesterol levels).

- **Suggested WHI Actions:**

- Group Nutritionists can inform participants who have diabetes that there is a good chance that carbohydrate intake may be up to 60% energy with the 20% fat DM Intervention goal.

1.1.4.2 Carbohydrate Type - Simple vs. Complex

- **ADA Recommendation:** The ratio of simple to complex carbohydrates can vary within the total amount of carbohydrate that supports the desired level of metabolic control (i.e., blood glucose, triglycerides, and cholesterol levels).

- **Suggested WHI Action:**

- Group Nutritionists can alert participants with diabetes that the DM Intervention is a self-choice model and the ratio of simple to complex carbohydrates can vary according to individual need and preference.

- **ADA Recommendation:** Sucrose may be consumed as part of the total carbohydrate (i.e., sucrose may be substituted for other carbohydrates within the meal plan).

- **Suggested WHI Actions:**

--Many of the low-fat recipes used in the DM Intervention, as well as low-fat products, often include extra sugar (simple). Participants could be getting extra amounts of simple sugars without realizing it. Group Nutritionists can alert participants to those recipes that contain sugar. For participants who prefer to avoid sugar, the Group Nutritionists can suggest optional WHI recipe modifications such as reducing sugar by half in recipes, or using sugar substitutes. Be sure that participants know that the recipes have been tested only as written.

1.1.4.3 Fat

- **ADA Recommendation:** Saturated fat intake should be no more than 10% of total energy intake and less than 300 mg cholesterol per day. Recommendations for total fat intake should be based on individual nutrition assessment (e.g., blood triglyceride levels, blood cholesterol levels, and blood glucose levels).

- **Suggested WHI Actions:**

--Group Nutritionists can reinforce that previous experience with WHT shows that saturated fat and cholesterol intakes are within ADA recommendations.

--Group Nutritionists can also suggest optional WHI recipe modifications such as using polyunsaturated oil or margarine, egg whites, or commercial egg substitutes. Be sure to let participants know that most of the recipes have been tested only as written.

1.1.4.4 Sodium

- **ADA Recommendation:** Sodium intake will vary according to individual nutrition assessment.

- **Suggested WHI Action:**

--For participants who are restricting sodium intake, Group Nutritionists can suggest optional WHI recipe modifications such as omitting salt from recipes, and using sodium-reduced foods whenever possible ("sodium reduced" sandwich meats, canned soups, canned vegetables, canned beans). Be sure to let participants know that most of the recipes have been tested only as written.

1.1.5 Lactose Restricted

Lactose intolerance occurs in adults from many populations groups, although the degree of lactose intolerance varies with individuals. Persons who normally consume lactose-restricted diets can participate in the 20% fat dietary change program of the DM Intervention. The DM Intervention focuses on reducing total fat intake and adding fruits, vegetables, and grains--not adding lactose-containing foods. Reference information is available in *Vol. 4, Section 3.1. - Suggested Readings*.

- **Suggested WHI Actions:**

--Group Nutritionists should be notified when a participant with lactose intolerance is randomized into the Dietary Change group. This notification could come from the participant, or unblinded CC staff who are aware of the condition.

--Group Nutritionists should have participants with lactose intolerance in the Dietary Change group maintain contact with their primary health care team and let their Group Nutritionist know of their lactose intolerance.

--Group Nutritionists should announce if foods being tasted during intervention sessions contain lactose.

--Group interventionists should emphasize that Session 3 of the DM Intervention covers dairy foods, but does not imply milk and milk products must be consumed. Lower-fat substitutions for non-dairy creamers can be part of the group discussion.

1.2 Nutritional Policy Issues

1.2.1 Use of Fruits, Vegetables and Grains

The DM Intervention focuses on increasing the use of a variety of fruits, vegetables and grains. The fruit and vegetable goal is five or more servings a day; the grain goal is six or more servings per day.

No single nutrient is being promoted by these goals (no specific vitamin, mineral or dietary fiber). A dietary intake higher in fruits, vegetables and grains is promoted because it is:

- Lower in fat (animal fat) and dietary cholesterol,
- Supplies essential vitamins, minerals and dietary fiber,
- Helps participants make up caloric deficits due to fat reductions,
- Facilitates an increase in total carbohydrate and complex carbohydrate-containing foods that help to maintain a lower-fat intake, and
- May provide a protective effect through some of the compounds contained in the foods.

Notable categories include:

- Potatoes and other starchy vegetables (e.g., corn, peas, onions) are considered vegetables.
- Fruit and vegetable juices (100% juice) are counted as a serving of fruit or vegetables, even though they are likely to be low in fiber.
- Beans and legumes are considered grains. They contain significant amounts of complex carbohydrates and are promoted in the DM Intervention sessions in combination with grains.

One serving of fruits, vegetables and grains is defined as follows:

Vegetables

1/2 cup raw, canned, cooked
 1 cup raw leafy
 1 small baked potato (1 3/4 - 2 1/4" diameter)
 1/2 cup boiled or mashed potatoes
 8 regular or 16 shoestring french fries
 6 oz. vegetable juice

Fruits

1/2 cup raw, canned, cooked
 1/4 cup dried
 1/2 banana (8" long)
 1/2 grapefruit (4" diameter)
 1/10 cantaloupe (5" diameter)
 1 medium piece of fruit (2 1/2" diameter),
 e.g., apple, peach, pear, etc.
 1/2 cup avocado
 6 oz. fruit juice

Grains

1/2 cup beans or legumes, cooked or canned
 1 slice of bread
 1/2 bagel, or hamburger (3" diameter) or hot dog bun
 1 whole English Muffin
 1 tortilla (6" diameter)
 1 oz. of ready-to-eat cereal or 1/2 cup cooked cereal
 1/2 cup of cooked pasta, rice, or other grain
 4 graham crackers (2 1/2" square) or 1 ounce crackers
 3 cups popcorn, popped
 1 cup chips or 1 ounce pretzels
 2 pancakes (4" diameter) or 1 waffle (4" square)

1.2.2 Weight Gain or Loss

The DM Intervention is not designed to encourage weight gain or loss. Weight is recorded at prerandomization and at the yearly follow-up visits. The Group Nutritionist may permit, but should not encourage, weight loss or gain provided adequate nutritional status is maintained.

1.2.3 Supplement Use

The use of vitamin and mineral supplements will not be promoted or encouraged, although they will be monitored on the Four-Day Food Record (*4DFR*).

1.2.3.1 Calcium Supplements

The DM Intervention encourages women to achieve recommended levels of calcium by the consumption of calcium from foods. Calcium supplements should not be encouraged, but their use is monitored on *Form 62 - 4DFR*, *Form 45 - Current Supplements*, and *Form 44 - Current Medications* (calcium-containing antacids).

1.2.3.2 Fiber Supplements

The use of fiber supplements are not promoted or encouraged but their use is monitored listed on the *4DFR* and on *Form 44 - Current Medications*. Use of fiber supplements can interfere with dietary predictors of colon cancer and Coronary Heart Disease (CHD) incidence rates. The DM Intervention includes a goal for each participant to consume five servings of fruits and vegetables, and six servings of grains or grain products per day. Foods that are good sources of dietary fiber can be selected within these food groups, however there is no specific fiber goal.

1.2.3.3 Fat-Containing Supplements

DM Intervention participants who use fat-containing supplements (cod liver oil, lecithin, fish oil capsules) should monitor intake of these supplements on their Food Diary or Fat Scan. All of these supplements may contribute significant amounts of fat to an individual's dietary intake.

1 TB cod liver oil	11.0 grams of fat
1 fish oil or lecithin capsule	1.0 grams of fat
1 lecithin tablet	0.5 grams of fat

1.2.4 Cholesterol

Participants may be interested in the cholesterol content of their diets because of the current national focus on serum cholesterol reduction. Participants are not specifically advised to reduce their cholesterol intake. However, the current DM Intervention is designed to contribute an average of less than 300 mg of dietary cholesterol per day. Refer participants to their private health care providers or health organizations (e.g., American Heart Association, or National Cholesterol Education Program) if they want more specific information regarding cholesterol.

1.2.5 Use of Fat-Free Foods

The Group Nutritionist should use her/his best judgment when advising DM Intervention participants on the use of foods found in the grocery store or listed in the Fat Counter as "fat-free." The current rule, listed on page 5 of the Fat Counter states: "Record 1 gram of fat, if you eat three servings of a fat-free food."

The original WHT showed that women found it easier to replace high-fat foods with lower-fat or fat-free substitutes than to add foods or modify their eating patterns to include more fruits, vegetables and grains. Thus, the intent of the "fat-free rule" in the Fat Counter was to accomplish the following:

- Dissuade participants from consuming excessive amounts of “fat-free” commercial products that contain small amounts of fat.

Food products that are labeled “fat-free” may have up to 0.5 grams of fat per serving. Thus, three servings of these food products often contain at least 1 gram of fat.

- Dissuade participants from consuming excessive amounts of truly “fat-free” commercial products with minimal nutritional value at the expense of fruit, vegetables and grains.

Certain foods that are labeled “fat-free” truly contain no fat, such as popsicles, hard candy and alcohol. These foods should not be considered in the “fat-free rule.” However, the Group Nutritionist should advise participants to use these foods in moderation.

- Convince participants to increase their servings of fruits, vegetables and grains.

Sometimes a participant may become so concerned about the fat content of a food that she avoids eating it. We recognize that fruits, vegetables, and some grains contain minimal amounts of fat, but they are listed in the Fat Counter as being “fat-free” to encourage participants to consume them. The fruits, vegetables and grains listed in the Fat Counter as containing zero grams of fat are considered to be “fat-free” in any amounts.

1.2.6 Involvement in DM Intervention Activities

1.2.6.1 Using Volunteers

The Group Nutritionist may use volunteers to support DM Intervention activities such as shopping, food preparation, set-up and clean-up for group sessions, and duplicating or collating DM Intervention materials. However, the volunteer cannot participate in any of the WHI Trial components (DM, HRT, or OS). Women who are screened but not randomized to the CT are potentially eligible for the OS and should not be volunteers unless they choose not to be in the OS.

1.2.6.2 Participation by Family and Friends

General guidelines for the attendance of family and friends or other guests at DM Intervention group sessions are detailed in *Vol. 2, Section 6.10.2. - Family and Friends Attendance at Group Sessions*:

- Size of meeting room.
- Feeling of other groups members.
- Not involving participants who are randomized to the DM Comparison group or other WHI study components (OS, HRT).

Ideally the DM Intervention should be conducted in a way that does not contaminate any potential WHI participants. Age-eligible women should not be encouraged to attend potlucks or other DM Intervention sessions as a way of promoting interest in DM. It would be best if the CC staff encouraged interested, age-eligible family and friends of Dietary Change participants to go through the WHI screening process.

Age-eligible women who provide key support for participants randomized to the Dietary Change group would be an exception. These women would not be good candidates for DM due to their close working relationship with Dietary Change group participants.

It is at the discretion of the CC to allow a volunteer or a friend of a Dietary Change group participant permission to attend DM Intervention group sessions.

The CC cannot make DM Intervention materials available to a volunteer or a friend of a Dietary Change group participant, if they choose to attend a group session.

1.2.7 Handling Dietary Intake Concerns from DM Intervention Participants

The dietary changes to be made by women in the Dietary Change group have no known risks for women who keep consuming a well-balanced diet (*Vol. 1, Section 2-A4. - Protocol Appendix 4-2A4.4. - Consent Form for the Dietary Part of the WHI Clinical Trial*).

If a participant reports possible side effects to a Group Nutritionist, the Nutritionist should take the following steps:

- Note the side effect in the individual's nutrition progress notes;
- Remind the participant to report the side effect or other event at a regularly-scheduled CC contact (semi-annual or annual); and, if appropriate
- Review the participant's dietary information (Food Diary, Fat Scan) if the side effect may be related dietary intake.

Group Nutritionists should use clinical judgment to make dietary recommendations and/or recommendations for the woman to contact her primary care provider.

1.2.8 Sharing Recipes in DM Intervention Groups

The Group Nutritionist should review any recipes that participants bring to share with other group members. The following guidelines should be used:

- Fat grams and serving size are listed on the recipe.
- Fat grams listed on the recipe are accurate.
- Fat grams per serving fit into the WHI program (e.g., main dish with 10 grams of fat or less per serving; dessert with 4 grams of fat or less per serving).

1.3 Food Handling Guidelines

At each session the Group Nutritionist provides a food sample for the participants to taste. It is anticipated that at least one food item per group meeting would be available for participant tasting. Suggested foods for tastings are provided at the front of each session in *Section 5 - Group Nutritionist Session Materials*. The Group Nutritionist is also encouraged to plan social functions throughout the trial so that participants feel part of a group. (See *Vol. 2, Section 6.12.4. - Social Activities for DM Intervention Participants*.)

All staff and study participants must use safe food-handling guidelines when preparing any food. The Lead Nutritionist (Dietary Intervention) should check for local food handling regulations (e.g., FDA, OSHA) with their facility's administrative unit.

Buying Foods:

- Don't use food from damaged containers.
- Avoid using cracked eggs, or foods that contain raw eggs.

Storing Foods:

- Never leave food in a hot car. Take food directly to a refrigerator if you are not going to eat it immediately.
- Freeze fresh meat, poultry or fish immediately if you can't use it within a few days.
- Never leave foods out of the refrigerator for more than two hours, especially meat, poultry or fish.
- Store meat, poultry and fish in the coldest part of your refrigerator.
- At potlucks, keep cold foods on ice or serve them from refrigerated platters. Likewise, divide hot foods into small portions. Keep the foods refrigerated until time to warm them up for serving.
- When in doubt, throw it out.

Food Preparation:

- Wash your hands with soap before and after preparing food.
- Use tongs or other utensils and gloves if food samples are cut, portioned or handed out.
- Wash countertops, dishes, or any utensils that have touched raw meat, poultry or fish. Use soap to wash, and rinse with hot water.
- Wash fruits and vegetables thoroughly.
- Don't cut vegetables on a surface where you just cut meat, poultry or fish.
- Thaw food in the microwave or refrigerator, NOT the kitchen counter.

Cooking Foods:

- Cook meat, poultry and fish completely (red meat 160° F, poultry 180° F).
- When cooking ahead, divide large portions of food into small, shallow containers for refrigeration. This ensures safe, rapid cooling.
- Microwaves can sometimes have cold spots where bacteria survive. Stir or rotate dish for even cooking. Observe the standing time called for in a recipe or on a package. The food finishes cooking during the standing time.

Section 1
General Information

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