

SECTION 1-A.6 PROTOCOL APPENDIX 6

DIETARY INTERVENTION PROGRAM AND DIETARY ASSESSMENT METHODS

1-A6.1 Dietary Intervention Program

Several psychosocial and behavioral themes have been identified as central in the Women's Health Initiative (WHI) intervention. These central themes are grouped into six categories: motivation and reinforcements, self-management, skills training, social support, relapse prevention, and self-reliance and self-efficacy.

Reinforcements and Motivators

The process of successful long-term behavior change begins with a guided self-analysis of initial motivations to participate. Each woman is encouraged to understand her own motivations during the first few sessions as a way of strengthening her resolve to change her diet. The most common motivators in the Women's Health Trial (WHT) Feasibility Trial were: helping in a scientific research project; health; having a close relative or friend with breast cancer; fear of cancer; and learning more about nutrition.

The intervention emphasizes different motivations later in the behavior change process. These include improved self-confidence and self-efficacy, a sense of empowerment and self-control, greater or improved social support, and healthier living. The intervention also counters barriers to change at a very early stage. Some barriers include time and financial costs, increased awkwardness in social and eating situations, guilt for non-adherence, and decreased enjoyment of eating preferred foods. The costs of the intervention are discussed periodically with participants throughout the sessions and methods of minimizing cost barriers are continually identified.

Self-Management

Proven behavioral modification and self-control techniques are used throughout. Participants learn these techniques through a series of steps: self-monitoring of targeted behaviors; defining specific behaviors to be changed; setting quantifiable intervention goals; breaking complex behaviors down into smaller steps; specifying an action plan; getting evaluation of behavior changes and feedback from support network; and reinforcing progress and encouraging self-praise.

Skills Training

Most people need new skills to complete the process of behavior change. The feasibility studies identified several skills needed to modify fat in the diet. Each of these skills has been linked with an appropriate nutritional topic and is being deliberately taught and reinforced throughout the first year. These skills are:

- Problem-solving and analysis, to allow participants to handle new situations with knowledge and confidence;
- Assertiveness and communication, to allow participants to actively seek out necessary foods, ingredients, and workable situations;
- Stress-management, to help participants cope with stressful situations and feelings of stress and fatigue by using non-eating strategies; and
- Cognitive, such as cognitive restructuring and imagery, to assist participants to identify potentially dangerous self-talk and replace it with more healthful thoughts and feelings.

Social Support

Social support is critical in the maintenance of behavior change. The intervention provides social support in three ways. First, the group facilitator is a main source of support and encouragement. Group facilitators are trained in listening and empathy skills, as well as nutritional knowledge and skills. Participants can discuss any aspect of the trial and trial-related events with the group facilitator, who is trained to remain open to participants' problems and concerns. Second, the group itself serves as a supportive environment. The tone of the group, set initially by the facilitator and continued by the participants, has to be open, honest, sharing, and understanding. In the WHI intervention, problem-solving is a group effort. Participants bring their most difficult situations to the group, which affirms the participant and helps to solve the issue.

The third source of support for participants has to be their family and/or other significant persons in their lives. Long-term dietary change is most easily maintained when it "fits" with normative family behavior. Changing a woman's eating habits often modifies the family's eating habits as well. Women are asked to involve significant others in the change process. Problems regarding others' acceptance of the low-fat eating plan are addressed as part of the intervention. Most solutions will need a combination of the participant soliciting help, receiving support from significant others, and learning to cook low-fat meals that are acceptable to family members.

Relapse Prevention

Maintaining changed behavior requires a series of steps (known as relapse prevention strategies) to avoid the characteristically high relapse rates of appetitive and addictive behaviors (Marlatt, 1985). Relapse prevention techniques are introduced near the end of the first year. High risk situations, such as holidays, parties and eating in restaurants, are identified so that participants can prepare for them. Next, participants learn to label a "high fat" dietary behavior as a momentary lapse. They are taught to substitute low-fat dietary behaviors to prevent relapse back to original high-fat consumption. Slipping gradually back to old high fat patterns is perceived as a specific low-fat dietary change relapse. Techniques for managing lapse and relapse, tested in other situations, are applied in this intervention near the end of the first year. Relapse prevention is a major focus in years two and beyond.

Self-Reliance and Self-Efficacy

In a long-term intervention like WHI, participants must be able to rely on their own choices instead of relying on strict adherence to a prescribed dietary plan (Mahony et al, 1978). Self-efficacy is the belief that participants can actually change and maintain dietary behaviors leading to a low-fat eating plan (Bandura, 1977; Bandura, 1982). The belief that these behaviors will have the desired effect on dietary fat and risk of cancer and heart disease is also important. The intervention provides deliberate opportunities to increase self-reliance and self-efficacy. For example, women are taught skills necessary to feel more competent and assured in uncomfortable situations. They also learn ways to improve social support as a means to promoting confidence with new ways of eating. In the current intervention, nutritionists will encourage participants to discover their own "inner power" by regular reinforcement of personal accomplishments, no matter how small (Janis, 1984). This process of empowerment and emphasis on self-control is necessary to enable women to maintain dietary changes over the long term.

Intervention Session Summary

The schedule for sessions in the first year of intervention is shown in *Table 1-A6.1*. Appropriate nutritional and behavioral concepts are integrated into each session. Both the nutritional and the behavioral concepts are carefully ordered to produce maximum effect. The early sessions (Sessions 1-8) cover the major sources of fat in the U.S. diet and critical nutritional skills (shopping, recipe modification, restaurant selection) needed for major fat consumption changes. Later nutritional topics are more specialized and include increasing fish consumption and low-fat party foods. Nutritional topics that deal with maintenance (fats and oil, creating long-term guidelines) are included in the last sessions.

The behavioral session topics are organized into groups around strategies and are ordered to facilitate behavior change. The first two behavioral topics are self-management (self monitoring, goal setting, behavior modification, cognitive-restructuring), and motivations for low-fat dietary change (e.g. family and personal health, contributing to science, etc.). Self-management steps form the core of necessary behavior skills, and the identification and reinforcement of motivations are included in the first session to develop and maintain participants' interest in changing. Social influences and support are included in the next five sessions because of the critical nature of social influences on eating and on successful health behavior change. Time management, problem-solving, and coping with stress are introduced after the initial large decreases in fat consumption have occurred to help incorporate the new low-fat behaviors into everyday living. Finally, relapse prevention is included in the last sessions to assist with long-term maintenance.

Nutritional and behavioral strategies are integrated into each session for several reasons. The intervention materials consistently focus on dietary behaviors, not nutrients, as a means of changing fat consumption. Therefore, integrating the two types of strategies in each session is important. Participants and nutritionists in the WHT Feasibility Study were initially uncomfortable during sessions with no nutritional (i.e. only behavioral) content, so complementary nutritional and behavioral topics were included in each session. Implementing the philosophy of the WHT as a self-directed, self-controlled eating plan means that each nutritionist and participant must view dietary changes as a series of activities that will ultimately become part of everyday life. Integrating dietary plans with behavioral strategies in each session helps participants integrate them in daily life. The relative focus on nutrition is highest in the early sessions during the time of most intensive dietary change, while the emphasis on behavioral strategies to maintain the early dietary changes increases in later sessions.

Table 1-A6.1
Summary of DM Intervention Sessions

Session No.	Session Objectives	Nutritional Topics	Behavioral Topics
<u>Weekly</u>			
1	Review goals and objectives of the WHI trial. Discuss the benefits and responsibilities of being a participant. Identify lower-fat food choices, especially fruits, vegetables and grains. Identify the amount of fat in foods.	Awareness of fat in foods. Awareness of fruits, vegetables, and grains.	Awareness of costs/benefits to trial participants. Social support in group and home setting. Communication skills.
2	Discuss ways to reduce added fats. Use "Fat Counter" to calculate Fat Score. Use self-monitoring to evaluate dietary changes.	Awareness of current fat intake. Method to record fat intake.	Self-monitoring of dietary behavior.
3	Identify high fat dairy foods currently used. Discuss skills for selection and use of low-fat dairy foods. Identify reasons for goal setting as a component of behavior change. Set goals using Guidelines for Goal Setting.	High fat dairy foods. Low-fat substitutes. Low-fat calcium sources.	Definition of problem behavior. Setting goals for behavior change.
4	Identify how other people influence their eating patterns. Read and interpret nutrition labels and marketing techniques.	Nutrition label reading. Shopping skills. Food availability.	Social influences on eating. Self-control skills.
5	Identify high fat entrees. Discuss skills for selection and preparation of low-fat entrees. Practice modification of entree recipes. Identify strategies to accommodate family and friends in the low-fat eating plan.	Low-fat entree substitutes. Vegetarian entrees. Entree recipe modification.	Support from home eating partners. Problem solving skills. Communication skills.
6	Discuss skills and strategies for eating in social situations. Learn the skill of fat budgeting. List strategies for low-fat restaurant eating. Practice menu selection using local restaurant menus.	Fat budgeting skills. Evaluation of restaurant menus. Low-fat dining options.	Problem-solving skills. Communication skills.

Session No.	Session Objectives	Nutritional Topics	Behavioral Topics
<u>Bi-Weekly</u>			
7	Learn how to use fruits and vegetables as low-fat snacks. Identify family and friends' influences on snacking patterns. Learn ways to say "no" to high-fat snacks. Use shorter self-monitoring tool (Fat Scan).	High-risk foods. Fruit and vegetable snack alternatives. Short self-monitoring tool (Fat Scan).	Social influences on snacking. Self-monitoring. Resistance skills.
8	Discuss ways sweets are used as a reward. Select low-fat dessert alternatives. Identify social support strategies to deal with sweets and desserts. Identify people who can help and ask for support.	High-risk food situations. Fruit dessert alternatives.	Asking for social support. Foods as reinforcers.
9	Share low-fat eating experiences with other WHI participants. Identify ways eating partners can support each other.	Low-fat recipe exchange. New food preparation ideas.	Promotion of group cohesiveness.
(I)	Individual Session: Provide individual support and feedback. Discuss dietary changes made to date. Evaluate nutritional variety and balance of current eating habits. Identify potential problems and plan for long-term maintenance.	Nutritional evaluation. Current eating habits.	Evaluation of current behavior. Reinforcing change. Planning for future change.
<u>Monthly</u>			
10	Review group progress. Identify potential situations that interfere with low-fat eating. Learn how to use the skill of problem solving. Learn the skill of problem solving.	Areas that interfere with low-fat eating.	Barriers to change. Self-management strategies.
11	Explain how self-talk influences actions. Identify negative thought patterns by listening to self-talk. Replace negative self-talk with positive thoughts. Identify low-fat lunch ideas.	Low-fat lunch ideas. Vegetables for lunch.	Cognitive restructuring.
12	Identify the challenges that vacations and holidays present to low-fat eating. Review strategies to handle vacations and holidays. Identify lower-fat alternatives to modify home-baked goods.	Vacation/holiday foods. Recipe modification of baked goods.	High-risk situations. Self-management strategies.

Session No.	Session Objectives	Nutritional Topics	Behavioral Topics
<u>Monthly</u>			
13	Discuss time-saving strategies to reduce time spent in food management activities. Plan three days of menus and make a shopping list. Identify ways to increase fish consumption.	Meal planning skills. Fish preparation ideas.	Organizational and planning strategies and skills.
14	Identify sources of complex carbohydrates. Identify and describe ways to increase complex carbohydrate intake. Discuss techniques for introducing new cuisines to eating partners.	Sources of complex carbohydrates. Tasting meatless recipes.	Communication skills. Social support.
15	Identify sources of stress that interfere with ability to change. Demonstrate strategies to cope with stress. Practice relaxation exercise. Identify methods and recipes for quick meal preparation.	Preparation of quick meals.	Stress management. Relaxation.
16	Explore the events and emotions that may trigger slips. Identify strategies to recover from a slip. Practice strategies to prevent setbacks. Taste new low-fat alternatives for "out-of-routine" situations.	High-risk foods. Low-fat alternatives for "out-of-routine" situations.	Relapse prevention.
17	Identify factors that help maintain dietary changes. Learn how loss of motivation can lead to "drift" in eating patterns. Identify self-monitoring ideas to maintain dietary changes. Learn ways to add flavor without fat.	Dietary variety. Fats and oils.	Reinforcement of current changes. Self-mastery. Self-help groups.
18	Review strategies that help maintain a low-fat plan. Review the progress made in WHI. Identify sources of continued support for low-fat eating.	Recipe exchange featuring new food products.	Review. Celebration. Group support.

1-A6.2

Dietary Assessment Methods

The dietary assessment strategies for the WHI will be based on those used in the Women's Health Trial: Feasibility Study in Minority Populations (WHT:FSMP). All procedures for dietary assessment, training, and quality control have been developed in the WHT:FSMP. These dietary assessment protocols are being validated and modified, as necessary, to optimize their use in the WHI. This work is described in detail below.

Four-Day Food Records

The University of Minnesota's Nutrition Coordinating Center's (UM-NCC) Nutrition Data System will be used for analysis of food records. THE UM-NCC Nutrition Data System consists of data entry software, analysis software, and comprehensive food product and nutrient databases. The UM-NCC was developed to support nutrient analyses for randomized intervention trials in 1974, and has since developed into the United States' leading resource for nutrient database and analysis systems for scientific research. The recent addition of data entry software that prompts coders for information in English makes the Nutrition Data System simple to use. Most importantly, the Nutrition Data System obviates the need for a large programming, data entry, and nutritional sciences staff to support diet record analyses. This system has gained rapid and widespread acceptance by many nutrition research groups, including the National Health and Nutrition Examination Survey.

a. Nutrient database

The UM-NCC has pioneered a comprehensive approach to the collection, maintenance and documentation of its food composition database. Details have been published in several peer-reviewed journals, most recently by Sievert et al (1989). Here we review briefly the highlights of the system:

The UM-NCC database contains over 16,000 foods and 5,000 brand name products. The combination of these foods and the analysis software allows over 150,000 food variants, differing in preparation methods and ingredients. The database is purposefully broad, including culturally unique foods such as foods used in the southern U.S., Hispanic foods and American Indian foods. The database is updated at least annually to reflect new analytic data, new foods, and changes in composition of manufactured foods.

The primary sources for nutrient values in the database are the USDA Nutrient Data Base for Standard Reference (1987) and its periodic revisions. Additional sources include other USDA publications, information from food manufacturers, scientific literature and international food tables. A detailed description of sources used for the UM-NCC database has been published (Schakel et al, 1988). Database maintenance is through an extensive and standardized set of procedures designed to minimize many sources of error. Missing values exist only when there is no information on the presence of the nutrient in the given food; otherwise, values are imputed based on a standardized protocol (Schakel et al, 1988).

The database contains values for 93 nutrients, listed in *Table 1-A6.2*. The software can output a variety of reports, including a list of foods consumed and their nutrient content. A machine-readable file is also generated, allowing the use to prepare customized reports, manipulate raw data and export nutrient analyses into other datasets.

Table 1-A6.2
Nutrients Calculated from Nutrition Data System Database

Energy	Vitamin D	MFA 14:1	Aspartame
Protein	Vitamin D	MFA 16:1	Saccharin
Total fat	Thiamin	MFA 18:1, oleic acid	
Total carbohydrate	Riboflavin	MFA 20:1	Animal protein
Alcohol	Niacin	MFA 22:1	Vegetable protein
% calories from protein	Folacin		
% calories from fat	Pantothenic acid	PFA 18:2, linoleic acid	Tryptophan
% calories from carbohydrate	Vitamin B ₆	PFA 18:3, linoleic acid	Threonine
	Vitamin B ₁₂	PFA:18:4	Isoleucine
% calories from alcohol	Cholesterol	PFA 20:4	Leucine
	Total SFA	PFA 20:5, EPA	Lysine
	Total MFA	PFA 22:5	Methionine
	Total PFA	PFA 22:6, DHA	Cystine
Calcium	% calories from SFA		Phenylalanine
Iron	% calories from MFA	Polyunsaturated to	Valine
Magnesium	% calories from PFA	Saturated fat ratio (P:S)	
Phosphorous			Arginine
Potassium	SFA 4:0	Cholesterol Saturated	Histidine
Sodium	SFA 6:0	fat Index (CSI)	Alanine
Zinc	SFA 8:0		Aspartic acid
Copper	SFA 10:0	Dietary fiber	Glutamic acid
Selenium	SFA 12:0, lauric acid	Water soluble dietary	Glycine
	SFA 14:0	fiber	Proline
Total Vitamin A	SGA 16:0, palmitic acid	Water insoluble dietary	Serine
Beta-carotene	SFA 17:0	fiber	
Retinol	SFA 18:0, stearic acid	Pectins	Ash
	SFA 20:0	Starch	Water
	SFA 22:0	Sucrose	
Total alpha-tocopherol equivalents		Galactose	
Alpha-tocopherol		Glucose	
Beta-tocopherol		Fructose	
Gamma-tocopherol		Lactose	
Delta-tocopherol			

System Modification

The following modifications will be made to the UM-NCC Nutrition Data System to enhance analysis capabilities related to food classifications and serving sizes. For epidemiological analyses, especially of the relationships of vegetable foods with cancer risk, it is useful to analyze diet in terms of servings of certain food groups. While the UM-NCC system allows analysis of nutrients from types of foods, analyses of number of servings within food groups will require specifications of serving sizes for each type of food and the means to sum over these servings for each individual record. The UM-NCC has developed a food grouping system for the Health and Nutrition Examination Survey based on the USDA classification scheme, but this scheme is used for historic reasons and is relevant more to agricultural economics than health research.

Food Frequency Questionnaire (FFQ)

The underlying principle of the food-frequency approach is that average long-term diet intake, for example, intake over weeks, months, or years, is the conceptually important exposure rather than intake on a few specific days. The FFQ consists of three basic components: a food list, a frequency response section for subjects to report how often each food was eaten, and portion size information.

A modified version of the FFQ developed for the WHT:FSMP has been adapted for use in WHI. The WHI FFQ and all FFQs used in the Nutritional Assessment Shared Resource are modifications of the NCI/Block FFQ. The WHT:FSMP FFQ was designed to be sensitive to sources of fat and modifications in fat-related diet habits that are components of the WHI nutrition intervention. Many "adjustment" questions that allow more refined analysis of estimated nutrients were incorporated. For example, questions about types of cookies, types of popcorn, and types of added fats such as mayonnaise, are used in order to be sensitive to the fat-modified foods that will be used by low-fat intervention group women. A secondary emphasis of the FFQ is on nutrient-rich fruits and vegetables to support analyses related to other cancers and cardiovascular disease. These FFQs are now used in over 30 studies at the FHCRC and in research institutions throughout the country.

In June of 1993, an *ad hoc* WHI dietary assessment working group convened and designed the WHI FFQ, which was subsequently operationalized by the WHI Clinical Coordinating Center (CCC). The resultant WHI FFQ is divided into three sections: 1) adjustment questions; 2) food items; and 3) summary questions. Adjustment questions consist of 19 questions on types of food and preparation techniques, which are used to alter how analysis software calculates the nutrient content of specific food items. Most of the adjustment questions in the first three pages of the instrument allow more refined analyses of fat intake (e.g., by asking about types of added fats) and fiber (e.g., by asking for usual types of breakfast cereals). The main section consists of 122 food items, with question on usual frequency of use and portion size. Finally, the summary questions consist of four questions on the usual intake of fruits, vegetables, and fat in cooking. These questions are used to reduce the measurement bias to over-report total food consumption when there are long lists (e.g. 25 vegetables) within food groups. In addition, many examples of Southern foods were added to line items (e.g., okra was added to the line item: "Summer squash, such as zucchini"). Twelve foods were added to reflect Hispanic eating patterns (e.g., tamales, chilaquiles, flautas), and Indian Fry bread was included for Native Americans.

The FFQ will be modified during the study to include new foods, especially those foods with modified fat content. Although updating the FFQ during WHI will complicate analysis, it will be necessary given the duration of the planned research.

24-Hour Dietary Recalls (24HRs)

The UM-NCC NDS system will be used for administration and analysis of 24-Hour Recalls. All 24-Hour Recalls will be unannounced (not scheduled) and administered by trained interviewers at the CCC. Protocol for administering 24-Hour Recalls will be based on that used in WHT:FSMP.

Nutrient Database

The nutrient database used by CCC FFQ analysis software is based on the UM-NCC nutrient database. Nutritional scientists at the CCC maintain a self-documenting, spreadsheet-based system for generating each FFQ nutrient database. Each spreadsheet contains the specific food or foods from the UM-NCC database that are included in each FFQ item. A computer program has been developed to use the NDS system to convert these spreadsheets into a matrix of serving size and nutrient values used by the FFQ analysis system. This allows simple periodic updates of FFQ databases based on changes in the FFQ itself or on updates to the UM-NCC nutrient database. Nutrients available from the CCC software are given in *Table 1-A6.2* above. However, all nutrients derived from the FFQ will not be considered to be of equal validity. It is recommended that nutrient analysis of the FFQs focus on the following: percentage of energy from macronutrients, dietary fiber, beta-carotene, vitamins A, C, E, calcium and iron. The baseline FFQ study using Four-Day Food Records (4DFRs) and 24-Hour Recalls to validate the FFQs will suggest other nutrients (e.g., B vitamins) that can be analyzed.

Section 1-A6
Protocol Appendix 6
Dietary Intervention Program and
Dietary Assessment Methods

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