



# Intervention MOP Table of Contents

<b>Chapter</b>	<b>Description</b>	<b>Current Version</b>
30	Overview	1.1
31	Behavior Strategies	1.0
32	Leader's Guide	1.2
33	Participant Manual	1.0
34	Food and Fitness Guide	1.0
35	Adverse Events, Symptoms, and Medical Events/Referrals Detected During Intervention	1.1
36	Dietary Intervention	1.1
37	Physical Activity Intervention	1.0
38	Self Monitoring Materials	1.0
39	Masking & Blinding	1.0
40	Nutrition Supplements	1.0
41	PREMIER A Intervention	1.2
42	Group Sessions	1.1
43	PREMIER B and C Individual Visits	1.0
44	Intervention Monitoring: Nutrition Adequacy and Attendance Alerts	1.0
45	Intervention Data Collection	1.0
46	Participant Follow-Up	1.0
47	External Resources Policies	1.0
48	Adherence, Compliance, and Retention	1.0
49	Intervention Training	1.2

<b>Chapter</b>	<b>Description</b>	<b>Current Version</b>
51	Intervention Quality Assurance	1.0
52	Intervention Evaluation	1.0
53	Site Specific Materials	1.0
54	Food Handling	1.0
55	Significant Other	1.0
56	Minority Implementation	1.0
57	Closeout	1.0
58	Obesity and Weight Loss	1.0
59	Intervention Tools/Products	1.0

## PREMIER Intervention Manual of Procedures

<b>30. OVERVIEW</b>	<b>3</b>
<b>Rationale</b>	<b>3</b>
<b>Intervention Overview</b>	<b>3</b>
PREMIER A (Advice-Only Control Condition)	3
PREMIER B (Comprehensive Lifestyle Intervention)	3
PREMIER C (Comprehensive Intervention plus DASH Diet)	4
<b>Description of the Lifestyle Intervention: Format, Structure, and Content</b>	<b>8</b>
Theoretical Background, Structure, Content, and Delivery	10
Intervention Materials	10
PREMIER Intervention Guidelines — see Table 3	10
Structure for Intervention Delivery	11
Session Content and Behavior Modification Curriculum	11
Behavioral Self-Management	11
Weight Loss	12
Reduced Fat Intake	12
Sodium Reduction	12
Alcohol Limitation	13
Physical Activity	13
DASH Dietary Pattern	14
<b>Cultural Adaptation of the Intervention</b>	<b>17</b>

**PREMIER Intervention Manual of Procedures**

**Summary of Edits**

5/4/01- Miscellaneous edits

## **PREMIER Intervention Manual of Procedures**

### **30. Overview**

#### *Rationale*

The PREMIER interventions are comprehensive, multicomponent, lifestyle programs which recognize that achievement of meaningful lifestyle changes requires information, time, extended follow-up, educational materials, and provider resources (Budd & Gruman, 1995; Harris et al., 1996; Mant, 1997; TACP, 1992). These interventions are designed to fit into this evolving health care model which 1) place more emphasis on patient self-care and lifestyle changes and 2) funnel patients from primary care clinics to specialized centers for specific medical needs (e.g., Tulkin, 1995; Harris et al., 1996; Zapka et al., 1997).

#### *Intervention Overview*

At the randomization visit, participants are randomly assigned to one of three treatment conditions (see Figure 1): 1) PREMIER A -- a usual care advice-only control group; 2) PREMIER B -- a comprehensive lifestyle intervention implementing longstanding nonpharmacologic recommendations for BP control; and 3) PREMIER C -- the comprehensive lifestyle intervention program plus the DASH dietary recommendations.

#### *PREMIER A (Advice-Only Control Condition)*

Participants assigned to this condition receive advice to follow the guidelines established by the National High Blood Pressure Program (NHBPEP) (JNC VI, 1997), for patients with above-optimal blood pressure and stage 1 hypertension. These recommendations include: weight loss if overweight, limiting dietary intake of alcohol and sodium, regular physical activity, and eating a healthful diet. Recommendations for general cardiovascular health include reducing dietary fat and cholesterol. These recommendations are provided at two individual visits, one at randomization and the second after data collection at the six-month time point. Printed educational materials are provided at these visits.

#### *PREMIER B (Comprehensive Lifestyle Intervention)*

This multi component lifestyle intervention program is based on the current clinical practice guidelines for BP control specified by JNC VI including weight loss if overweight, limiting sodium and alcohol intake, regular physical activity, and eating a reduced fat diet. (see table 1).

The specific intervention goals are:

- reduce weight by 7 kg (15 lb.) or more if overweight (the study goal is for an average loss of 10 lbs. if overweight, the initial intervention goal set at 15 lbs. in order to achieve the 10 lb. average loss over the course of the 18 month intervention period)
- limit daily sodium intake to 100 mmol or less
- limit fat intake to 30% or less of total Kcal

## **PREMIER Intervention Manual of Procedures**

- engage in 180 minutes per week or equivalent of moderate physical activity
- limit alcohol intake to no more than one ounce of ethanol per day (men), or no more than 0.5 ounces of ethanol per day (women)

### *PREMIER C (Comprehensive Intervention plus DASH Diet)*

This treatment group is also provided with a multicomponent lifestyle intervention program. The goals of this intervention include the same weight loss, sodium, physical activity and alcohol goals as the comprehensive lifestyle intervention, but this treatment arm also incorporates the DASH dietary pattern, which focuses on optimizing intakes of specific foods (fruits and vegetables and low-fat dairy) and reduced saturated fat and total fat. The specific intervention goals are:

- reduce weight by 7 kg (15 lb.) or more if overweight (the study goal is for an average loss of 10 lbs. if overweight, the initial intervention goal set at 15 lbs. in order to achieve the 10 lb. average loss over the course of the 18 month intervention period)
- limit daily sodium intake to 100 mmol or less
- limit fat intake to 25 percent or less of total kcal, with an emphasis on reducing saturated fat to 7% or less of total Kcal
- 180 minutes per week or equivalent of moderate physical activity
- limit in alcohol intake to no more than one ounce of ethanol per day (men), or no more than 0.5 ounces of ethanol per day (women)
- 9-12 servings of fruits and vegetables per day
- 2-3 servings of low-fat dairy products per day

PREMIER B and PREMIER C interventions differ in fundamental ways. PREMIER C is built around the dietary recommendations from the DASH trial. (Sacks et al., 1995; Appel et al., 1997b). Participants receiving the DASH dietary recommendations set specific fat-consumption ceilings and monitor their daily intake of fat as a technique for achieving this goal. In PREMIER B, the weight-loss component focuses on reduction of total calorie intake by monitoring total food and calories only. (see Table 1).

Another major difference is that for PREMIER C, fruit and vegetable and low-fat dairy consumption is emphasized. Whereas the PREMIER B intervention recommends reducing intake of high-calorie foods, the PREMIER C intervention encourages substituting fruits and vegetables for high-fat foods. The multiple health benefits of increasing fruit and vegetable consumption is emphasized in this intervention, and participants are helped to develop specific fruit and vegetable consumption goals (i.e., 9-12 servings per day depending on total energy consumption) and keep dietary records to monitor fruit and vegetable consumption.

The treatment groups also differ in recommendations for dairy products. The PREMIER C participants are encouraged to include at least two servings of low-fat or non-fat dairy products daily. To facilitate this change, they have this as an additional category in their food record

## **PREMIER Intervention Manual of Procedures**

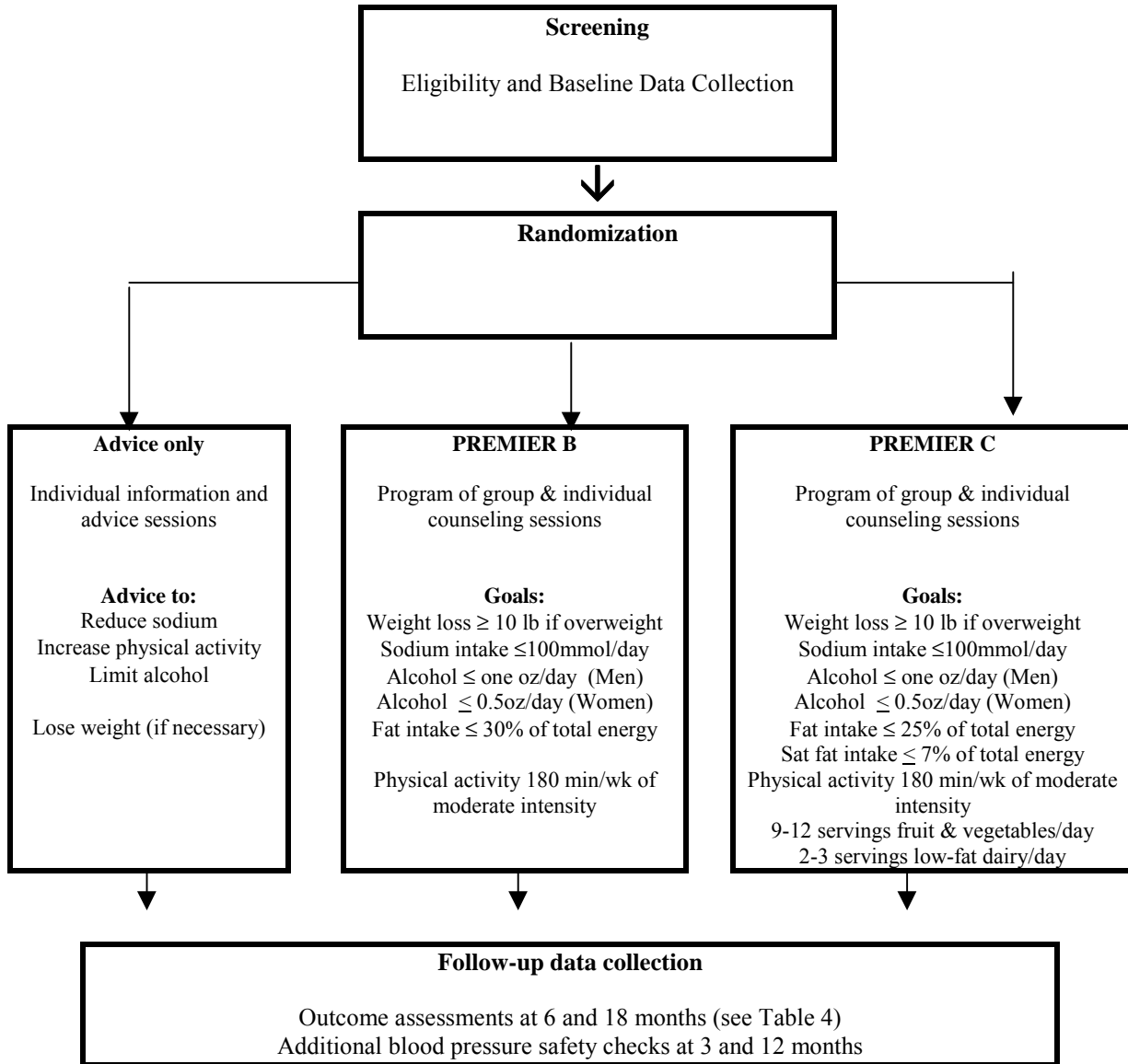
checklist. The PREMIER B intervention (without DASH) participants are not asked to set goals for dairy products.

All three treatment groups are given advice on smoking cessation, as requested, from the “Two-Three” initiative from the Agency for Health Care Policy and Research (AHCPR).

A primary objective of the program is to achieve a distinction between the B & C arms in relation to total fat, fruit and vegetables, and dairy consumption.

# PREMIER Intervention Manual of Procedures

## Figure 1. PREMIER Design Overview





**PREMIER Intervention Manual of Procedures**

**Table 1. Aspects of the PREMIER Lifestyle Interventions**

	PREMIER B				PREMIER C			
	Recommend	Emphasis in Intervention	Self-Monitoring	Outcome Assessment	Recommend	Emphasis in Intervention	Self-Monitoring	Outcome Assessment
Physical Activity	180 min/wk	Yes	Yes	7 day activity recall, fitness test	180 min/wk	Yes	Yes	7-day activity recall, fitness test
Sodium	≤100 mmol/d	Yes	Yes	24-hr urine Na 24-hr recall	≤100 mmol/d	Yes	Yes	24-hr urine Na 24-hr recall
Alcohol	≤1 oz/d (♂) ≤0.5oz/d (♀)	Yes	No	Alcohol questionnaire	≤1 oz/d (♂) ≤0.5oz/d (♀)	Yes	No	Alcohol questionnaire
Weight*	≥10 lb loss at 18 months	Yes	Yes	Weight at 18 months	≥10 lb loss at 18 months	Yes	Yes	Weight at 18 months
Total Calorie	Individualized	Yes	Yes	24-hr diet recall	Individualized	Yes	Yes	24-hr diet recall
%Kcal Fat	≤ 30%	Yes	No	24-hr diet recall	≤ 25%	Yes	Yes	24-hr diet recall
%Kcal Sat Fat	≤ 10%	No	No	24-hr diet recall	≤ 7%	Yes	No	24-hr diet recall
Fruits + Veggies	Not specified	No	No	Food groups from 24-hr recalls 24-hr urine K	9-12 servings	Yes	Yes	Food groups from 24-hr recalls 24-hr urine K
Dairy	Not specified	No	No	Food groups from 24-hr recalls 24-hr urine phosphorus	2-3 servings	Yes	Yes	Food groups from 24-hr recalls 24-hr urine phosphorus

\* Weight loss recommended only for those with BMI ≥ 25  
Daily number of servings adjusted for individual caloric intake

## **PREMIER Intervention Manual of Procedures**

### ***Description of the Lifestyle Intervention: Format, Structure, and Content***

#### **Format**

Using the lifestyle-change intervention methods developed in our earlier studies (Whelton et al., 1998; Young et al., 1996; Elmer et al., 1995a; Elmer et al., 1995b; Blair et al., 1998; Stevens et al., 1993; Lasser et al., 1995), PREMIER employs a series of group and individual sessions to help participants make appropriate lifestyle changes and develop the skills to maintain these changes over the long term. The meeting schedules for PREMIER B & C are the same (see Table 2).

**PREMIER Intervention Manual of Procedures**

**Table 2. Intervention Contact Schedule**

Tx Group																													
PREMIER A	Week		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24			
	Group																												
	Individual	R/																											
		Single intervention contact; printed materials only																											
PREMIER B	Week		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24			
	Group		G1	G2	G3	G4			G5	G6	G7	G8			G9			G10			G11			G12			G13		G14
	Individual	R/ I						I2						I3							I4								
		R/I window 3 to 4 weeks. Intervention contact weekly with 2 week breaks: 8 group meetings, 3 individual meetings												Intervention contact every other week: 6 group meetings, one individual meeting															
PREMIER C	Week		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24			
	Group		G1	G2	G3	G4			G5	G6	G7	G8			G9			G10			G11			G12			G13		G14
	Individual	R/ I						I2						I3							I4								
		R/I window 3 to 4 weeks Intervention contact weekly with 2 week breaks: 8 group meetings 3 individual meetings												Intervention contact every other week: 6 group meetings, one individual meeting															

Tx Group															
PREMIER A	Month	M6	M7	M8	M9	M10	M11	M12	M13	M14	M15	M16	M17	M18	
	Group														
	Individual	I-2													
		Single intervention contact; printed materials only													
PREMIER B	Month		M7	M8	M9	M10	M11	M12	M13	M14	M15	M16	M17	M18	
	Group		G15	G16	G17	G18	G19	G20	G21	G22	G23	G24	G25	G26	
	Individual			I-5				I-6			I-7				
		Intervention contact monthly: 12 group meetings, 3 quarterly individual meetings													
PREMIER C	Month		M7	M8	M9	M10	M11	M12	M13	M14	M15	M16	M17	M18	
	Group		G15	G16	G17	G18	G19	G20	G21	G22	G23	G24	G25	G26	
	Individual			I-5				I-6			I-7				
		Intervention contact monthly: 12 group meetings, 3 quarterly individual meetings													

## **PREMIER Intervention Manual of Procedures**

### *Theoretical Background, Structure, Content, and Delivery*

The PREMIER interventions have been derived from social cognitive theory (Bandura, 1986), self-applied behavior modification techniques—behavioral self-management—(Watson & Tharp, 1989), and the relapse prevention model (Marlatt & Gordon, 1985), and have been constructed with use of the transtheoretical, or stages-of-change model (Prochaska & DiClemente, 1983; Marcus et al., 1992). Both social cognitive and behavioral self-management approaches stress the importance of an individual's ability to regulate his/her behavior by setting goals, monitoring progress toward the goals, and using modeling and observational learning to attain skills necessary to reach goals. Self-efficacy, or one's confidence in performing a given behavior, and one's outcome expectancies from the behavior are critical mediators in determining which behaviors are attempted and the amount of effort placed in adopting a new behavior. Relapse-prevention training provides specific skills to decrease the risk of slips turning into relapse when acquiring and maintaining a new behavior. The transtheoretical model recognizes that behavior change is a dynamic process of moving through different motivational readiness-for-change stages. It allows for different behavioral strategies to be emphasized depending on the individual's stage of change. Congruent with these theories/models are behavioral skills training and self-regulation that are necessary to adopt and maintain a new behavior. Motivational interviewing (Miller & Rollnick, 1991) also provides a useful framework for helping participants make crucial decisions in light of these behavioral theories.

Intervention strategies that are congruent with PREMIER's theoretical foundation, and that have been used successfully in previous trials (e.g., Whelton et al., 1998; TOHP1, 1992; TOHP2, 1997; Elmer et al., 1991; Elmer et al., 1995a, Stamler R. et al., 1987; Stamler R. et al., 1989; Jeffery, 1991; Grimm et al., 1990; King et al., 1991), are employed in this program, including frequent and extended contacts, opportunities for group interactions and social support, goal-setting and self-negotiation, problem solving, examples of new behavioral options and decision-making approaches, individual contacts which tailor the intervention to the individual's preferences and readiness to change, and other contact formats (mail, telephone, and special events) that support behavior change and provide content material, behavior cues, and reinforcement in the participant's environment.

### *Intervention Materials*

Participants in the lifestyle change programs are provided with program materials, with separate editions of these materials for PREMIER B & PREMIER C. Both have the same physical activity, sodium, alcohol, and smoking-cessation materials but differ in the dietary sections, with the DASH dietary recommendations featured prominently in materials for the PREMIER C.

### *PREMIER Intervention Guidelines — see Table 3*

PREMIER Food and Fitness Guide — a food, nutrient, and physical activity guide listing the calorie, fat, and sodium content of foods and physical activity points for physical activities. For

## **PREMIER Intervention Manual of Procedures**

PREMIER C this guide lists calories, fat, and sodium, and highlight fruits and vegetables, low-fat dairy, and low saturated fat choices. In both PREMIER B and C versions, the guide contains the treatment group specific recommendations regarding food purchasing, preparation, and key behavioral cues.

PREMIER Food and Fitness Diary — a self-monitoring tool where participants record food intake and physical activity. Participants in PREMIER B monitor calories, sodium, and physical activity points. Those in PREMIER C monitor servings of fruits and vegetables, low-fat dairy, calories, fat, sodium, and physical activity points.

PREMIER Participant Manual— a manual with details on the program content; self-assessments and goal setting procedures; approaches for self-monitoring food and activity, cooking and meal pattern guides.

### *Structure for Intervention Delivery*

Both PREMIER B & PREMIER C treatment groups start with an individual counseling session conducted immediately after random assignment (R/I) but before the start of group meetings. This first individual counseling session is designed to tailor the intervention to the individual's needs and set initial goals.

Individual sessions focus on social support, specific behavior change goals, problem solving, and maintaining motivation during challenging situations.

### *Session Content and Behavior Modification Curriculum*

Each session follows a similar structure and includes six main curriculum components: 1) main content area (e.g., meal patterns, calories and sodium, identifying alternative types of moderate physical activity, and weight loss in both interventions, and fruits, vegetables and dairy and dietary fat in PREMIER C,) 2) behavioral skills training, 3) self-monitoring activity, 4) review of progress since last session, 5) social support-group sharing, and 6) goal setting and action plans. The meetings are structured to be interactive with participant input and smaller group activities that foster problem solving, support, and program ownership. Sessions include tasting foods, cooking, and exercise demonstrations.

### *Behavioral Self-Management*

To enhance adherence, a variety of behavior modification and social learning theory approaches are incorporated into each intervention session. The goal of this portion of the intervention is to teach the participants how to effectively manage their dietary behavior and maintain their personal exercise program when confronted with the full spectrum of daily environmental challenges. That is, rather than have the intervention staff attempt to control the participants' behavior, the basic strategy is to train the participants to manage their own behavior to achieve and maintain diet and lifestyle change. The essential components of successful self-management

## **PREMIER Intervention Manual of Procedures**

include setting reasonable short-term goals, formulating specific plans of action to achieve those goals, developing reinforcement and social support for carrying out each major element of the plan, keeping a record to assess progress, and regularly evaluating and modifying plans using the self-management records (Watson & Tharp, 1989).

### *Weight Loss*

Overweight is defined as having BMI  $\geq 25$  (NHLBI, 1998). We expect a majority of the PREMIER participants to meet this definition. The goal of the weight-loss portion of the intervention programs is to help participants who are overweight lose 10 lb. (4.5 kg) or more and maintain this weight loss for the duration of the trial. The PREMIER weight-loss strategy is modeled after our previous programs that achieved successful weight loss (Elmer et al., 1995a; Stevens, 1993; Whelton et al., 1996; Stamler R. et al., 1987). Specific strategies common to these include: 1) self-monitoring of diet and physical activity, 2) development of personalized dietary and physical activity plans, 3) moderate caloric reduction, 4) increased physical activity, 5) identifying problematic situations for undesired behavior and developing and rehearsing specific plans of action to deal with those situations, 6) graphing individual weight and behavioral progress, 7) developing core food-choice competencies, and 8) reducing portion sizes, substituting alternative foods, and modifying the original items to be lower in calories and fat. Group support and telephone follow-up are key components of this program. For those with a BMI below 25, the intervention focuses on preventing weight gain. In addition, those with a BMI between 20 and 25 are offered individualized goal setting to help them lose small amounts of weight if they so choose.

### *Reduced Fat Intake*

We anticipate a decrease in fat in PREMIER B—the materials and program are geared for a diet at 30 percent or less kcal from total fat. Previous trials of this type of intervention reported fat intake reached 31-34 percent of total kcal. It is unlikely to decrease below these levels without special emphasis and effort. In contrast, PREMIER C emphasizes monitoring total fat intake to achieve fat intake of 25 percent (or less?) and encourage substitution of fruits, vegetables, and low-fat dairy products (i.e., fruit as snacks/dessert). Participants have a specific goal to eat 9-12 servings of fruits and vegetables per day.

### *Sodium Reduction*

The goal of the sodium intervention is to help participants reduce sodium intake to 100 mmol per day or less. Key curriculum content and behavioral strategies include identifying the sodium content of foods using the Food and Fitness Guide and food labels, and devising sodium reduction strategies. The latter include: finding sodium-modified food products, substituting lower-sodium items for very high sodium foods, learning to make more appropriate food choices in restaurants, and adapting taste preferences. Providing participants with the opportunity to taste low-sodium foods and providing product samples have been key components enhancing the success of our previous sodium-reduction programs. We employ these techniques in PREMIER

## **PREMIER Intervention Manual of Procedures**

and work with major food manufactures to provide product samples to the clinical centers. During early sessions, and periodically thereafter, participants monitor their sodium intake by keeping food records.

### *Alcohol Limitation*

The alcohol component of this intervention is not designed for problem drinkers. Screening excludes those who report consuming more than 21 alcohol-containing drinks per week. For PREMIER the goal of the alcohol intervention is to limit alcohol consumption to no more than one ounce of ethanol per day (men) or no more than 0.5 ounces of ethanol per day (women). Participants monitor alcohol intake on their food records and discuss strategies for reducing alcohol if needed. Alcohol consumption is also addressed in the individual counseling sessions.

### *Physical Activity*

The goal of the physical activity component in both PREMIER B and C is to engage in regular aerobic physical activity according to national recommendations from the Surgeon General's Report on Physical Activity and Health (USDHHS, 1996), the Centers for Disease Control and the American College of Sports Medicine (Pate et al., 1995), and the National Institutes of Health (NIH Consensus Conference, 1996). The national recommendations are for 150 kcal in moderate-to-vigorous physical activity, or 30 minutes of moderate-intensity activity such as walking, on most, preferably all, days of the week.

Aerobic activity that increases heart rate to 50-69 percent of maximal heart rate or has a rating of perceived exertion (Borg, 1982) of 11-12 (i.e., fairly light to somewhat hard) meets the definition of moderate-intensity activity (USDHHS, 1996) and has been described as activity that is as intense as a brisk walk. Vigorous activity increases heart rate to 70-89 percent of maximal heart rate and is characterized by a rating of perceived exertion of 13-16 (i.e., somewhat hard to hard). Moderate-intensity activity tends to be preferred over vigorous activity by many adults (King et al., 1990), is associated with lower injury rate than vigorous exercise (Pollock et al., 1991), and has been tested in some efficacy studies and seen to lower BP (Braith et al., 1994, Hagberg et al., 1989; Roman et al., 1981). Therefore, moderate-intensity activity is emphasized in the PREMIER interventions. However, to be consistent with the national recommendations, and to reflect the fact that most of the efficacy studies that have shown that exercise reduces BP have tested vigorous-intensity exercise (Fagard, 1995), for those participants who wish to engage in vigorous activity and have no contraindications (see IMOP chapter 37, Physical Activity Intervention, Progression from moderate to vigorous activity section), vigorous activity is permitted.

To allow flexibility for moderate or vigorous activity, as well as to allow for patterns that include both intensities, a point system is used for instruction and self-monitoring. The participant goal is to accumulate at least 180 points per week divided into at least three different days. Each minute of moderate-intensity activity equals one point; each minute of vigorous activity equals two points. If a sedentary person who does no moderate or vigorous activity were to achieve this

## **PREMIER Intervention Manual of Procedures**

intervention goal by replacing sitting time with moderate or vigorous activity, the result would be an increase of 1.1 kcal/kg/day overall, or 1.7 kcal/kg/day in moderate-to-vigorous activity, measured by the 7-day Physical Activity Recall. Following are examples of activity patterns that meet this goal:

- a) Moderate-intensity activity six times per week for 30 minutes each time
- b) Moderate-intensity activity four times per week for 45 minutes each time
- c) Vigorous-intensity (very hard) activity three times per week for 30 minutes each time
- d) Moderate-intensity activity two times per week for 30 minutes each time PLUS vigorous-intensity activity three times per week for 20 minutes each time.

Bouts of moderate-to-vigorous activity engaged in for 20 minutes or longer is the goal. The 20-minute duration is selected because that is the minimum duration used in randomized trials that have shown that BP is lowered by exercise. Participants who are initially sedentary are encouraged to engage in shorter bouts of activity to work up to the 20 minutes. For those participants who wish to engage in vigorous activity, the importance of warm-up and cool-down periods and the need to work up to vigorous activity by first engaging in regular moderate-intensity activity, is emphasized in the intervention. Participants are given examples of types of activity that are moderate (e.g., brisk walking, gardening, shooting baskets) and vigorous (e.g., running/jogging, aerobic dancing, playing skilled singles tennis, walking briskly uphill), the submaximal treadmill testing provides experience estimating perceived exertion using the Borg scale (Borg, 1982), and participants are taught how to determine their target heart rate range for moderate and vigorous intensity activity and to take their pulse.

The intervention focuses on helping participants determine how best to fit physical activity into their lives and takes into account each participant's initial motivation, current activity patterns, and intensity desires. Group and individual sessions include information and behavioral skills relevant to the physical activity component of the intervention. Specific behavioral strategies for increasing physical activity include identifying pleasurable activities for participants, self-monitoring physical activity patterns, scheduling daily time to be physically active, goal-setting, identifying barriers to physical activity, and problem-solving to develop specific strategies to deal with barriers.

### *DASH Dietary Pattern*

The DASH diet promotes low-fat dairy products, fish, poultry, and lean meats to reduce total and saturated fats and increase protein and calcium. It includes fruits and vegetables to increase potassium, magnesium, and dietary fiber. For an intake of 2000 kcal/day, this dietary pattern contains approximately four to five vegetable servings, four to five fruit servings, seven to eight servings of grains and grain products, two to three servings of low-fat dairy products, and two or fewer servings of meat, poultry, or fish. Potassium, magnesium, and calcium levels in the DASH diet correspond to approximately the 75th percentile of consumption for general Americans.



## **PREMIER Intervention Manual of Procedures**

The intervention strategies for translating the fruit and vegetable component into the everyday setting have been successfully developed in two previous programs for increasing fruit and vegetable intake. In these programs individuals increased fruit and vegetable consumption to an average of 11 servings per day and maintained these intakes for one year. (Elmer et al., 1995b; Elmer et al., 1994.)

Three specific dietary goals are emphasized during the PREMIER C group and individual sessions in order to achieve the DASH dietary pattern: (1) eat no more than a specific number of grams of fat per day—a target based on caloric needs to achieve/maintain weight loss; reduction of saturated fat will also be emphasized by focusing on reduced consumption of red meat and regular-fat dairy products; (2) eat 9-12 servings of fruits and vegetables per day; and (3) eat two to three servings of low-fat dairy products per day. These goals are critical because each represents a key aspect of the DASH dietary pattern.

PREMIER uses a number of strategies to incorporate these dietary components into the daily eating pattern. For example, the fruit and vegetable pattern can include two to three servings of fruit at breakfast, typically juice and another serving of fruit, perhaps with cereal. Lunch can include three to four servings of fruit and vegetables such as soup, salads, sandwiches, juice, and fruit as dessert. Dinner can include three to four servings of fruits and vegetables. Large salads can be a part of many meals, as well as raw vegetables for pre-meal items and one to two fruits or vegetables as snacks. Typically participants increase the portion size of vegetables to increase the numbers of servings. Setting goals for meals, focusing on key fruits and vegetables for additional consumption goals, and increasing portion sizes are strategies that have been successfully used in previous fruit and vegetable intervention programs (Elmer et al., 1995a; Elmer et al., 1995b). In addition to emphasizing fruits and vegetables, we also emphasize low-fat dairy products, such as low-fat or skim milk, low/non-fat yogurt, and low-fat cheeses, as well as limited portions of lean cuts of beef, chicken, and fish (Elmer, 1996a; Elmer 1996b).

Information obtained from the PREMIER Pilot Minority Implementation Focus Groups and from previous studies regarding minority intervention have been incorporated into the curriculum.

**PREMIER Intervention Manual of Procedures**

**Table 3. Lifestyle Guidelines**

<p><b>PREMIER B</b></p> <ol style="list-style-type: none"> <li>1. Lose weight (if recommended) <i>If recommended, lose 15 pounds (or your individual goal)</i></li> <li>2. Eat a low-fat diet <i>Eat 30% or less of total calories from fat</i></li> <li>3. Eat a low-sodium diet <i>Eat 2400 mg or less of sodium every day</i></li> <li>4. Be physically active on a regular basis <i>Be physically active for 30 minutes or more per day, six days per week, or accumulate 180 minutes of moderate activity each week.</i></li> <li>5. If you drink alcohol, limit your intake <i>Women: Drink no more than one alcoholic drink per day</i> <i>Men: Drink no more than two alcoholic drinks per day</i> <i>1 drink = 12 oz. beer, five oz. wine or one jigger 80-proof liquor</i></li> <li>6. Keep records of what you eat and your physical activity. <i>Record your food intake at least three days each week. Record your minutes of at least moderate physical activity every day.</i></li> </ol>	<p><b>PREMIER C</b></p> <ol style="list-style-type: none"> <li>1. Eat a diet rich in fruits and vegetables <i>Eat 9-12 servings of fruits and vegetables every day</i></li> <li>2. Eat a diet rich in low-fat dairy foods <i>Eat 2-3 servings of low-fat dairy foods every day</i></li> <li>3. Lose weight (if recommended) <i>If recommended, lose 15 pounds (or your individual goal)</i></li> <li>4. Eat a low-fat diet <i>Eat 25% or less of total calories from fat with 7% or less of total calories from saturated fat or 30 grams of fat for women and 40 grams of fat for men for weight loss.</i></li> <li>5. Eat a low-sodium diet <i>Eat 2400 mg or less of sodium each day</i></li> <li>6. Be physically active on a regular basis <i>Be physically active for 30 minutes or more per day, six days per week, or accumulate 180 minutes of moderate activity each week.</i></li> <li>7. If you drink alcohol, limit your intake <i>Women: Drink no more than one alcoholic drink per day</i> <i>Men: Drink no more than two alcoholic drinks per day</i> <i>1 drink = 12 oz. beer, five oz. wine or one jigger 80-proof liquor</i></li> <li>8. Keep records of what you eat and your physical activity. <i>Record your food intake at least three days each week. Record your minutes of at least moderate physical activity every day.</i></li> </ol>
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## **PREMIER Intervention Manual of Procedures**

### ***Cultural Adaptation of the Intervention***

The PREMIER investigators put a high priority on developing lifestyle interventions that are appropriate for African Americans, a group at high risk for hypertension and obesity. To this end, the Intervention Committee considered minority issues throughout. The Minority Implementation Committee reviewed all intervention plans and materials. Strategies include: 1) minority representation at all levels of implementation; 2) social support systems for participants; 3) effective communication, including demonstrations; 4) involvement of family and community; 5) participant input (identification and ownership); and 6) food guides and other intervention materials that are consonant with the various cultures represented among study participants.

Participants from many programs indicated a preference for a demonstration-oriented program, particularly with regard to physical activity and food preparation. One popular technique is for two to three participants to prepare a dish for tasting at a group meeting. The staff can work with the participants to modify the recipes to be consistent with their group's dietary goals. A similar approach can be used to demonstrate physical activity techniques. For example, the exercise instructor would go for walks with groups of participants and demonstrate the pace appropriate for individual participants.

See PREMIER Protocol for complete reference citations.

**PREMIER Intervention Manual of Procedures**

**31. BEHAVIOR CHANGE STRATEGIES 3**

**Purpose for Using Behavior Strategies in PREMIER \_\_\_\_\_ 3**

**Description of Behavior Strategies Used in PREMIER \_\_\_\_\_ 3**

- Motivational Interviewing \_\_\_\_\_ 4
- Goal Setting/Action Planning \_\_\_\_\_ 4
- Self-Monitoring and Self Assessment \_\_\_\_\_ 4
- Modifying Environmental Influences \_\_\_\_\_ 4
- Reinforcement \_\_\_\_\_ 5
- Modeling \_\_\_\_\_ 6
- Identification of Barriers \_\_\_\_\_ 6
- Problem-Solving \_\_\_\_\_ 6
- Assertiveness Training \_\_\_\_\_ 6
- Elicitation of Social Support \_\_\_\_\_ 7
- Time Management \_\_\_\_\_ 7
- Relapse Prevention \_\_\_\_\_ 7
- Making Choices/Substitutions \_\_\_\_\_ 7
- Cognitive Methods \_\_\_\_\_ 8

**PREMIER Intervention Manual of Procedures**

**Summary of Edits**

## **31. Behavior Change Strategies**

### ***Purpose for Using Behavior Strategies in PREMIER***

Behavior change is not simple, and knowledge of facts alone is not sufficient to achieve and maintain healthful behaviors, particularly in an environment that counteracts healthful choices. Thus the PREMIER intervention incorporates numerous behavior change strategies that have been successful in other studies.

Within PREMIER, behavior change strategies encompass those lifestyle-change intervention methods that enhance participant motivation, select targets for behavior change, and assist participants in making and maintaining the dietary and physical activity changes.

Behavioral intervention strategies for PREMIER have been derived from Bandura's (1986) social cognitive theory, Watson & Tharp's (1989) behavioral self-management model, Marlatt & Gordon's (1985) relapse prevention model and Prochaska et al.'s (1986) transtheoretical model of behavior change. The specific techniques outlined below are designed to facilitate participant adherence to the PREMIER program and enhance the likelihood of participants reaching the lifestyle goals.

A variety of behavior modification and social learning theory approaches are incorporated into each intervention session. The intervention is structured so that the simpler and more important behavioral approaches are introduced earlier and the addition of advanced techniques builds on that framework. These behavioral techniques allow participants to effectively manage their diet and physical activity programs when confronted with the full spectrum of daily environmental challenges. Emphasis is placed on the participant, who learns to control his/her behavior to achieve and maintain the PREMIER dietary and physical activity goals. The group classes provide hands-on activities that employ the behavioral strategies for eating and physical activity behaviors.

### ***Description of Behavior Strategies Used in PREMIER***

Specific behavior change strategies used in the PREMIER intervention are described below. Note that some examples are relevant to more than one behavior change strategy and there is some overlap in the strategies.

(Note: The strategies may occur in sessions other than those indicated.)

**PREMIER Intervention Manual of Procedures**

<p><i>Motivational Interviewing</i>          This technique involves a mutual give-and-take between interventionist and participant to motivate participation in the program and behavior change. This method includes assessing decisional balance and motivation to change, focusing on success, providing social support, positive reinforcement or verbal praise, giving feedback on visible signs of progress, or teaching stress management techniques. In addition, it incorporates differing counseling strategies depending on the participant’s stage of change (precontemplation, contemplation, action, relapse, or maintenance) (Prochaska &amp; DiClemente, 1986).</p>	<p>Used primarily in <b>all individual sessions &amp; individual contacts</b></p>
<p><i>Goal Setting/Action Planning</i>          These include techniques for helping participants set and achieve realistic, attainable goals that are personalized for their own motivation and situation. Performing periodic self-assessments (including evaluating influences on health behaviors), prioritizing, planning ahead, getting organized, and establishing a plan of action are all methods that can assist participants in personal goal setting (Watson &amp; Tharp, 1986). Participants are encouraged to set realistic short-term goals and to modify their behaviors a little at a time to eventually achieve long-term goals such as the PREMIER lifestyle targets</p>	<p>Used in <b>all sessions</b></p>
<p><i>Self-Monitoring and Self Assessment</i>          These techniques include teaching participants to accurately observe and record their behaviors, in particular their diet and physical activity. The goal is to increase awareness of the amounts and types of foods eaten, including amounts of targeted nutrients in the diet, and amount of exercise engaged in, to provide feedback and reinforcement toward achieving the PREMIER goals. Self-monitoring and self assessment can also help identify the influences on health behaviors and contingencies that maintain behaviors. Self-monitoring can incorporate food record forms, physical activity diaries, checklists, etc. (Watson &amp; Tharp, 1986).</p>	<p>Used in all group and individual sessions in Phase I; revisited in Phase II</p>
<p><i>Modifying Environmental Influences</i>          These approaches are designed to alter the environmental circumstances under which behaviors are typically expressed (Bandura, 1986; Watson &amp; Tharp, 1986). This is also called “stimulus control” because the purpose is to modify the stimulus for a health behavior. For example, if a participant “always” eats potato chips on the couch when watching television, removing the potato chips from the home and teaching the participant to watch television from a chair would be methods of stimulus control. Specific approaches to modifying environmental influences or specific stimulus control procedures include:  <u>Identification of “cues” and “triggers”:</u>          This is a form of self-assessment used to identify specific circumstances that precipitate poor dietary or physical activity choices for the particular individual, or to identify high-risk situations. For example, a commercial on TV may be a “cue” to go to the kitchen to get a snack. Identifying personal cues for unhealthy behaviors can help the participant avoid them or develop more healthful responses to those cues.</p>	<p>Used primarily in sessions <b>G2, G6, G7</b> and <b>G8</b> as well as in several Phase II sessions</p>

**PREMIER Intervention Manual of Procedures**

<p><u>Removing unwanted (unhealthy) foods from the home:</u>          This is a strategy for avoiding high-fat and high-calorie, foods, snack foods, and “convenience” foods that require no preparation, and are usually higher in fat and sodium. This method is helpful for reduction of dietary sodium, reduction of dietary fat, and weight control.</p> <p><u>Modification of eating behavior:</u>          Examples include placing one’s eating utensils down between each bite of food, and taking short (5 min) breaks during meals in order slow down eating and refocus attention to feelings of satiety. This method is helpful for weight control.</p> <p><u>Restricted eating:</u>          Teaching participants to restrict eating to only one place in the home (such as the kitchen), and to engage in no other behaviors while eating (such as reading or watching television) is intended to restrict food associations and prevent “mindless” eating. This method is helpful for weight control.</p> <p><u>Behavioral prompts:</u>          These techniques include using “prompts” and reminders, such as placing program materials in view while eating, posting program goals on the refrigerator or pantry door, taking a “heart-healthy” grocery list to the grocery store, posting a schedule for exercise in a visible location (like on a daily/monthly calendar posted on a bulletin board), or putting out exercise clothes or walking shoes in a visible location as a reminder to exercise that day. These techniques are useful for weight control, dietary sodium and fat, and physical activity.</p> <p><u>Utilization of competing behaviors:</u>          This technique involves teaching the participant to engage in more healthful behaviors that compete with less healthful behaviors. For example, a participant could take a walk instead of eating at times when impulsive or “mindless” eating is likely to occur.</p>	
<p><i>Reinforcement</i>          These techniques include those that provide positive or negative reinforcement contingent on engaging in the targeted healthful behavior (Watson &amp; Tharp, 1986). One example is self-reinforcement, such as “rewarding” oneself with a favorite activity after successfully sticking to the PREMIER diet for 5 days or compensation for dietary lapse with an extra hour of physical activity. Another type is extrinsic reinforcement, where others provide rewards such as program staff and family or friends. Examples include providing participants with a T-shirt, or other tokens, contingent on their attendance at program sessions.</p>	<p>Used primarily in sessions <b>G2, G6, G7 and G8</b></p>



**PREMIER Intervention Manual of Procedures**

<p><i>Modeling</i>          This is a technique that involves exposing the participant to one or more individuals, either in person or via media (video, audio, or print), who demonstrate the behaviors to be adopted by the participant (Watson &amp; Tharp, 1986). This approach provides “vicarious reinforcement” for behaviors (Bandura, 1986), particularly if the role model shares characteristics with the participant (for example, the same race or gender). Particularly useful is modeling that demonstrates realistic examples of overcoming barriers. Role playing is another form of modeling, which is used for skill practice. For example, a participant can role-play asking a spouse or friend to provide social support for exercise, or a participant can role-play various tempting dining situations while the instructor, and then the participant, demonstrate healthful responses.</p>	<p>Secondary technique, can be used in any session</p>
<p><i>Identification of Barriers</i>          This technique involves identifying tempting, problem, or high-risk situations, or other factors that the participant finds “gets in the way” of doing the targeted behaviors. Perceived barriers can include lack of time, lack of skills, lack of knowledge, and times of emotional distress. Each participant may have different barriers, and the barriers may differ for diet and physical activity. Each participant’s unique history is important in defining problem situations that are relevant to the individual (Watson &amp; Tharp, 1986). In many cases, the barriers are perceived, but may not be actual. For example, a participant may perceive that her husband won’t watch the children while she exercises, but he would (if only she would ask).</p>	<p>Used primarily in sessions <b>G3, G6, G7</b> and <b>G8</b></p>
<p><i>Problem-Solving</i>          Subsequent to the step of barrier definition is the generation, evaluation, and implementation of alternative responses which are designed to help the participant overcome the barriers to reaching or maintaining their behavioral goals (Marlatt &amp; Gordon, 1985). For example, teaching a participant to anticipate times when it may be inconvenient to prepare a healthful meal, and to have a “back-up” meal prepared in advance for this circumstance. Another example is a participant identifying specific times in a daily schedule to exercise in order to overcome the barrier of perceived lack of time.</p>	<p>Used primarily in sessions <b>G3, G6, G7</b> and <b>G8</b></p>
<p><i>Assertiveness Training</i>          These are procedures aimed at increasing participants’ ability to express themselves and interact with others in an honest and straightforward manner (Marlatt &amp; Gordon, 1985). In the context of the PREMIER intervention goals, this can include the teaching of food refusal skills at social gatherings, the making of special food preparation requests of restaurant staff when dining out, asking a family member or friend to join in a brisk walk, or asking someone to watch the children to be able to exercise.</p>	<p>Used primarily in sessions <b>G5</b> and <b>G8</b></p>

**PREMIER Intervention Manual of Procedures**

<p><i>Elicitation of Social Support</i>          This method is aimed at teaching participants how to appropriately solicit and attain support from friends, family, and peers for their behavioral changes (Marlatt &amp; Gordon, 1985). Examples of this technique include participating in group exercise classes with others who share similar goals, recruiting a spouse to help with healthful meal preparation, forming a “walking club” to engage in regular brisk walks, or verbal encouragement and reinforcement for healthful behaviors from family or friends.</p>	<p>Used primarily in sessions <b>G6</b> and <b>G8</b></p>
<p><i>Time Management</i>          Participants can be taught how to adequately plan and schedule their activities in advance, in order to insure that ample time is available for both required and desired activities (Marlatt &amp; Gordon, 1985). Time management can include such skills as learning to use a calendar or daily planner, or teaching participants how to successfully schedule and prioritize various responsibilities. This is a particularly important issue for physical activity, as lack of time is noted as a barrier for many people.</p>	<p>Used primarily in sessions <b>G4</b> and <b>G5</b></p>
<p><i>Relapse Prevention</i>          These include techniques that anticipate, and plan for, the fact that participants will occasionally “slip” back into their old behavior patterns, as well as those techniques that promote generalization of behavior change patterns. These techniques include teaching the participant the difference between a “lapse” and a “relapse” (the former is shorter), the identification of high-risk situations for lapsing/relapsing, the teaching of urge control, refusal and stress management skills, teaching the participant to elicit appropriate social support, and distraction and avoidance procedures (Marlatt &amp; Gordon, 1985). It is important for participants and interventionists both to recognize that lapses and relapses are common in health behavior change (they are the rule, rather than the exception). Lapses/relapses are not to be considered a “failure” and should be temporary, if the participant is motivated to getting “back on track.”</p>	<p>Used primarily in later sessions</p>
<p><i>Making Choices/Substitutions</i>          This approach encourages participants to choose the more healthful choice every time they have a choice, or to substitute a more healthful option for a lesser healthful option. For eating, choices are made every time one prepares food, eats, grocery shops, or dines out. Choices can be made among various options for each meal. For example, lower fat food preparation approaches (e.g., baking) can be chosen over higher-fat preparation approaches (e.g., frying), and lower-sodium snacks can be chosen over higher-sodium snacks. For physical activity, how one spends one’s time is a choice. For example, dancing could be chosen as a social activity instead of going to a movie.</p>	<p>Used in all sessions, with emphasis in <b>G1, G4, G5, and G8</b></p>

## PREMIER Intervention Manual of Procedures

<p><i>Cognitive Methods</i></p> <p>Cognitive techniques are aimed at modifying knowledge, thoughts, feelings, and behavior about lifestyle changes by identifying and altering incorrect or illogical patterns of thinking (Bandura, 1986). These illogical patterns of thinking are termed “cognitive errors” and can include “all-or-none” thinking, when situations are perceived from the perspective of one extreme or the other, or “catastrophizing”, when an individual automatically thinks the worst about a situation. For example, for physical activity participants should be taught that it is not correct that if you don’t do all the physical activity targeted, you might as well not do any. The transmission of knowledge (facts) is also considered a cognitive method. Knowledge, however, although often necessary is usually not sufficient for behavior change. barrier for many people.</p>	<p>Used in all sessions</p>
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## **PREMIER Intervention Manual of Procedures**

<b>32. LEADER'S GUIDE</b>	<b>3</b>
<b>Purpose</b> _____	<b>3</b>
<b>Table of Contents of the Leader's Guide</b> _____	<b>5</b>
<b>Format for Chapters 1-26</b> _____	<b>5</b>
<b>Using the topic sheets</b> _____	<b>6</b>

## **PREMIER Intervention Manual of Procedures**

### **Summary of Edits**

Changes to 1.0 are: Page 4 Table of Contents of Leader's Guide number III deleted. Under Format for Chapters 1-26, number II subheadings deleted, number III heading reworded, number V. deleted. Also the sentence above 'Using the topic sheets' deleted.

Changes to 1.1 are: Page 3 added goals for Phase I, II and III. Page 4 added clarification about the use of leaders' guides and priority to behavior change discussions over content delivery. Page 5 added template used for Phase III leader's guides outlines.

## PREMIER Intervention Manual of Procedures

### 32. Leader's Guide

#### *Purpose*

The Leader's Guide provides a standardized framework and structure for each group session and provides resource materials for session discussions. There are separate leader's guides for PREMIER B and PREMIER C.

- All PREMIER interventionists read and become thoroughly familiar with the entire leader's guide.
- The Leader's Guides are sequenced specifically to achieve the goals for Phase I and II which are:
  - Phase I
    1. To become familiar with the PREMIER lifestyle guidelines and goals.
    2. To assess individual starting point and set personal goals for change.
    3. To initiate a series of small lifestyle changes toward PREMIER lifestyle guidelines and goals and begin to build a support network for making changes.
    4. To learn how to identify barriers inhibiting change and learn to problem-solve possible solutions.
  - Phase II
    1. To build a support network for making lifestyle changes.
    2. To refine strategies for becoming proficient with all PREMIER lifestyle guidelines.
    3. To continually identify barriers for change and problem-solve possible solutions.
    4. To become familiar with relapse and initiate skills for preventing relapse.
    5. To create a long-term personal change plan.
- Phase III Leader's Guides are not sequenced, but rather provide a menu of options for the site to select from depending on the needs and preferences of the groups. The group sessions of Phase III, however, are designed with similar group process structure used in Phase I and Phase II. The goals of Phase III are:
  1. Maximize participant adherence to the recommended diet, weight loss and exercise guidelines.
  2. Maximize the proportion of participants who are actively involved in the interventions.
  3. Implement strategies for different categories of participants:
    - maintainers - those who have reached their intervention assignment goals
    - relapsers - those who were at one time doing well, but have fallen away
    - non-responders - those who have never been adherent to the PREMIER goals
  4. Develop effective procedures for helping participants with unusual adherence concerns.
  5. Implement strategies to enhance adherence of minority participants

## **PREMIER Intervention Manual of Procedures**

- The written materials should be used to guide for group facilitation. Once participants are familiar with the lifestyle guidelines (first 3-4 group sessions) the focus should shift to mainly behavior change and problem-solving rather than delivery of nutrition content.
- Group interventionists should be flexible within the structure of the group session, being sure to regularly incorporate the behavior-change techniques outlined in the leader's guide (checking progress, problem-solving, action planning, goal setting, and self monitoring).
- Priority should be given to behavior change discussions and activities over nutrition and physical activity content delivery.

## PREMIER Intervention Manual of Procedures

### *Table of Contents of the Leader's Guide*

- I. Introduction/Overview
- II. Chapter 1-26 (one chapter for each session, same order as session description)
- III. Topic Sheets
- IV. Recipes

### *Format for Chapters 1-26*

The following template is used for Phase I and Phase II group sessions (G2-G14):

- I. Session Agenda
- II. Materials to gather ahead of time
- III. Session Objectives
- IV. Session Outline
  - 1. **Taste It!/Check-in**
  - 2. **Progress Check/Re-Cap**
  - 3. **Try it!** (includes)
    - Activity
    - Demonstration
    - Discussion
    - All above includes:
      - Lifestyle Patterns: Eating and Physical Activity
      - Change Strategies
      - Knowledge & Skills: Nutrition & Physical Activity
  - 4. **Next Steps**
    - Plan for the Week
    - Tracking (self-monitoring)
    - On Your Own

The following template is used for Phase III group sessions (G14-G26)

#### **Check-in**

Weigh-in and data collection

#### **Introduction/Progress Check:**

Use this time to ask each participant about their progress and experiences since the previous session. Use the sample discussion questions in the leader's guide outline and emphasize group support, problem-solving, and barrier identification.

#### **Taste It! (scaled back and simple):**

Less formal and structured than in Phase I and II, however, a very important part of the session when applicable. Taste It themes do not necessarily need to correlate with the content topic for the session, but should always meet the PREMIER B and C guidelines. Example may include potlucks, recipe exchanges, and food sharing between participants



## **PREMIER Intervention Manual of Procedures**

to add variety and participation. If the session is an outing, the Taste It could be an example of a good choice to take “on the run.” If the outing or activity is to a restaurant or grocery store, there may be no need for a separate Taste It component to the session.

### **Do It! (include when appropriate, not a component of every group session)**

Time to do actual physical activity during the group session. Group walk, “step” routine, chair aerobics, etc. This component should always be flexible based on the needs of the group.

### **Session Content and/or Theme**

Keep the focus in Phase III on ways to help the participant re-commit, focus on their success, stay involved and motivated to continue making positive lifestyle changes. The content is not the end in and of itself, it is the means for continued facilitation of behavior change.

### **Next Steps**

Participants can be self-led and/or self-directed for the Next Steps portion during Phase III. Whatever is working for participants should be the focus of the discussion.

#### **Plan for the Week**

Participants make short-term goals (plan for the week that move the participant one step closer toward the long-term study goals).

#### **Tracking Your Progress (self-monitoring)**

Participants determine what self-monitoring and record keeping they will do in the following week to help them follow their plan.

#### **On your Own**

Participants determine something new to try on their own before the next group session.

### ***Using the topic sheets***

The topic sheets are for the PREMIER group interventionist to reference when an unplanned topic discussion occurs.

**PREMIER Intervention Manual of Procedures**

**33. PARTICIPANT MANUAL 3**

<b>Purpose</b> _____	<b>3</b>
Use of the Participant Manual _____	3
For the PREMIER C manual only: _____	3

**PREMIER Intervention Manual of Procedures**

**Summary of Edits**

## PREMIER Intervention Manual of Procedures

### 33. Participant Manual

#### *Purpose*

The PREMIER participant manual provides participants with the general format, outline and worksheets for each session. The participant manual is one tool among many used in PREMIER and where appropriate the manual emphasizes changing behaviors and includes information about diet and physical activity. It is intended to complement and supplement the group session process and content and serve as a workbook during the group session and as a reference for participants.

There is not a participant manual for PREMIER A. A separate participant manual exists for PREMIER B and PREMIER C.

#### *Use of the Participant Manual*

The participant is given the participant manual (containing Phase I materials at minimum) at the first randomization visit. Participants are requested to bring the manual to each group and individual visit unless informed otherwise by the group interventionist. During the group sessions, the interventionist refers to the manual when appropriate.

#### Table of Contents

- I. Introduction
- II. Chapters 1-26, one chapter associated with each group session. Each chapters has the following sections:
  - What you can expect from this session* (learning objectives)
  - Just the facts!* (basic topical information as it pertains to the group session)
  - Worksheets and Activities*
  - Next Steps:*
    - “My plan for the week” (short term goals with action plan)
    - “Tracking my Progress” (plan for record keeping and self-monitoring)
    - “On my own” (new things to try in the coming week, suggested or otherwise)
- III. Topical reference chapters that are not associated with a given group session and may contain non-essential, detailed information related to specific nutrition, behavior and physical activity topics.
- IV. Recipes
- V. “My Notes” (Place for participants to keep their own notes, file data reports and graphs from individual visits, etc.)

#### *For the PREMIER C manual only:*

In addition to the content differences between the PREMIER B and PREMIER C group, fruit & vegetable and dairy messages appear frequently in margins and text.

**PREMIER Intervention Manual of Procedures**

<b>34. FOOD &amp; FITNESS GUIDE</b>	<b>3</b>
<b>Purpose</b> _____	<b>3</b>
The PREMIER Food & Fitness Guide _____	<b>3</b>
<b>Description</b> _____	<b>3</b>

**PREMIER Intervention Manual of Procedures**

**Summary of Edits**

## PREMIER Intervention Manual of Procedures

### 34. Food & Fitness Guide

#### *Purpose*

##### *The PREMIER Food & Fitness Guide*

- Provides a reference of nutrient values for commonly consumed food items that helps participants self-monitor their food intake and develop skills for making appropriate food choices.
- Provides information on the PREMIER Study Guidelines, nutrition topics such as nutrition labeling, fat gram guidelines, recipe modification and physical activity.
- Facilitates behavior change and the achievement and maintenance of the PREMIER Lifestyle Guidelines. [Note: the lifestyle guidelines are the intervention goals. The Study goals are broader and include comparison of groups to answer the research question.]

#### *Description*

- The *Food & Fitness Guide* is a reference book that comes in two versions, one for PREMIER B and the other for PREMIER C. They both list the calories, grams of fat, and milligrams of sodium for standard serving sizes of commonly consumed food items, such as raw foods, processed and convenience foods, mixed dishes, and restaurant items. Additionally, the Food and Fitness Guide for PREMIER C lists grams of saturated fat and contains a guide for what counts as a fruit, vegetable and dairy serving.
- The nutrient values listed in the *Food & Fitness Guide* were compiled from the Nutrition Data System for Research (NDS-R) software, developed by the Nutrition Coordinating Center (NCC), University of Minnesota, Minneapolis, MN, Food and Nutrient Database 29, released in December 1998.
- The *Food & Fitness Guide* also includes a section on Physical Activity that provides information on the benefits of physical activity, as well as instructions on how to use the PREMIER Physical Activity Point System to monitor frequency and intensity of physical activity.
- The *Food & Fitness Guide* provides an alphabetical index of all listed foods.

In the “Food Listings” section of the guide, foods are grouped by category (for example, “Breads, Cereals and Other Grain Products”). Categories are arranged alphabetically and individual foods are arranged alphabetically within categories (for example, bagel, biscuit, bread...). There is also an alphabetical listing of foods (index) at the end of the book. To locate a particular food item, participants can use either the food category listing or alphabetical listing.

Nutrient values for prepared foods like macaroni and cheese, and spaghetti and meatballs are based on standard recipes and include fat and salt normally added during preparation. Salt added at the table is not included in the sodium values listed for a particular food.

## **PREMIER Intervention Manual of Procedures**

Many of the food categories include Fat Gram Guidelines to help participants select lower-fat foods. The Fat Gram Guidelines are also summarized on the back cover of the Food and Fitness Guide.



**PREMIER Intervention Manual of Procedures**

<b>35. ADVERSE EVENTS, SYMPTOMS AND MEDICAL EVENTS/REFERRALS DETECTED DURING INTERVENTION</b>	<b>3</b>
<b>Detection and Documentation</b> _____	<b>3</b>
<b>Specific adverse events/symptoms</b> _____	<b>4</b>
Musculoskeletal injuries _____	4
Prevention and treatment for certain physical activity related injuries _____	4
Lactose intolerance _____	5
Increased fiber intake _____	5

## **PREMIER Intervention Manual of Procedures**

### **Summary of Edits**

#### **Summary of changes between Version 1.0 and 1.1**

- Minor edit to musculoskeletal injuries: deleted “from a musculoskeletal injury” from last sentence, paragraph 3; changed “etiology” to “significance” in first sentence of paragraph 4.

## 35. Adverse Events, Symptoms and Medical Events/Referrals Detected During Intervention

### *Detection and Documentation*

In addition to the formal monitoring of adverse events during follow-up measurement at clinical visits (see Clinic MOP Chapter 23, Safety), it is possible that participants may report adverse events to interventionists informally. It is not the interventionist responsibility to solicit information about symptoms or events, and they do not need to question participants specifically about them. These guidelines are to be used in the event that a participant brings information to the interventionist's attention spontaneously. If participants report **minor symptoms** such as *bloating, gas, other minor gastrointestinal discomfort, muscle ache or minor sprain or strain or other minor musculoskeletal discomfort*, no action from the interventionists is required except to give standard common-sense advice on how to deal with the problem (eg. Lactaid for use with dairy, PRICE for minor injuries (see below)). No documentation on trial-wide forms is required. Local documentation is required to the extent needed to provide appropriate follow-up for the participant's safety and comfort.

If any potentially significant symptom is reported by the participants, interventionists complete Form #31 (Participant Reported Event Form), and refer the participant to the study clinician for further action. If the interventionist has any doubt deciding if the symptom is significant or not, he/she should talk to study clinician. Examples of significant symptoms include the following:

- prolonged nausea and vomiting
- chest pain with exertion
- difficulty breathing
- dizzy spells
- emergency room visit
- hospitalization
- physician visit for other than routine care
- severe diarrhea or constipation
- other major gastrointestinal symptoms
- fever with abdominal pain
- musculoskeletal injury with excessive swelling and/or prolonged disability.
- other major musculoskeletal symptoms

When a significant symptom is brought to the attention of the interventionist in this way, in addition to completing the Participant Reported Event Form (#31), the interventionist should note the symptom on the participant's progress note, and bring it to the attention of study clinician, who will record if this symptom is an Adverse Event and note whether a referral is needed (for detailed instructions regarding definition and documentation of adverse events, see Clinical MOP Chapter 23, Safety). It is the clinician's responsibility, NOT the interventionist's, to complete the AE form.

## **PREMIER Intervention Manual of Procedures**

### *Specific adverse events/symptoms*

#### *Musculoskeletal injuries*

Participants are screened for orthopedic or rheumatologic problems that might limit their ability to participate in the physical activity component of the intervention. Participants in intervention groups B and C are taught techniques for stretching, warm-up, and cool-down as a component of the intervention to reduce risk of musculoskeletal injuries.

In the case of severe injuries or potentially clinically significant symptoms, a study clinician should determine 1) if the physical activity portion of the intervention should be terminated either permanently or pending a clinical evaluation; and 2) whether referral for further evaluation or treatment is warranted.

In some situations where there are musculoskeletal symptoms or an injury has occurred that will take some time to heal, it may be appropriate for the interventionist to advise the participant on adapting his/her physical activity program. (For example, an individual who has sustained a leg injury may be advised about alternatives to walking, or if a participant has a broken leg, he/she could still exercise his/her arms by stretching arms and shoulders or by using light handheld weights). During **active** recovery from heat-related illness, participants should be advised not to engage in physical activity.

If there is any question about the significance of an injury or the need for treatment, the participant is referred to the study clinician who determines whether a referral is needed. If a participant is not willing to follow recommendations for referral, the study clinician is notified and determines if further action is required.

#### *Prevention and treatment for certain physical activity related injuries*

Sprains (overstretching or tearing of ligaments) and strains (overstretching or tearing of muscle or tendon) are the most common injuries associated with adult physical activity programs. Injuries to joints or soft tissues require the immediate application of PRICE = Protection, Rest, Ice, Compression, and Elevation. Ice should be applied for 15-20 minutes and reapplied hourly or if pain is experienced. Application of ice should be continued from 24-72 hours, depending on the severity of the injury. A compression bandage (e.g. ACE bandage) should be wrapped firmly (but not tightly) around the area to minimize swelling. Elevation should be above the heart, if possible. If the sprain or strain is moderate to severe, the study clinician should be consulted, who will determine if a referral is needed.

Another possibility for musculoskeletal injuries is a fracture. If there is any suspicion of a possible fracture, the participant should be referred to their physician for further evaluation.

## **PREMIER Intervention Manual of Procedures**

Heat-related problems are also a possible consequence of physical activity. To prevent heat injury: acclimatize to heat and humidity by training over a period of 7-10 days; hydrate prior to activity and frequently during activity; decrease the intensity of exercise if the temperature or humidity is high; monitor weight loss by weighing before and after workouts and drink a lot of fluid if more than 3% of body weight is lost. In addition, wear appropriate clothing for hot or humid weather conditions: expose as much skin surface as possible, wear light-colored clothing, and wear natural fibers (like cotton). Symptoms of overexertion include nausea or vomiting, extreme breathlessness, dizziness, unusual fatigue, muscle cramping, and headache. Symptoms of heat illness include hair standing on end on chest or upper arms, body chills, headache or throbbing pressure, nausea or vomiting, labored breathing, dry lips or extremely dry mouth, faintness, muscle cramping, and cessation of sweating. If these symptoms occur, activity should be stopped immediately, the participant should seek shade or air conditioning and lie down, and a lot of fluids should be consumed. If the symptoms persist or if there is collapse, emergency medical help (911) should be called immediately.

### *Lactose intolerance*

Since increasing consumption of dairy products is one of the lifestyle goals for PREMIER C, it is possible some participants in this group may experience symptoms of lactose intolerance. These symptoms include abdominal discomfort or pain, gas, or diarrhea. If this condition is noticed during intervention sessions, or from questionnaire assessment, participants should be counseled to use lactaid-treated dairy products, or to use lactaid before consuming dairy products. Interventionists should maintain records of those participants that are lactose intolerant and follow-up with them on this condition during individual visits.

### *Increased fiber intake*

It is possible that participants in the PREMIER C may experience unpleasant GI symptoms (such as bloating and constipation) due to increased fruits and vegetables consumption, which increases their fiber intake. Increases in legumes and whole grains also increase fiber intake. This condition is more likely for those participants who usually consume little fiber in their diet. Participants should be advised to drink plenty of fluid, increase fruits and vegetables (and other high-fiber foods) consumption gradually, use over-the-counter medications for gas, or consult their physicians if necessary.

**PREMIER Intervention Manual of Procedures**

<b>36. DIETARY INTERVENTION</b>	<b>3</b>
<b>Introduction</b>	<b>3</b>
<b>Description of the Dietary Interventions</b>	<b>3</b>
PREMIER B	3
PREMIER C	3
<b>Description of Approach to Dietary Change</b>	<b>3</b>
<b>Implementation: General</b>	<b>4</b>
<b>Dietary Guidance Implementation</b>	<b>5</b>
<b>PREMIER B</b>	<b>5</b>
<b>PREMIER C</b>	<b>6</b>
<b>Appendix A – Fat Contents of Menus at 3 Calorie Levels</b>	<b>8</b>
<b>Appendix B – Rationale for PREMIER C Fat Gram Goals</b>	<b>9</b>
<b>Appendix C – What Counts as One Fruit or Vegetable Serving?</b>	<b>10</b>
<b>Appendix D – What Counts as a Fruit or Vegetable?</b>	<b>11</b>
<b>Appendix E – What Counts as One Dairy Serving?</b>	<b>12</b>
<b>Appendix F – Mixed Dishes</b>	<b>13</b>
<b>Appendix G – Premier C Eating Pattern Example</b>	<b>14</b>

## **PREMIER Intervention Manual of Procedures**

### **Summary of Edits**

#### **Summary of changes between Version 1.0 and 1.1:**

- general grammatical and textual changes throughout (including appendices).
- p. 5, PREMIER B, added 1800 kcal per day for women and 2300 kcal per day for men to the interventionist recommendations for participants who do not need to lose weight to target their initial daily calories.
- p. 6, PREMIER C, added 1800 kcal per day for women and 2300 kcal per day for men to the interventionist recommendations for participants who do not need to lose weight to target their initial daily calories.
- p. 8, Appendix A, changed fat gram, in the 2500 kcal menu column, to 3 , the total fat grams to 72, and the % fat to 25.4%.
- p. 10, Appendix C, changed Serving Size under Vegetables to 1 piece and Example to medium tomato, medium baked potato.
- p. 12, Appendix E, added to Serving Size (¼ cup) to 4 TB grated cheese.
- p. 13, Appendix F, in Description column for pizza changed ½ cup grated to 1 slice (1.5 oz) Mozzarella cheese, whole milk, shredded. In “Tally of F, V, and D” column for pizza changed Dairy to 1.
- p. 14, Appendix G, added to Lunch sample menu ½ cup raw baby carrots and changed apple to 1 medium. In the number of servings for F & V, added 1 serving next to raw baby carrots and changed 1 medium apple to 1 serving.

## **PREMIER Intervention Manual of Procedures**

### **36. Dietary Intervention**

#### *Introduction*

There are two dietary interventions: PREMIER B and PREMIER C. Both are multi-component lifestyle interventions based on current clinical practice guidelines for blood pressure control and cardiovascular health. For both intervention arms, the recommendations are to lose weight if overweight, reduce sodium intake, limit alcohol intake, engage in regular physical activity, and eat a reduced fat diet. Participants in PREMIER C, in addition, are recommended to follow the DASH dietary pattern by increasing intakes of fruits, vegetables, and low-fat dairy products, and reducing intake of total fat and saturated fat. This chapter focuses on the dietary components of the interventions. Physical activity is addressed in Chapter 37.

#### *Description of the Dietary Interventions*

##### *PREMIER B*

The PREMIER B participants are asked to reduce weight by 15 lb (7 kg) or more if overweight, reduce daily sodium intake to no more than 2400 mg (100 mmol) per day, limit alcohol intake to no more than one (for women) or two (for men) drinks per day, and reduce total fat intake to no more than 30% of calories per day.

##### *PREMIER C*

The PREMIER C participants are asked to reduce weight by 15 lb (7 kg) or more if overweight, reduce daily sodium intake to no more than 2400 mg (100 mmol) per day, limit alcohol intake to no more than one (for women) or two (for men) drinks per day, and reduce total fat and saturated fat intake to no more than 25% and 7% of calories per day, respectively. In addition, participants are asked to follow the DASH dietary pattern by increasing intakes of fruits and vegetables to 9-12 servings per day and dairy foods to 2-3 servings per day. The actual number of servings depends on calorie levels.

#### *Description of Approach to Dietary Change*

The intervention focuses on behavior change rather than on specific nutrients. The focus is based on the concept of lifestyle patterns for eating. The intervention is theory-based, derived from social cognitive theory, and uses elements of behavioral self-management, relapse prevention, and stages-of-change. It is designed to increase self-efficacy and social support, which are expected to help mediate behavior change, promote skills to acquire and maintain new dietary behaviors, and take into account the participant's stage of readiness to change. Behavioral strategies used include: frequent and extended contacts; opportunities for group interactions and social support; goal-setting and self-monitoring of dietary intake; problem-solving; examples of new behavioral options and decision-making approaches for changing



## **PREMIER Intervention Manual of Procedures**

eating habits; individual contacts which tailor the intervention to the individual's food and eating pattern preferences and readiness to change; and other contacts that support dietary behavior change, provide content material, and teach the participant how to incorporate behavioral cues and reinforcement in the participant's environment. In the group sessions most of the time is spent on activities designed to develop and practice new dietary behaviors and skills. Content information to impart knowledge is also provided and integrated with activities and facilitated discussions.

Participants set their own goals, based on their current eating habits and readiness to change. The intervention builds slowly, teaching new eating behaviors and food choices progressively so that the PREMIER dietary guidelines will eventually be met. Interventionists use motivational interviewing as well as facilitated discussions during progress checks and in the group sessions to help participants determine their motivation to change, identify barriers to dietary change, and develop problem-solving skills to overcome these barriers. Interactive, facilitated discussion allows for integration of informational content and stresses how to make better food choices.

### ***Implementation: General***

Since people tend to eat the same foods most of the time and follow similar patterns of eating from day to day, the dietary intervention focuses on food choices and substitutions. Participants identify their personal eating patterns and the foods most often eaten (their individual top 10 list of most frequently consumed foods, for example). This allows participants to identify better alternatives and set goals for potential changes. Dietary patterns are segmented into breakfast (or morning) meals, lunch (or noontime/midday) meals, dinner (or evening) meals, and snacks, and intervention sessions target one segment at a time. For each segment participants identify better patterns and choices with the help of the PREMIER Food and Fitness Guide and nutrition labels on food packages (where the amount of calories or sodium, for example, can be compared among different choices), worksheets in the Participant Manual, and facilitated discussion during progress check and elsewhere in the intervention sessions. Participants then develop personalized action plans for potential changes. A similar process is used for eating out and eating during special occasions: participants identify better choices that could be available in a menu or at a special occasion and develop action plans to accomplish their goals.

Specific nutritional information is provided in topic sheets and covered as needed in the Leaders Guide, Participant Manual, and Intervention Manual of Procedures. Information on the sodium, total fat and saturated fat content is straightforward and covered in detail in the PREMIER Food and Fitness Guide. Serving sizes of fruits, vegetables, and dairy are also included. Additional detailed information relevant to the PREMIER C intervention on fruit, vegetable, and dairy food classifications and their serving sizes is provided as appendices to this chapter (Appendix C – G).

## **PREMIER Intervention Manual of Procedures**

### ***Dietary Guidance Implementation***

#### ***PREMIER B***

PREMIER B participants are counseled to eat a variety and balance of foods, eat in moderation, and eat lower salt foods. A specific food pattern is not recommended nor are food guides used such as the Food Guide Pyramid. The goal is to help participants eat a variety and balance of foods, reduce their calories enough to lose weight, if necessary, and eat foods lower in sodium to achieve the study sodium goal. Some participants may not need to lose weight; therefore, the message for these participants is to eat a variety and balance of foods, eat a calorie level to maintain weight, and eat foods lower in sodium to achieve the study sodium goal.

Participants in the PREMIER B intervention are:

- Counseled to reduce their calories enough to lose weight, if weight loss is recommended.
- Counseled to eat 2400 mg or less per day of sodium.
- Asked to limit alcohol to no more than two alcoholic drinks per day for men and one for women.

Participants are asked to record what they eat for a minimum of three days per week, but are encouraged to record as many days as possible to assess their progress and adherence to the study goals. The participants use the study Food and Fitness Guide to calculate the number of calories they eat and the amount of sodium they consume each day they record. There is a general fat goal of 30% or less of calories from fat to reflect current recommendations for promoting cardiovascular health, and participants are given general guidelines for fat grams for various types of foods. However, do not calculate the number of grams of fat they consume and do not ask them to eat less than a specific amount of fat each day.

At the R/I visit the interventionist recommends to participants who do not need to lose weight to target their initial daily calories to 1800 kcal per day for women and 2300 kcal per day for men (see Appendix C for rationale). For participants who need to lose weight the goal is about 1500 kcal per day for women and 2000 calories per day for men. The purpose of this recommendation is to give participants a calorie target and to make sure they do not eat too few calories. Later participants learn the number of calories they need to eat to lose and/or maintain their weight by keeping food records and observing their weight pattern in relationship to their physical activity and recorded caloric intake. The interventionist monitors participants' food intake by regularly reviewing the Food and Fitness Diaries. If the participant's recorded calorie intake drops below 1200 for women and 1500 for men or if the participant appears to be making unhealthy food choices, the interventionist intervenes (see chapter 44 on Nutrition Adequacy).

Aids are used to help participants lose weight. Participants are:

- Shown how to read the Food and Fitness Guide and food labels to select foods that contain fewer grams of fat and/or fewer calories.

## **PREMIER Intervention Manual of Procedures**

- Guided to select foods using the Food and Fitness Guide or food labels that are at or below the study fat gram guidelines for that food group. See Appendix A for an example of fat content of menus at 3-calorie levels.
- Helped to find foods or groups of foods in their Food and Fitness Guide that they can alter or not eat to consume 500 fewer calories per day, if weight loss is recommended.

### ***PREMIER C***

Participants in the PREMIER C intervention arm of the study are counseled to eat a diet that is built around the DASH dietary pattern in addition to eating a variety and balance of food, eating in moderation, and eating lower salt foods. Participants in this arm of the study are:

- Given a fat gram goal:
  - If they do not need to lose weight, their goal is 65 grams of fat per day for men and 50 grams of fat per day for women to achieve 25% or less of their calories from fat (see Appendix B for rationale).
  - If they need to lose weight, their goal is 40 grams of fat per day for men and 30 grams of fat per day for women to achieve 25% or less of their calories from fat.  
Alternatively, their goal could be a reduction from current intake of 40 grams for men and 30 grams for women (see Appendix B for rationale).
- Counseled to eat 9 to 12 servings of fruits and vegetables per day.
- Counseled to eat 2 to 3 servings of dairy foods per day.
- Counseled to reduce their calories enough to lose weight, if weight loss is recommended.
- Counseled to eat 2400 mg or less per day of sodium.
- Asked to drink no more than two alcoholic drinks per day for men and one for women.

Participants are asked to record what they eat for a minimum of three days per week, but encouraged to record as many days as possible to assess their progress and adherence to the study goals. The participants use the Food and Fitness Guide to calculate the number of calories, fat and sodium, in addition to the number of servings of fruits, vegetable and dairy foods. Although there is a saturated fat goal of 7% or less of calories, participants do not monitor the amount of saturated fat they eat and are not given a specific number of grams of saturated fat as a target.

At the R/I visit the interventionist recommends to participants who do not need to lose weight to target their initial calorie intake to 1800 kcal per day for women and 2300 kcal per day for men (see Appendix C for rationale). For participants who need to lose weight the goal is about 1500 kcal per day for women and 2000 calories per day for men. The purpose of this recommendation is to give participants a calorie target and to make sure they do not eat too few calories. Later participants learn the number of calories they need to eat to lose and/or maintain their weight by keeping food records and observing their weight pattern in relationship to their physical activity and recorded calorie intake. The interventionist monitors participants' food intake by regularly reviewing the Food and Fitness Diaries. If the participant's recorded caloric intake drops below

## **PREMIER Intervention Manual of Procedures**

1200 for women and 1500 for men or if the participant appears to be making unhealthy food choices, the interventionist intervenes (see Chapter 44 on Nutrition Adequacy).

An emphasis is placed on fruits, vegetables, and dairy products low in fat. Specific fruits and vegetables used in the DASH study are emphasized and used in menus and recipes. Legumes and legume products do not count as vegetables, but are recommended for a healthy diet. Foods low in saturated fat are also emphasized. Information on assessing intakes of fruits, vegetables, and dairy products is provided in Appendix C-F of this chapter, and an example of an eating pattern that meets PREMIER C goals for fruits, vegetables, and dairy, is shown in Appendix G.

Aids are used to help the participants lose weight. Participants are:

- Encouraged to eat fruits and vegetables as a substitute for high fat/high calorie foods.
- Guided to select low fat foods using the FFG or food labels to meet their fat gram goal.
- Helped to find foods or groups of foods that they can alter or not consume to reduce their calories by 500 calories per day, if weight loss is recommended.

More information on PREMIER B (Appendix A) & PREMIER C (Appendix B-G) is provided in appendixes to this chapter.

- Appendix A – Example of Fat Content of Menus at 3 Calorie levels
- Appendix B - Rationale for PREMIER C Fat Gram Goal and Fat Gram Reduction Goal
- Appendix C – Example of What Counts as One Fruit or Vegetable Serving
- Appendix D – Examples of Foods that Do Not or May Not Count as a Fruit or Vegetable
- Appendix E - Examples of What Counts as One Dairy Serving
- Appendix F – Mixed Dishes- An Approach to Calculate Servings of Fruits, Vegetables, and Dairy.
- Appendix G – Example of an Eating Pattern that Meets PREMIER C Goals for Fruits, Vegetables, and Dairy.

**PREMIER Intervention Manual of Procedures**

**Appendix A – Fat Contents of Menus at 3 Calorie Levels**

Example of fat content of menus at 3 calorie levels that meet both B & C total fat targets.

<b>1500 kcal menu:</b>			<b>2000 kcal menu:</b>			<b>2500 kcal menu:</b>		
	fat, g	kcal		fat, g	kcal		fat, g	kcal
<b>Breakfast</b>			<b>Breakfast</b>			<b>Breakfast</b>		
1 C milk, 1%	3	100	1 C milk, 1%	3	100	1 C milk, 1 %	3	100
1 C oat bran flakes	2	110	1 C Life	2	110	1 C oat bran flakes	2	110
1 slice wheat bread	1	65	1 sl wheat bread	1	65	2 sl wheat bread	2	130
1 tsp jam	0	20	1 tsp tub margarine	4	35	2 tsp tub margarine	8	70
6 oz OJ	0	85	1 tsp jam	0	20	1 TB jam	0	50
			6 oz OJ	0	85	8 oz OJ	0	115
<b>Lunch</b>			<b>Lunch</b>			<b>Lunch</b>		
3 oz water-pack tuna	1	100	3 oz drained tuna in oil	7	170	3 oz drained tuna in oil	7	170
1 TB LF mayo	5	50	1 TB LF mayo	5	50	2 TB LF mayo	10	100
2 sl wheat bread	2	130	1 white hard roll, 3-1/2"	2	145	1 white hamburger bun	4	250
12 oz diet cola	0	0	12 oz cola	0	155	12 oz diet cola	0	0
1 med apple	0	80	1 large apple	0	125	1 large apple	0	125
<b>Dinner</b>			<b>Dinner</b>			<b>Dinner</b>		
1/2 C salad	1	25	1 C salad	1	45	1 C salad	1	45
2 TB LF dressing	5	55	2 TB LF dressing	5	55	2 TB LF dressing	5	55
1.5 svg frozen entrée	12	495	1.5 svg frozen entrée	12	495	2 svg frozen entrée	16	660
1/2 C green beans	0	20	1/2 C pasta	1	110	1 C pasta	2	215
1 tsp tub margarine	4	35	1/4 C spaghetti sauce	2	65	1/2 C spaghetti sauce	4	130
1/2 C light ice cream	5	115	1/2 C light ice cream	5	115	1/2 C light ice cream	5	115
12 oz water	0	0	12 oz water	0	0	12 oz water	0	0
<b>Snacks</b>			<b>Snacks</b>			<b>Snacks</b>		
3 rye wafers	2	110	3 rye wafers	3	110	3 rye wafers	3	110
<b>TOTAL</b>	<b>43</b>	<b>1595</b>	<b>TOTAL</b>	<b>53</b>	<b>2055</b>	<b>TOTAL</b>	<b>72</b>	<b>2550</b>
<b>% fat</b>	<b>24.3%</b>		<b>% fat</b>	<b>23.2%</b>		<b>% fat</b>	<b>25.4%</b>	

## **PREMIER Intervention Manual of Procedures**

### ***Appendix B – Rationale for PREMIER C Fat Gram Goals***

#### ***For participants who need to lose weight:***

##### **Rationale for Fat Gram Goal**

Because participants are monitoring their fat intake, it may be important to give the participants a fat gram number that they can keep in mind as a goal. The fat gram goal is based on “generic” caloric levels commonly used in weight loss interventions, as agreed upon by the Intervention Committee: 1200 kcal for women and 1500 kcal for men. Fat intakes of 30 g and 40 g represent 25% of kcal from fat for the two calorie levels. This approach avoids the need to have fat gram goals be based on true caloric requirements. Assessing caloric requirements is not practical, and there is no way for participants to self-monitor their true caloric requirements. However, since their fat gram goals may be close to what they are reporting, the thrust of the intervention would still be on reducing their fat grams to 30 g and 40 g, respectively, for women and men.

##### **Rationale for Fat Gram Reduction Goal of 30g and 40 g (women and men)**

Based on NHANES III data, men’s self-reported caloric intake was about 2470 (age range 30-69), with about 96 g of fat. The respective numbers for women age 30-69, were 1700 kcal and 67 g fat. A reduction of 500 kcal for each sex results in caloric intake goals of 1970 for men and 1200 for women. Using 25% of kcal from fat as the dietary fat goal results in a fat gram goal of 55 g for men (or a reduction of 41 g) and 34 g for women (or reduction of 33 g for women). Rounding to the nearest zero (and coincidentally, resulting in the same values as the absolute goals), the fat gram reduction goals become 30 g and 40 g for women and men. These are likely underestimates and participants could do better, but these could be presented as minimum fat gram reductions from current intake.

#### ***For participants who do not need to lose weight:***

##### **Rationale for Absolute Fat Gram Goal**

Participants who are counseled to maintain their weight also monitor their fat intake. It may be important to also give these participants a fat gram number that they can keep in mind as a goal. The fat gram goal for participants who do not need to lose weight is based on “generic” caloric levels as given by the Daily Value in nutrition labels, i.e., 2000 kcal for women and 2500 kcal for men. Because under-reporting of caloric intake has been commonly observed, ranging from 10% to over 35%, for purposes of establishing an absolute fat gram goal we assume 10% under-reporting. Thus, a reported intake of 1800 kcal for women (10% less than 2000 kcal) would contain 50 grams of fat to achieve a fat intake of 25% of calories. Likewise, a reported intake of 2250 kcal for men (10% less than 2500 kcal) would contain 62.5 grams of fat to achieve a fat intake of 25% of calories. Rounding up, the fat gram goal is set to 65 grams for men. Thus, the fat gram goals for participants who do not need to lose weight are 50 grams for women and 65 grams for men.

## PREMIER Intervention Manual of Procedures

### *Appendix C – What Counts as One Fruit or Vegetable Serving?*

#### Examples of What Counts as One Fruit or Vegetable Serving

Serving Size	Example
<b>FRUITS</b>	
1 medium fruit	apple, banana, orange, pear
$\frac{3}{4}$ C (6 oz) 100% fruit juice	apple juice, apricot nectar, orange juice,
$\frac{1}{2}$ C berries	blackberries, blueberries, strawberries
$\frac{1}{2}$ C chopped	melons (cantaloupe, honeydew, watermelon)
$\frac{1}{2}$ C canned, cooked, or frozen	applesauce, peach, pear, pineapple
$\frac{1}{4}$ C dried fruit	apples, apricots, figs, pears, prunes, raisins
<b>VEGETABLES</b>	
1 piece	medium tomato, medium baked potato
1 C raw leafy vegetables	green leaf lettuce, Romaine lettuce, spinach
$\frac{3}{4}$ C (6 oz) 100% vegetable juice	low-sodium V-8 juice, low-sodium tomato
$\frac{1}{2}$ C raw, chopped	carrots, green peppers, tomatoes
$\frac{1}{2}$ C canned, cooked, or frozen	beans, broccoli, cabbage, carrots, cauliflower, green peas, mustard greens, potatoes, spinach, squash, sweet potatoes, turnip greens

**Note:** Dried beans, peas, and legumes (chili beans, lentils, chickpeas, split peas) and soy products (tofu, garden burgers) do not count as a vegetable although they are considered part of a healthy diet.

## PREMIER Intervention Manual of Procedures

### *Appendix D – What Counts as a Fruit or Vegetable?*

#### Examples of Foods that Do Not or May Not Count as a Fruit or Vegetable

Certain foods do not count as fruits or vegetables because they are too high in fat or sugar, or because they contain very little fruit or vegetable. Highly processed vegetables, particularly those that are fried and highly salted, are not recommended.

- jams, jellies, and preserves
- fruit filling in pastry, cookies, or breakfast bars
- fruit-flavored alcoholic drink (strawberry daiquiris, pina coladas)
- fruit punch, Kool-Aid, fruit-aid, Tang, fruit seltzers
- fruit flavoring or bits of fruit in ice cream, sherbet, sorbet, frozen and regular yogurt
- fruit flavoring or bits of fruit in muffins, breads, pancakes
- fruit flavored candies (gummies, Sunkist gels)
- pickled vegetables (sweet or dill pickles, relish, pickled asparagus, mushrooms, or cabbage)
- sauerkraut
- olives (black, green)
- fried potatoes (including French fries and hash browns)
- fried and battered vegetables (Tempura, egg roll with skin)
- fried salted snacks (potato chips, corn chips, Doritos)
- tomato condiments (catsup, chili sauce, cocktail sauce)

Some foods may not count unless there is sufficient amount of fruits and vegetables and their fat content is not too high:

- avocado (vegetable is high in fat, but the fat is monounsaturated; should be within fat gram budget)
- soups must have at least ½ cup of vegetables per serving
- dehydrated meals in a cup must have at least ½ cup of vegetables per serving
- salsas must have at least ½ cup of vegetables or fruit per serving



## PREMIER Intervention Manual of Procedures

### *Appendix E – What Counts as One Dairy Serving?*

#### Examples of What Counts as One Dairy Serving

Serving size	Example
1 C (8 fl oz) milk	fat free milk, 1% milk
1 C yogurt	Nonfat or low-fat plain or fruited yogurt
½ C frozen yogurt	Nonfat or low-fat frozen yogurt
½ C pudding	pudding made with fat free or 1% milk
1.5 oz cheese (2 thin slices)	Nonfat, part skim, or low-fat cheese
4 TB grated cheese (1/4 cup)	Parmesan, Romano cheese
½ cup other cheese	Nonfat or 1% cottage cheese, nonfat or part-skim Ricotta cheese, farmer cheese

**Note:** All dairy foods count as a serving regardless of the fat content. However, nonfat and low-fat dairy foods are recommended.

## PREMIER Intervention Manual of Procedures

### Appendix F – Mixed Dishes

Mixed Dishes- An Approach to Calculate Servings of Fruits, Vegetables, and Dairy.

Consumption of foods eaten as mixtures has grown dramatically in the past decade. Mixed dishes often cannot be placed easily into food group categories, which makes monitoring the number of servings of fruits, vegetables, and dairy difficult. To count servings of fruits, vegetables, or dairy, these mixtures must be disaggregated. The goal is to try to estimate fruits, vegetables, and dairy in terms of standard serving sizes. This may be done by visualizing how much of a standard 8-oz measuring cup the amount of fruit, vegetable, or dairy found in the mixed dish would fill. Fractions of servings ( $\frac{1}{4}$ ,  $\frac{1}{2}$ ,  $\frac{1}{3}$ ,  $\frac{2}{3}$ , and  $\frac{3}{4}$ ) may be used for individual components, as long as the total mixture provides at least  $\frac{1}{2}$  serving.

The following are examples of commonly consumed mixed dishes:

Mixed Dish	Description	Estimated serving amount	Tally of F, V, and D
1 C. lasagna	$\frac{1}{2}$ C. noodles $\frac{1}{4}$ Ricotta cheese 1 sl. Mozzarella cheese, part-skim $\frac{1}{4}$ C tomato sauce	$\frac{1}{2}$ svg dairy $\frac{1}{2}$ svg dairy $\frac{1}{2}$ svg veg	1 Dairy $\frac{1}{2}$ Veg
2 slices plain pizza (14" pie)	1 slice (1.5 oz) Mozzarella cheese, whole milk, shredded 1 Tbsp grated parmesan cheese 2 Tbsp ( $\frac{1}{8}$ C) tomato sauce	1 svg dairy $\frac{1}{4}$ svg dairy $\frac{1}{4}$ svg veg	1 Dairy 0 Veg
1 cheeseburger	1 hamburger roll 1 slice American cheese 3 oz ground beef	$\frac{1}{2}$ svg dairy	$\frac{1}{2}$ Dairy
1 C vegetable soup	$\frac{1}{2}$ C peas, carrots, potatoes, onion $\frac{1}{2}$ C broth	1 svg veg	1 Veg
1 C chicken pot pie	$\frac{1}{3}$ C peas, carrots, potatoes 2 oz chicken pastry dough	$\frac{2}{3}$ svg veg	$\frac{2}{3}$ Veg
bacon, lettuce & tomato sandwich	2 slices whole wheat bread 1Tbsp mayonnaise, reg. 4 slice bacon 1 slice lettuce 1 slice tomato ( $\frac{1}{8}$ cup)	$\frac{1}{8}$ svg veg $\frac{1}{4}$ svg veg	0 Veg
grilled cheese sandwich	2 slices whole wheat bread 2 slices American cheese 2 sl. medium tomato ( $\frac{1}{4}$ C)	1 svg dairy $\frac{1}{2}$ svg veg	1 Dairy $\frac{1}{2}$ Veg
1 C cottage cheese with strawberries	$\frac{1}{2}$ C cottage cheese $\frac{1}{2}$ C strawberries	1 svg dairy 1 svg fruit	1 Dairy 1 Fruit

**PREMIER Intervention Manual of Procedures**

**Appendix G – Premier C Eating Pattern Example**

Example of an Eating Pattern that Meets PREMIER C Goals for Fruits, Vegetables, and Dairy.

<b>Breakfast</b>	<b>Sample Menu</b>	<b>Number of Servings</b>	
		<b>F &amp; V</b>	<b>Dairy</b>
(3 F&V; 1 Dairy)	6 oz. orange juice	1	
	8 oz. fat free milk		1
	1 cup bran cereal		
	1 medium banana	1	
	½ cup grapes	1	
<b>Lunch</b>			
(4 F&V; 1 Dairy)	1 cup salad greens	1	
	chicken salad sandwich with ½ cup sliced tomatoes		
	½ cup raw baby carrots	1	
	1 medium apple	1	
	8 oz. fat free milk		1
<b>Dinner</b>			
(4 F&V)	1 cup tossed salad	1	
	1 small baked potato	1	
	1 cup steamed broccoli	2	
	Baked flounder		
<b>Snacks</b>			
(1 F&V; 1 dairy)	8 oz. plain fat-free yogurt		1
	¼ cup raisins	1	
	<b>GOAL: 9-12 Servings F&amp;V 2-3 Servings Dairy</b>	<b>12</b>	<b>3</b>

## PREMIER Intervention Manual of Procedures

<b>37. PHYSICAL ACTIVITY INTERVENTION</b>	<b>4</b>
<b>Purpose of Physical Activity for this Study</b>	<b>4</b>
Background	4
PREMIER physical activity goals	4
National guidelines for physical activity	5
Description of PREMIER physical activity intervention	6
<b>Physical Activity Monitoring and Point System</b>	<b>7</b>
Background	7
The point system	7
<b>Moderate and Vigorous Intensity Aerobic Activity</b>	<b>8</b>
Definition of aerobic activity	8
Moderate intensity activity	9
Vigorous intensity activity	9
<b>Determining Target Heart Rate</b>	<b>11</b>
Estimation of maximal heart rate	11
How to count pulse rate	11
<b>Determining Ratings of Perceived Exertion</b>	<b>12</b>
Background	12
Scale	12
<b>Physical Activity Initiation and Progression</b>	<b>13</b>
Sedentary participants	14
Irregularly active participants	14
Regularly active participants	14
Progression from moderate to vigorous activity	14
<b>Warm-up, Cool-down, and Flexibility Exercises</b>	<b>15</b>
Warm-up exercises	15
Cool-down exercises	15
Flexibility exercises	15
<b>Exercise Adherence</b>	<b>16</b>
Self-monitoring, goal-setting, intrinsic/extrinsic reward systems	16
Enjoyment of activity	17
Identifying and overcoming barriers	17
Environmental prompts	18
Social support	18
Relapse prevention strategies	18
<b>Safety Considerations in Adopting and Maintaining a Physical Activity Regimen</b>	<b>19</b>

**PREMIER Intervention Manual of Procedures**

General issues _____	19
Special Issues _____	20
Injuries _____	20

**PREMIER Intervention Manual of Procedures**

**Summary of Edits**

## **37. Physical Activity Intervention**

### *Purpose of Physical Activity for this Study*

#### *Background*

Evidence from numerous observational studies and experimental trials suggests that increased physical activity can reduce blood pressure. Numerous studies have found a negative correlation between habitual physical activity and the development of hypertension. Most of the experimental studies evaluating the impact of physical activity on blood pressure have incorporated aerobic training protocols at vigorous intensities (i.e., > 60% maximal oxygen uptake or > 70% maximal heart rate) at least three sessions per week for at least 30 minutes of activity per session. In the studies that have evaluated moderate intensity activity, it has been shown that moderate intensity physical activity (i.e., 40% to 60% maximal oxygen uptake or 50% to 70% maximal heart rate) decreases blood pressure to an extent similar to vigorous activity. The entirety of these studies indicates that regular moderate to vigorous intensity aerobic physical activity lowers blood pressure by 10/8 mmHg in hypertensives and 2/3 mmHg in normotensives independent of weight loss. The cumulative evidence that regular physical activity lowers blood pressure has led policy-making bodies to recommend regular, moderate-intensity physical activity as a means to reduce blood pressure.

#### *PREMIER physical activity goals*

The PREMIER physical activity goals are congruent with national recommendations for physical activity and health. The PREMIER physical activity goal is to “engage in regular moderate-intensity activity.” Physical activity in PREMIER must be aerobic in nature, must be purposeful (i.e., expends energy that is greater than that expended in daily activities), must be of at least a moderate intensity, and, after building up from shorter duration’s (see below), should be of at least 20 minutes in duration for each session (see p.37-7 for more information).

The only PREMIER physical activity exclusionary criterion is the inability to engage in physical activity; hence, PREMIER participants will enter the study at a variety of physical activity levels and abilities. For sedentary participants, regular participation in moderate intensity activity is an appropriate goal and the PREMIER physical activity intervention is designed to assist them in meeting this goal. However, some participants will already be engaging in moderate intensity activity and may wish to increase their physical activity intensity to a vigorous level. If there are no contraindications to this (determined from data collected during screening and eligibility provided from the coordinating center to interventionists), the PREMIER intervention can assist the participants in meeting the PREMIER goals by engaging in vigorous activity. Similarly, some participants will have previous experiences with physical activity and will be interested in progressing quickly to vigorous activity. Finally, some participants may already be engaging in vigorous activity, and the PREMIER intervention will assist them in maintaining their current level of activity.

## **PREMIER Intervention Manual of Procedures**

### *National guidelines for physical activity*

There are current physical activity guidelines for: (1) developing and maintaining cardiorespiratory and muscular fitness; (2) producing health benefits; and (3) controlling blood pressure. Although somewhat different, these three guidelines are complementary. The 1998 position stand of the American College of Sports Medicine on the Recommended Quantity and Quality of Exercise for Developing and Maintaining Cardiorespiratory and Muscular Fitness, and Flexibility in Healthy Adults is as follows:

#### Cardiorespiratory Fitness and Body Composition

*Frequency of training:* 3 to 5 days per week

*Intensity of training:* 55/65% to 90% of maximum heart rate, or 40/50% of maximal oxygen uptake. The lower intensity values (55-65% maximal heart rate or 40-49% maximal oxygen uptake) are most applicable to individuals who are quite unfit.

*Duration of training:* 20 to 60 minutes of continuous or intermittent (minimum of 10-minute bouts) aerobic activity. Duration is dependent on the intensity of the activity; thus lower-intensity activity should be conducted over a longer period of time (30 minutes or more).

*Mode of activity:* Any activity that uses large muscle groups, which can be maintained continuously, and is rhythmic and aerobic in nature.

#### Muscular Strength and Endurance, Body Composition, and Flexibility

*Resistance training:* One set of 8 to 10 exercises that conditions the major muscle groups 2 to 3 days per week.

*Flexibility training:* Flexibility exercises that develop and maintain range of motion should stretch the major muscle groups and be performed a minimum of 2 to 3 days per week.

Because intervention studies have demonstrated that aerobic physical activity reduces blood pressure while blood pressure-reducing effects for resistance training have not been shown, the PREMIER physical activity intervention focuses on aerobic activity. The resistance training information is provided to ensure an understanding of the entirety of current recommendations. Further, the American College of Sports Medicine (ACSM) does not recommend resistance training to lower blood pressure in individuals with hypertension when done as the only form of exercise.

The current recommendations for the necessary amount of physical activity for producing health benefits are provided in documents from the Center for Disease Control and Prevention (CDC)/ACSM and the Surgeon General's Report on Physical Activity and Health.

The CDC/ACSM recommendations state that "every US adult should accumulate 30 minutes or more of moderate-intensity physical activity on most, preferable all, days of the week." It states that health benefits can be accrued with moderate-intensity activity that expends approximately 200 kcal per day. It further states that these recommendations are intended to complement, not supersede, the exercise recommendations described above.

The Surgeon General's Report on Physical Activity and Health states that significant health benefits can be obtained by including a moderate amount of physical activity (e.g., 30 minutes of



## **PREMIER Intervention Manual of Procedures**

brisk walking or raking leaves, 15 minutes of running, or 45 minutes of playing volleyball) on most, if not all, days of the week. A moderate amount of activity is roughly equivalent to physical activity that uses approximately 150 kcal of energy per day, or 1,000 kcal per week. Additional health benefits can be gained through greater amounts of physical activity. People who can maintain a regular regimen of activity that is longer in duration or of more vigorous intensity are likely to derive greater benefit.

All of these recommendations state that activity of at least a moderate intensity is necessary to achieve benefits and that greater amounts of physical activity (i.e., higher intensity, and longer duration) will produce greater benefits. These recommendations are consistent with the knowledge derived from the observational and intervention studies evaluating the effects of physical activity and blood pressure.

### *Description of PREMIER physical activity intervention*

Participants will primarily perform physical activity outside of the PREMIER individual and group sessions, although physical activity demonstrations will occur in some group sessions. Self-monitoring, group and small-group problem-solving, skill-building, and social support are primary tools used in the intervention. The intervention starts with the participant's self-assessment of current physical activity level and aids the participant to build slowly and progressively until study goals are met. All participants are expected to engage in moderate-intensity activity. Those who are eligible and wish to participate in vigorous-intensity activity may do so.

The intervention is focused on sustained physical activity (i.e., at least 20 minutes of moderate or vigorous intensity activity). For sedentary participants, an adaptation time may be necessary to build up to this duration. Progression to the 20-minute duration is negotiated with the participant and interventionist during group and individual sessions using motivational interviewing techniques (see section #6 below). Although it is known that routine ways of being more active (e.g., taking the stairs instead of the elevator, parking further away, etc.) contribute to overall caloric expenditure, these are not the target of the physical activity intervention and are not emphasized in PREMIER. The focus of the intervention is to encourage purposeful, sustained, at least moderate-intensity physical activity. Light-intensity activity is not sufficient.

Group and individual sessions include information on how to conduct a safe and effective physical activity program and develop the behavioral skills to meet study physical activity goals. Specific information to be delivered include: target heart rate calculation, target ratings of perceived exertion, realistic expectations for physical activity, benefits of regular physical activity, proper shoes and clothing for different types of activity and weather conditions, importance of warm-up and cool-down activities, and safety issues. Specific behavioral strategies include identifying pleasurable activities, self-monitoring physical activity, time management skills, short- and long-term goal-setting, identifying barriers to physical activity, and problem-solving to develop specific strategies to deal with barriers. These strategies are discussed in section #7.

## **PREMIER Intervention Manual of Procedures**

### ***Physical Activity Monitoring and Point System***

#### *Background*

The group sessions focus on moderate-intensity activity and on self-monitoring the number of minutes of moderate-intensity activity. Participants are instructed to record the number of minutes of moderate-intensity physical activity they engage in. The concept of physical activity points is introduced during individual sessions. Each minute of moderate-intensity activity counts as one point.

In general, most participants will not be engaging in vigorous activity when they enter the PREMIER trial. During the R/I visit, the interventionist receives notification of whether the participant is currently engaging in vigorous activity. Individuals engaging in vigorous activity may count two points for each minute of vigorous activity. If a participant is not sure he/she is doing vigorous activity, chances are he/she isn't.

The point system will be used in later individual sessions to help participants who want to progress to vigorous activity after being successful in moderate-intensity activity. Participants who are not cleared for vigorous activity are told that they should stick with moderate intensity activity. One point is given for each minute of moderate-intensity activity, and two points are allowed for each minute of vigorous activity.

The point system introduced in individual sessions also allows for combining moderate and vigorous intensity activity across different days – for example moderate intensity on some days and vigorous intensity on others. Thus the points allow individual flexibility in meeting the *PREMIER* physical activity goals for those participants cleared for vigorous activity.

#### *The point system*

The participant goal is to accumulate at least 180 points per week divided into at least 3 different days. Twenty minutes duration or longer is the goal. Activity must be at least moderate; lighter activities will not count. The 20-minute duration is selected because that is the minimum duration used in randomized trials that have shown that BP is lowered by exercise. Bouts as short as 10 minutes can be counted, but should not be encouraged. The long-term goal is 180 points per week.

Any of the following examples of activity patterns meet the goal of 180 points a week. Some of the patterns are exclusively moderate intensity (180 minutes a week of moderate), some are exclusively vigorous (90 minutes a week of vigorous), and others combine moderate with vigorous. It is noted which of the national guidelines, described earlier, each of the patterns meet.

- 1) moderate-intensity 6 times a week for 30 minutes each time  
= 1 point x 6 times x 30 minutes = 180 points

## **PREMIER Intervention Manual of Procedures**

(this pattern is consistent with the ACSM-CDC and the Surgeon General's recommendations for health and with the ACSM recommendations for exercise for hypertension)

2) moderate-intensity 4 times a week for 45 minutes each time  
= 1 point x 4 times x 45 minutes = 180 points

(this pattern is also consistent with the same recommendations given above in #1)

3) vigorous-intensity 3 times a week for 30 minutes each time  
= 2 points x 3 times x 30 minutes = 180 points

(this pattern is consistent with the ACSM guidelines for cardiorespiratory endurance and is similar to what was used in several randomized trials of exercise and BP)

4) moderate-intensity 2 times a week for 30 minutes each time PLUS

vigorous-intensity 2 times a week for 30 minutes each time

= (1 x 2 x 30) + (2 x 2 x 30) = 60 + 120 = 180 points

(this type of activity pattern allows one to combine moderate and vigorous intensity during the week; this type of pattern may be especially useful for those who want some, but not too much, vigorous activity)

Participants may also use the points to establish short-term, interim, goals. The participant individualizes their goals for physical activity points by choosing a number of points per week as their personal short-term goal. The following are some examples of activity patterns that could be short-term goals:

1) 30 points per week = moderate-intensity 3 times a week for 10 minutes

2) 50 points per week = moderate-intensity 5 times a week for 10 minutes

3) 60 points per week = moderate-intensity 3 times a week for 10 minutes PLUS  
vigorous-intensity 3 times a week for 5 minutes

The number of minutes of moderate and vigorous activity each day are recorded on the Physical Activity Monitoring Log, converted to points, and summed to obtain the number of points for the week.

### ***Moderate and Vigorous Intensity Aerobic Activity***

#### *Definition of aerobic activity*

Aerobic physical activity, or activity "with oxygen," is that in which exercising muscles receive an adequate amount of oxygen to produce energy using oxidative pathways. Aerobic activity can continue for extended periods of time without fatigue. Physical activities that are continuous, rhythmic, use large muscle groups, and can be maintained over time are considered aerobic. Examples include walking, running, and bicycling. When muscles work at a level that is greater than can be sustained by the supply of oxygen that is delivered to them, waste products, such as lactic acid, accumulate in the muscles and fatigue results. This type of physical activity is called

## **PREMIER Intervention Manual of Procedures**

"anaerobic." Anaerobic activity is usually characterized by short, intense bouts of activity. Examples of anaerobic activity are running sprints and lifting weights.

The ability of an individual to exercise continuously depends on how effectively the heart, lungs, arteries, capillaries, cells, and veins can transfer oxygen, carbon dioxide, nutrients, and waste products to and from the exercising muscles. As an individual begins physical activity, the body adapts to the increased demand for energy. Energy stores of glycogen are mobilized from the muscles to provide an immediate source of fuel necessary, while at the same time, heart rate and respiration increase to provide more oxygen to the muscles so the activity can be sustained.

### *Moderate intensity activity*

Moderate intensity physical activity is defined as activity that demands 40% to 60% of maximal aerobic power, which is equivalent to 50% - 69% of maximal heart rate (see section #4, below). This corresponds to a rating of perceived exertion of 11 to 13 (see section 5). Activities requiring energy expenditure 3 to 6 times that expended at rest (i.e., 3 - 6 METs, or metabolic equivalents) is an objective determination of moderate-intensity activity. Brisk walking is a common activity that operationalizes this definition for most people. Brisk walking has been defined as walking a 3 to 4 mph for most healthy adults (i.e., 15 to 20 minutes per mile). However, for elderly people or those who have poor cardiorespiratory fitness, walking at this speed may exceed moderate intensity. Conversely, for young people who are highly fit, walking at this speed may be a light intensity activity. Therefore, the actual speed for "brisk walking" will vary depending on the individual. Nonetheless, for most individuals and potential participants of PREMIER, brisk walking is likely to be a good marker for moderate intensity physical activity.

Examples of moderate intensity activity that expend 3 to 6 METs are:

- brisk walking
- hiking
- moderate bicycle riding
- swimming laps, slow to moderate pace
- dancing (e.g., "fast" dancing, square dancing, swing dancing)
- shooting baskets
- golf (walking, pulling or carrying clubs)
- ice-skating, roller-blading
- volleyball
- softball
- badminton
- racquetball

### *Vigorous intensity activity*

Vigorous or hard intensity activity is that which demands 60% to 84% of aerobic power. This is equivalent of 70% to 89% of maximal heart rate, and corresponds to rating of perceived exertion in the range between 14 and 17. Activities that expend more than 6 times the energy expended at rest (i.e., > 6 METs) provide an objective measure of vigorous activity. It can be operationalized

## **PREMIER Intervention Manual of Procedures**

by activity that is about as intense as jogging or running. Performing vigorous activity will yield the greatest improvements in cardiorespiratory fitness, although it is also associated with a greater risk of overuse injuries (e.g., musculoskeletal strains and sprains). Vigorous activity results in large increases in heart rate and breathing, and is usually associated with sweating.

Examples of vigorous intensity activity that expend greater than 6 METs are:

- jogging or running
- fast bicycle riding
- swimming laps, fast pace
- cross-country skiing
- high-impact or fast aerobic dancing
- soccer
- ice or field hockey
- basketball

Light-intensity activities, or those that expend less than 3 times resting energy expenditure (i.e., < 3 METs), are not a sufficient stimulus for lowering blood pressure. Therefore, activities such as shopping, walking at a stroll, light household activities (e.g., dusting, picking up around the house), and light gardening are not part of the PREMIER physical activity intervention.

The PREMIER recommendations can be easily incorporated into one's daily life. Following are some examples:

- When walking, pick up the pace from leisurely to brisk. Choose a hilly route.
- Walk or bike to the store instead of driving.
- Walk the dog (brisk walk).
- Go out for a walk before breakfast or after dinner (brisk walk).
- Brainstorm ideas with a co-worker while going for a walk (brisk walk).
- Catch up with a friend by meeting for an exercise date.
- Walk in the airport while waiting for a plane (brisk walk).
- Stay at hotels that have fitness centers or swimming pools while on trips, and use the facilities.
- Walk, run, or cycle through a new town to sightsee.
- Join a recreation league at your company or in your community.
- Join (and use) a fitness center near your home or work.
- Schedule exercise time on the calendar and make it as important as any other appointment.
- Exercise during lunch break at work.
- Exercise after work before going home.
- Exercise before work.
- Plan family outings and vacations that include physical activity (hiking, backpacking, swimming, etc.)
- Go out dancing -- or take dancing lessons.

## **PREMIER Intervention Manual of Procedures**

### ***Determining Target Heart Rate***

#### *Estimation of maximal heart rate*

Maximal heart rate is measured during a maximal exercise and is defined as the heart rate reached when further increases in exercise workload do not produce accompanying heart rate increases. For the purposes of PREMIER, maximal heart rate will not be measured, it will be estimated. Maximal heart rate can be estimated using the following equation:

$$220 - \text{Age} = \text{Estimated Maximal Heart Rate}$$

This method has a variability of about 10%, or about plus or minus 10 to 12 beats per minute. Older individuals (greater than 65 years of age) may have significantly greater maximal heart rates than that predicted by the formulas. So, calculating heart rate ranges for moderate or vigorous activity is a guide for an individual's level of exertion rather than a precise measure.

Example: How to determine estimated maximal heart rate and target heart rate range for moderate and vigorous intensity activity.

To calculate heart rate for a 60-year old female PREMIER participant:

$$220 - \text{Age} = \text{Estimated Maximal Heart Rate} = 220 - 60 = 160 \text{ beats/min}$$

Moderate intensity activity at 50% to 69% of maximal heart rate =

$$160 * 0.5 = 80 \text{ beats/min to } 160 * 0.69 = 110 \text{ beats/min}$$

This woman's target heart rate for moderate intensity is between 80 and 110 beats/min

To calculate vigorous intensity activity for a 35-year old male PREMIER participant:

$$220 - \text{Age} = \text{Estimated Maximal Heart Rate} = 220 - 35 = 185 \text{ beats/min}$$

Vigorous intensity activity at 70% to 89% of maximal heart rate =

$$185 * 0.7 = 130 \text{ beats/min to } 185 * 0.89 = 165 \text{ beats/min}$$

This man's target heart rate for vigorous intensity is between 130 and 165 beats/min

#### *How to count pulse rate*

Heart rate can be measured indirectly by placing the fingertips on a pulse site and counting for a period of time. This is termed "palpation.". Sites in which the pulse can be measured accurately are at the radial pulse on the wrist (on the thumb side) and the carotid artery on the side of the larynx (on the neck next to the "adam's apple").

To measure pulse rate at the wrist, the radial artery is located at the inner wrist in line with the base of the thumb just inside the bony notch on the thumb side of the wrist. The tips of the other hand's index and middle fingers are then placed over the artery and light pressure is applied until the pulse is felt. The thumb is not used to palpate because the thumb has its own pulse. To measure pulse at the larynx, the carotid artery is palpated, which is located on either side of the

## **PREMIER Intervention Manual of Procedures**

larynx towards the throat. Heavy pressure should not be applied to the carotid arteries because baroreceptors are located in that region that can sense the pressure that is applied and will respond by slowing the heart rate. Both carotid arteries should never be pressed at the same time, as this can cause fainting. The pulse is counted for 15 seconds, counting the first pulse beat as zero at the start of the 15-second period. Multiplying the 15-second pulse count by 4 yields pulse rate in beats per minute.

### ***Determining Ratings of Perceived Exertion***

#### ***Background***

In addition to heart rate, physical activity intensity can be measured by assigning a numerical value to the subjective feelings of physical activity exertion. The Ratings of Perceived Exertion (RPE) Scale was developed by Dr. Gunner Borg and is sometimes called the Borg Scale. The scale takes into account overall exertion, including psychological, musculoskeletal, and environmental factors. Extensive research shows that the RPE correlates well with cardiorespiratory and metabolic factors such as heart rate, breathing rate, oxygen uptake, and overall fatigue. Numerous clinical studies have demonstrated that the RPE scale is a reproducible measure of exertion within a wide range of individuals regardless of age, gender, or cultural origin.

The advantage of using RPE scales to estimate level of exertion is that it doesn't rely on the skills of palpation and counting pulse. In general, heart rate approximates  $RPE * 10 + 10-20$  beats/min for RPEs between 11 and 16. In most cases, physical activity at a level of 11 to 13 RPEs is associated with moderate intensity physical activity. Physical activity in which RPE is between 14 and 17 is generally considered vigorous activity. RPE level above 17 is near maximal effort, and RPE level below 11 is light-intensity physical activity.

Standard instructions for administering the RPE are: "We want you to pay close attention to how hard you feel the work rate is. This feeling should be your total amount of exertion and fatigue, combining all sensations and feelings of physical stress, effort, and fatigue. Don't concern yourself with any one factor such as leg pain, shortness of breath or exercise intensity, but try to concentrate on your total, inner feeling of exertion. Don't underestimate or overestimate, just be as accurate as you can."

#### ***Scale***

##### **Ratings of Perceived Exertion Scale**

6	
7	Very, very light
8	
9	Very light
10	
11	Fairly light

## **PREMIER Intervention Manual of Procedures**

12	
13	Somewhat hard
14	
15	Hard
16	
17	Very hard
18	
19	Very, very hard
20	

### ***Physical Activity Initiation and Progression***

The initiation and progression of physical activity will differ by individual. Each participant should be encouraged to start where they are. If they are currently not meeting the *PREMIER* physical activity goals, they should be taught to progress at their own pace until they do meet the goals.

Participants can be thought of as falling roughly into several general categories based on their initial physical activity levels:

- (1) sedentary – engaging in no moderate-to-vigorous activity (the office worker who goes home and watches TV all evening is an example)
- (2) irregularly active – engaging in some moderate, or some vigorous, activity (or some of both), but only sporadically (the occasional weekend golfer or tennis player is an example)
- (3) regularly moderately active – engaging in moderate-intensity activity for sustained durations (20-30 minutes) on most days of the week (the person who takes a daily brisk walk is an example).
- (4) regularly vigorously active – engaging in regular vigorous activity (the person who runs 3 times a week is an example)

Most *PREMIER* participants will be in the first two categories and will need to work up gradually to the *PREMIER* physical activity goals.

It is very important to clarify that the activity has to be AT LEAST of moderate intensity. Light activities do not count. For example, doing housework or walking slowly while shopping do not count. Nor do short duration activities built into the day, like taking the stairs instead of the elevator. During group sessions, participants will be taught to take their pulse. They will be taught to take their pulse during activity (or pause for 15 seconds to take the pulse) to determine if it is in the moderate-intensity range (see section #4 on target heart rates). Participants also can identify intensity through use of the ratings of perceived exertion scale (see section #5).

Participants will set their own short-term goals. Selection of short-term goals will allow for gradual implementation of physical activity in participants who are sedentary and unfit. This will help prevent injuries, gradually increase fitness, and allow for positive reinforcement to increase self-efficacy.



## **PREMIER Intervention Manual of Procedures**

### *Sedentary participants*

A sedentary participant may set a personal goal of walking briskly 5 minutes a day for three days a week. If he/she actually does the three 5-minute walks, then the participant meets her/his own short-term goal, should be reinforced for a job well done, and should then be encouraged to increase the duration for the next week. This process can continue until the minimum duration of 20 minutes is reached. Once 20-minutes is accomplished, the participant should be encouraged to maintain that duration. Frequency would be the next goal. For example, a participant chooses 3 days a week as his/her initial frequency then increases the number of days from 3 to 4, then to 5, then to 6. The increases in duration and frequency should occur over a period of several weeks or months.

### *Irregularly active participants*

Participants who are in the second category, irregularly active, should be encouraged to make activity a regular part of their lives. Often these people are motivated, but have barriers to engaging in activity, such as perceived lack of time. They should be encouraged to add activity to currently inactive days in order to reach the *PREMIER* goal.

### *Regularly active participants*

Participants who are already regularly active at a moderate or vigorous intensity (third and fourth categories, above) should be encouraged to continue their activity level. The goal for these participants is maintenance of this level of activity.

### *Progression from moderate to vigorous activity*

Some individuals who are currently engaging in regular moderate-intensity activity, or have progressed to this stage over several months of intervention, may wish to increase their intensity to vigorous. This increase may be desired for several reasons, which include: they would like to decrease the time needed for physical activity, they have had past experience with certain vigorous activities and wish to try those again, they just don't feel like they're "exercising" when participating in moderate intensity activities, or they feel better after exercising vigorously.

Participants will be allowed to progress to vigorous activity only if they are eligible to do so. Each participant is evaluated for eligibility for vigorous activity by the coordinating center at baseline and 6 months, and this information is conveyed to the interventionist. In the individual sessions, the interventionist informs the participant regarding their eligibility for vigorous activity.

To be eligible for vigorous activity, a participant must:

- (1) be currently regularly vigorously active, defined as 20 minutes or more of vigorous activity 2 days a week, or

## **PREMIER Intervention Manual of Procedures**

- (2) be under age 50 for women, or under age 40 for men, with fewer than 2 risk factors for coronary artery disease, or
- (3) have obtained approval from their personal physician and provide documentation of a negative exercise stress test within the past 6 months.

When progressing from moderate to vigorous activity, the recommendation is to begin by adding short durations of vigorous activity. For example, a person who has been walking and wants to begin running would be advised to intersperse a couple of minutes of running into the regular brisk walk. The individual might walk for 10 minutes, then jog for two, then walk for another 10 minutes, then jog for two, etc. (Some people call this “wogging”.) As the participant becomes fit, he/she can increase the duration of the jogging and decrease the duration of the walking.

Participants also have the option of mixing up moderate and vigorous intensity activity. For example, a participant may choose to run for 20 minutes twice a week (vigorous activity), play doubles tennis on the weekend (moderate activity), and swim at a moderate pace during the week (moderate pace).

### ***Warm-up, Cool-down, and Flexibility Exercises***

Warm-up, cool-down, and flexibility exercises are part of a well-rounded physical activity program. They are beneficial when performed in conjunction with moderate intensity activity, and are critical for vigorous activity.

#### *Warm-up exercises*

The purpose of warm-up exercises is to gradually increase heart rate, blood pressure, oxygen uptake, dilation of the blood vessels, and elasticity of the active muscles. By gradually increasing metabolic requirements and temperature of the muscles, it will reduce the likelihood of muscle injury, prevent the premature onset of blood lactic acid accumulation, and reduce the potential for myocardial ischemia. The warm-up phase includes a low-level (light) aerobic component followed by light stretching of the muscle groups that will be used during exercise.

#### *Cool-down exercises*

The purpose of cool-down exercises is to slowly decrease cardiac work and overall metabolism that have been elevated during aerobic physical activity. It helps prevent sudden pooling of blood in the veins and ensures adequate circulation to the skeletal muscles, heart, and the brain. It also helps to prevent delayed muscle stiffness and reduces any tendency towards post-exercise dizziness or fainting.

#### *Flexibility exercises*

The purpose of flexibility exercises is to increase and maintain the ability of a joint to move through a full and normal range of motion. Optimal joint flexibility minimizes risk of injury, reduces muscular soreness, and improves muscular balance. Static stretching, or a slow, gradual,

## **PREMIER Intervention Manual of Procedures**

and controlled elongation through a full range of motion, increases flexibility and has a low likelihood of causing injury. It requires slowly stretching a muscle to the point of mild discomfort and holding the position for 10 to 30 seconds.

Flexibility exercises should only be performed on muscles that have been warmed up. Easy stretching exercises performed prior to aerobic activity will help prevent muscular injury. Stretching exercises performed after the aerobic activity will ensure muscle relaxation, facilitate normal resting muscle length, and help to remove metabolic waste products.

Specific warm-up, cool-down, and flexibility exercises are illustrated in the Leader's Guide.

### ***Exercise Adherence***

Participant expectations about increasing their physical activity level must be realistic to avoid disappointment. If a participant is expecting a result from increased physical activity that is not likely to occur (or be noticed by the participant), they may give up trying to be physically active. Many of the benefits from the type of physical activity promoted in PREMIER occur over time and will not be noticeable early on as a person starts to increase physical activity. The benefits that may occur early on include: increased sense of well being after physical activity, feelings of accomplishment for reaching goals, and reduced feelings of stress. Health benefits, such as reduction in blood pressure and improvements in blood cholesterol take longer to accrue. Weight loss resulting from increased physical activity, without reducing daily caloric intake, is minimal. Over time, muscles will firm up from exercise, and if a participant includes stretching in their regular routine, he/she may discern an increase in flexibility and range of motion.

Participants may also expect some discomfort from exercise -- they may have sore muscles early on as they initiate physical activity, increase duration, frequency, or intensity of a given activity, or add a new activity to their physical activity repertoire. If this information is provided to the participant up front, it is less likely to cause concern.

Sedentary participants should not expect to accomplish the PREMIER goals immediately. They will have to work up to the duration of activity a little at a time over several weeks or months. The intervention is designed for participants to slowly start to increase their activity level if they are currently sedentary, so expectations such as completing a marathon or participating in a long-distance bicycle ride as a result of the PREMIER intervention are likely to be unrealistic for most participants. Communicating this to the participant can alleviate misconceptions about the type of activity the intervention is promoting.

### ***Self-monitoring, goal-setting, intrinsic/extrinsic reward systems***

In addition to monitoring and goal-setting specific to physical activity points, participants can monitor and set goals for a variety of other physical activity-related processes. For example, achieved target heart rate during physical activity, feelings after completing a physical activity session (e.g., relaxation, sense of accomplishment), different places in which activity is performed, documentation of new social networks developed, and developing skills and

## PREMIER Intervention Manual of Procedures

proficiencies for new physical activities are alternative physical activity goals that can be self-monitored.

### *Enjoyment of activity*

It is well established that individuals are more likely to continue activities that they enjoy. Many individuals may wish to identify a variety of activities they enjoy to reduce boredom. Although most PREMIER participants are likely to obtain their physical activity points from brisk walking, interventionists should encourage experimentation in a wide variety of activities.

### *Identifying and overcoming barriers*

Common barriers associated with physical inactivity and specific strategies to avoid these barriers are listed below:

<b>Barriers</b>	<b>Strategies</b>
time constraints	make physical activity a priority develop effective time management skills schedule specific time for exercise (i.e., appointment for activity) combine physical activity with other activities (e.g., socializing)
boredom	engage in a variety of physical activities alter location in which physical activity is performed learn a new skill be active with others to make it social combine with other activities (reading, music, TV, etc.)
travel	plan ahead to ensure hotels are equipped with health clubs or are in locations suitable for outdoor activity use layover time at airports to do brisk walking schedule vacations that provide opportunities for physical activity

## **PREMIER Intervention Manual of Procedures**

being too tired	schedule physical activity during times when energy level is high remember that post-exercise, most people feel refreshed even if they feel "too tired" to start engage in a fun activity
inconvenience	plan physical activity during work breaks do physical activity in home surroundings
weather	invest in cold weather exercise gear find an indoor place to exercise, like walking in a mall do physical activity in the home join an exercise class in the community
perceived lack of coordination	do physical activities that do not require coordination take a class to improve skill

### *Environmental prompts*

A variety of prompts at work and home helps remind participants to think about physical activity throughout their day. These can include scheduling physical activity in daily appointment books, laying out exercise gear the night before so it's ready for the morning workout, keeping an extra pair of walking shoes in the car or at the office, putting pictures of people exercising around the house, changing driving routes in order to pass by places to exercise (i.e., local parks, swimming pools, school tracks), putting on exercise clothes in the morning or after work and not changing clothes until after exercise.

### *Social support*

A strong predictor of adherence to physical activity programs is support from others. This can be achieved with buddy systems that can be developed with PREMIER participants as well as from friends and family of the participants. Support people can exercise with participants, remind them to exercise, discuss progress and goals, and give rewards when goals are met, or take over other activities to provide time for exercise (e.g., watching the children, fixing dinner). Someone who has been able to maintain a physical activity program can serve as a mentor and provide real-world strategies that have worked for them in the past that may be particularly salient for participants.

### *Relapse prevention strategies*

It is inevitable that participants will have periods of time in which they are unable to be physically active. How slips are handled determine if they will be temporary or permanent. When these can be anticipated and seen as being temporary rather than a breakdown in the success of the program, adherence is more likely to be maintained.

## **PREMIER Intervention Manual of Procedures**

Participants can be made aware of the defeatist attitude that accompanies the erroneous belief that once an exercise program is disrupted, total relapse or quitting is inevitable. In fact, many people relapse numerous times before physical activity becomes part of their routine. If physical activity is viewed as a process in which there will undoubtedly be times of less activity than other times, then participants will be less likely to consider themselves failures when they have to skip a session or two. Awareness of "high-risk" situations that decrease the likelihood of being active and pre-planning how to deal with these situations is an approach to relapse prevention.

### ***Safety Considerations in Adopting and Maintaining a Physical Activity Regimen***

#### *General issues*

A primary goal of the PREMIER intervention is to encourage bouts of at least moderate intensity physical activity that gradually increase in duration and/or frequency over time. Much of the success of this programmed approach lies in the participant's relatively comfortable, injury free progression to more time spent in physically active pursuits. Before implementing a routine of regular physical activity a number of basic safety issues should be considered.

1. Elements of a physical activity bout

Attention should be paid to appropriate warm-up, main bout, and cool-down components of a physical activity session. See section #7.

2. Clothing requirements

In general, clothing worn should be loose fitting and permit adequate flow of air over the body to assist cooling. For outdoor activities, bright colors and reflective materials are recommended. In warm weather, light colors that reflect solar heat are preferred. In cold weather, layers that can be taken off if necessary are best. For walking or running activities, appropriate shoes are required. These should be designed specifically for walking or running, be adequately cushioned, provide foot and ankle support, and not restrict the forefoot (toes should be unrestricted). The best way to get a proper fit for athletic footwear is to go to a reputable store that specializes in athletic shoes.

3. Nutritional and hydration status

Participants should be adequately nourished and take appropriate liquids, especially water, liberally in conjunction with physical activity. In warm or hot weather, carrying a water bottle is recommended. If uncomfortably full from a meal, a participant may wish to wait for 30 minutes to an hour before performing moderate physical activity. Only light meals should be eaten prior to vigorous physical activity.

4. Disease status

Participants should not engage in physical activity when running a significant fever, have musculo-skeletal pain, or other acute disease processes. It is fine to participate in physical activity if a participant has a mild upper respiratory tract infection, if the participant wishes to do so. Use of pain relievers or other medications should be from the approved PREMIER list or cleared by the clinical center beforehand.

## **PREMIER Intervention Manual of Procedures**

### *Special Issues*

#### Heat

Physical activity during the warmer months should be conducted during the cooler morning, evening hours, or indoors, whenever possible. Light-colored, lightweight clothing should be worn. If needed, short rest breaks during the activity are appropriate. Drinking as much water as comfortable (at least 2 cups) 15 to 20 minutes before exercise, a cup of water every 15 minutes during physical activity and more than thirst dictates after exercise will help to avoid dehydration. Water is the best replacement fluid unless the physical activity bouts exceed 60 minutes. If a participant weighs him/herself before and after exercise, every pound lost during physical activity should be replaced with 16 ounces of water. Physical activity should be discontinued if dizziness, lightheadedness, chills, piloerection, or nausea (i.e., signs of heat illness) occur.

#### Cold

During cold weather it is best to layer clothing. If physical activity is to be done in sub-freezing conditions, care should be taken to protect the face, hands, or other normally exposed areas of the body.

#### Darkness

For physical activity out of doors reflective clothing and battery operated lighting are recommended.

### *Injuries*

Muscle strains, pulls, or related complaints may occasionally occur. These typically are of minor significance and resolve by themselves in a few days. If a participant experiences such discomfort, physical activity should be discontinued until the condition has improved. Cuts, blistering, or bruising should be treated with appropriate padding or changes in clothing/shoes. Any condition that does not improve within 2-3 days should be referred to a physician. More serious injuries to the muscles or skeleton require physician attention. Immediate treatment involves the principles of RICE:

- Rest - Limit the use of an injured muscle or joint. Do not place weight on an injured joint. Use crutches with physician approval.
- Ice - Apply ice wrapped in a towel, especially for the first 24-48 hours. Avoid hot water baths or heat applications in the first few hours after injury as these encourage swelling.
- Compression - Use an ace wrap to help reduce swelling. Do not apply too tightly to an upper limb to avoid distal swelling. Knee immobilizers are discouraged except for comfort.
- Elevation (for leg injuries) - Elevate the leg higher than your heart to decrease pain and swelling.

As always, when in any doubt, the participant should be counseled to consult a physician.

## PREMIER Intervention Manual of Procedures

<b>38. SELF-MONITORING</b>	<b>3</b>
<b>Purpose</b> _____	<b>3</b>
<b>Materials</b> _____	<b>3</b>
Food and Fitness Diary _____	3
Food and Fitness Guide _____	4
<b>Implementation</b> _____	<b>4</b>
Monitoring Schedule _____	4
Self-Monitoring _____	5
Collecting Self-Monitoring Tools _____	5
Reviewing Self-Monitoring Tools _____	6
Participants Who Have Difficulty Self-Monitoring _____	6
Alternative Monitoring Tools _____	7
Participants Who Do Not Self-Monitor _____	8



**PREMIER Intervention Manual of Procedures**

**Summary of Edits**

## **PREMIER Intervention Manual of Procedures**

### **38. Self-Monitoring**

#### *Purpose*

Self-monitoring provides participants with feedback concerning:

- Calories (average number of calories consumed per day)
- Sodium (average milligrams of sodium consumed per day)
- Physical activity points (average total points acquired per week)
- Fat grams (average grams of fat consumed per day (PREMIER C only))
- Fruit, vegetable and dairy foods (average servings of consumed per day (PREMIER C only))

The aims of self-monitoring are to:

- Increase the participant's awareness of their food intake
- Provide feedback (and potentially positive reinforcement) to assist the participant in meeting the study goals
- For PREMIER B, help the participants make healthy foods choices while decreasing their calories and sodium
- For PREMIER C, help the participants make healthy food choices while decreasing their calories, fat, and sodium and increasing their servings of fruits, vegetables and low-fat dairy foods
- For both arms, increase the participants awareness of the amount and kind of physical activity they do
- Provide the interventionist with information about the participant's dietary and physical activity habits
- Provide a method for monitoring change

#### *Materials*

Self-monitoring materials include the Food and Fitness Diary and the Food and Fitness Guide.

#### *Food and Fitness Diary*

The diary used by PREMIER B contains a space to record seven days of food records and enter the nutrient values for calories, and milligrams of sodium. The diary used by PREMIER C also allows for seven days of food records, caloric values, and milligrams of sodium but, in addition, allows for recording grams of fat, servings of fruits and vegetables, and servings of dairy foods. Both versions contain an area to record daily physical activity points. The back page of the diaries allows participants to transfer daily information to calculate weekly averages for calories, grams of fat per day, average milligrams of sodium per day, average servings of vegetables, fruits and dairy foods, and total physical activity points when appropriate for their intervention arm. The Food and Fitness Diaries also include a space to record a weekly goal and action plan.

## **PREMIER Intervention Manual of Procedures**

Participants who elect to use a computerized program for recording daily food and activity, will be allowed to use their computerized nutrient database to keep a food diary and record physical activity. However, they must transfer weekly averages of the information from their computer to the Food and Fitness Diary Weekly Summary page. PREMIER will not collect information directly from computerized databases.

The participants are asked to record their calculations in whole numbers and not fractions using the following rounding rules: round up to the next whole number when the fraction/decimal is greater than 0.5 and round down the next whole number when the fraction/decimal is less than 0.5.

### *Food and Fitness Guide*

There are two versions of The Food and Fitness Guide, one for PREMIER B and one for PREMIER C. Both versions contain over 1,500 foods that are listed in food categories, but also indexed by individual foods in the back of the guide. Calories, sodium and fat gram values provided are from the Minnesota Nutrient Data System (NDS; University of Minnesota, 1992).

### ***Implementation***

#### *Monitoring Schedule*

All participants begin recording everything they eat and drink at the R/I visit. They are also expected to determine and record the caloric value of everything they eat and drink beginning at the R/I visit. Participants are encouraged to keep records for as many days as possible, with a minimum of three days each week for the duration of Phase I. Participants also begin recording their daily physical activity at the R/I visit.

The PREMIER B group begins to count milligrams of sodium at group session 3 (see Table 1 below).

The PREMIER C group begins to count calories, servings of fruits, vegetables and dairy foods at the R/I session, grams of fat at group session 1, and milligrams of sodium at group Session 3 (see Table 2 below).

## PREMIER Intervention Manual of Procedures

Table 1. PREMIER B Timetable for Introducing Self-Monitoring

	R/I	G1	G2	G3	G4
Food	X	X	X	X	X
Phy Act	X	X	X	X	X
Calories	X	X	X	X	X
Sodium				X	X

Table 2. PREMIER C Timetable for Introducing Self-Monitoring

	R/I	G1	G2	G3	G4
Food	X	X	X	X	X
Phy Act	X	X	X	X	X
Fruit, Veg, Dairy	X	X	X	X	X
Calories	X	X	X	X	X
Fat		X	X	X	X
Sodium				X	X

### *Self-Monitoring*

#### Guidelines:

- Use one form per day and make sure to fill in the day and date on the top of the form.
- Monitor food intake and physical activity for at least three days each week, preferably daily. At least one day should be a weekend day.
- Record one activity or food item per line.
- For each physical activity indicate the duration and the intensity, moderate (M) or vigorous (V).
- Be sure to record **all** food and beverages consumed. Do not forget to record condiments (e.g., mustard, ketchup, mayonnaise), salad dressings, sugar, creamer, candy, added margarine, and other extras.
- For each recorded food, indicate the amount actually eaten. Strive for accuracy in terms of serving sizes by using measuring cups, spoons or scales when unsure. See the Food and Fitness Guide for assistance in determining serving sizes.
- When recording prepared foods, indicate how the food item was prepared, e.g., fried, sautéed, steamed, baked, broiled.

### *Collecting Self-Monitoring Tools*

## **PREMIER Intervention Manual of Procedures**

The interventionist and/or intervention staff member collects the Food and Fitness Diaries during each session and records the intervention data on the Intervention Data Collection Form (Form #42, #43, or #44) for the specific study arm. If more than three days of monitoring are completed, the interventionist records the first three days of the designated recording period.

If the participant does not bring the Food and Fitness Diary to the session, the Data Collection Form is left blank and the participant is asked to complete the food diary and either mail the diary or bring to the next group session. If the participant completes the self-monitoring tools after the session, the interventionist goes back and records the information on the data sheet for that session. (See Intervention Data Collection Form for details). If the participant fails to turn in monitoring data by the next intervention session, the data are coded as N/A and the participant is asked to resume keeping three days of monitoring data for the next recording period.

### *Reviewing Self-Monitoring Tools*

The interventionist performs a cursory review of each Food and Fitness Diary during group sessions one through three. The purpose of this review is to look for participant misunderstanding. It is not expected that each food item, activity and calculation be checked carefully and corrected. Only look for gross errors (e.g. large errors in estimating caloric values, gross math errors) and misunderstandings (e.g., foods listed represent a significant departure from the program diet, participant has obviously misinterpreted how to compute activity points). If the interventionist identifies problems with the Food and Fitness Diary, he/she should review this with the participant as soon as possible in person or by telephone.

The interventionist should also perform a cursory review of the Food and Fitness Diaries in group sessions held a week prior to each individual session in Phase I and Phase II. Participants should be given feedback on their Food and Fitness Diaries at individual sessions.

If an interventionist discovers a significant error (e.g., off by several hundred calories) in a participant's calculations, he/she should correct and record the score on the Intervention Data Collection form and review the problem with the participant.

### *Participants Who Have Difficulty Self-Monitoring*

Some individuals take longer than others to acquire the habit of self-monitoring. Interventionist should reinforce attempts at self-monitoring even if they fall short of desired performance. Remember that simply recording food intake or occurrence of exercise can result in behavior change. Reasons for failure to monitor will vary, but may include math/literacy problems, inexperience keeping detailed records, fatigue, boredom, guilt, lack of perceived benefit, inability to make the self-monitoring part of their daily routine, lack of time, etc. The goal is to support the participant as much as possible in continuing to monitor their food and physical activity habits. The interventionist spends extra time with these participants to help motivate and encourage the participant to do the self-monitoring. Some techniques that can be used are:

## **PREMIER Intervention Manual of Procedures**

- Give written feedback on the tools. Write positive notes of encouragement.
- Explain that self-monitoring tools can insure success. Participants who record what they eat and the physical activity they do are more likely to lose weight, and meet the study goals. Previous research has shown that participants who record what they eat are more successful, particularly in weight loss.
- Point out that a self-monitoring tool can help the participant budget their calories, fat, servings of fruits, vegetables, and dairy foods, etc. When we record what we eat it is easier to plan a favorite food that is not necessarily low in fat and sodium. The food record can also help the participant identify how to add the foods the study asks to their diet, such as the fruits, vegetables and dairy foods.
- Use the metaphor with participants that the self-monitoring tool is like keeping a check book or family budget.
- Show the participant the math. Take them through a practice day to make sure the process is clear to them.
- Check food record keeping frequently in the group sessions. Help the group problem solve situations that are difficult to record. Ask the group for ideas.
- Show the participants how to save time recording by using abbreviations. Examples are:  
R = recipe  
L = label  
LF = low fat  
Cal = calorie  
W or w/o = with or without
- Ask how the self-monitoring is going frequently at the groups and ask the participants to identify techniques they use to help them record their food and physical activity habits.
- Send the participants a blank Food and Fitness Diary with a stamped, pre-addressed envelope when they miss a session to make returning the food diaries easier.
- When a participant falls short in one area, ask them to monitor a specific behavior.
- When a participant struggles, try to reduce their guilt. Because they haven't been able to keep up doesn't mean they are failing. Assess the barriers to recording.
- Review the data frequently with the participants to point out their progress.
- Have participant's record in their calendars the days they will keep records.
- When participants struggle suggest they record for one or two days, instead of three. Some information is better than no information.
- Ask the participants frequently in both group and individual sessions to discuss what they perceive are the benefits of self-monitoring.
- Use motivational interviewing techniques to discuss self-monitoring. What is working and what makes self-monitoring difficult?

### *Alternative Monitoring Tools*

If after three months, a participant is unwilling or unable to use the Food and Fitness Diary to self monitor, then offer an alternative monitoring tool. Alternative tools are best introduced when participants:

## **PREMIER Intervention Manual of Procedures**

- Have stopped self-monitoring all together. Some participants may respond more favorably to restarting if given the option to use a new tool.
- Insist they are bored with the current tool.
- Request self-monitoring tools that take less time.
- Ask for a more portable tool.
- Appear to have extreme difficulty with math calculations.

*Examples of alternative tools include:*

**PREMIER Quick Scan.** This food checklist allows respondents to indicate whether they have eaten from a list of common foods during a three-day period. From their responses an estimate of their food and beverage intake is determined. This checklist can also be adapted for the recall of physical activity.

**WIN Star System.** A weekly food and physical activity record containing pictorial categories (i.e., pictures of fruits and vegetables, dairy products, an individual in the act of running.) Respondents indicate their daily consumption of foods and beverages within categories by checking off stars, which represent servings. Physical activity is noted by checking off pictures of runners.

### *Participants Who Do Not Self-Monitor*

There will be participants who choose not to self-monitor. Continue to record their weight and attendance on the Intervention Data Collection form. Continue to work with the participant to try to encourage and motivate them to record what they eat and their physical activity.

**PREMIER Intervention Manual of Procedures**

<b>39. MASKING &amp; BLINDING</b>	<b>3</b>
<b>Intervention materials and binders</b> _____	<b>3</b>
<b>Intervention tote-bag</b> _____	<b>3</b>
<b>Clinical measurement visits</b> _____	<b>4</b>
<b>Scheduling interventionists</b> _____	<b>4</b>
<b>Scheduling of intervention sessions</b> _____	<b>4</b>



**PREMIER Intervention Manual of Procedures**

**Summary of Edits**

## **PREMIER Intervention Manual of Procedures**

### **39. Masking & Blinding**

Certain PREMIER staff members must be kept blind to participants' treatment assignment. The blinded staff include the data collectors who measure blood pressure, assess fitness and physical activity levels. The clinic coordinator, data entry staff and the interventionists are not blinded to treatment status, though they are blinded to outcome measures (BP). It is strongly recommended that each site maintain a record of the blinding status for all staff, update this record as needed and make all staff aware of the purpose of blinding, what information is being blinded and who are blinded.

At the Randomization visit, Premier participants learn their treatment assignment from one of the interventionists or designated unblinded staff members. This assignment should not be revealed to staff members involved in follow-up data collection. In addition, all intervention staff will be kept blinded to participants' blood pressure data. Participants are told their baseline blood pressure measurements and also receive a summary of their six-month blood pressure measurements when data are available. Provision of such information is appropriate in view of the fact that many participants have stage 1 hypertension. No further blood pressure information will be provided until the end of the study. At the conclusion of intervention, participants receive a complete set of blood pressure results along with a summary of their laboratory measurements. At the end of the trial, participants are informed about the overall findings. This may occur in the context of an individual interview, group meeting, or mailing.

During the intervention period, there are several possible ways that may cause staff to be inadvertently unblinded about participants' treatment assignment. The purpose of this chapter is to describe these possibilities and explain actions each site should take to avoid unblinding any staff member.

#### ***Intervention materials and binders***

At the beginning of intervention, each active treatment group participant will receive a color-coded binder containing appropriate color-coded materials. The color-coding system will be shared between the coordinating center, unblinded staff members and the interventionists only. The blinded clinical staff will not know which color is associated with which intervention arm. The color-coding system assures the accuracy and minimizes potential errors in the processes of printing, sorting and delivery of intervention materials and binders.

When the coordinating center mails the color-coded binders and materials to the clinical sites, it should be addressed to an unblinded staff at each site. Blinded staff at each site should not have access to these color-coded binders and materials.

#### ***Intervention tote-bag***

All Premier participants will receive a tote-bag for their intervention materials and binder. This way, blinded staff will not be able to identify a participants treatment assignment from seeing if

## **PREMIER Intervention Manual of Procedures**

they carry a tote-bag. An empty tote-bag may indicate an advice only participant, so Premier A participants will be asked to put something in their tote-bag.

Participants will be instructed to keep the tote-bag zippered to avoid revealing the colored materials or binder to any blinded clinical staff. Furthermore, participants should be instructed to check their tote-bags at the front desk (if possible) prior to a clinical visit to avoid the risk of unblinding the clinical staff. Participants will also be provided with identification tags so they can be given the correct bag back upon completion of the clinic visit.

### ***Clinical measurement visits***

It is possible that clinical staff, if clinic visits are not scheduled on a particular day, may recognize those in the active treatment groups while coming in for intervention sessions. Clinic sites will develop procedures where blinded clinic staff are not likely to see participants coming in for intervention sessions only. Clinic sites will try to separate the intervention session area from the clinic visit area if possible. Participants will be advised to avoid approaching the clinic area while attending intervention sessions only.

### ***Scheduling interventionists***

It is recommended that the interventionists are cross-trained to lead all treatment groups. Clinic staff can become unblinded by knowing a certain interventionist is teaching a certain treatment group. There are pros and cons to having the same interventionist always teach the same active treatment group. The major advantage is that the interventionist will be able to concentrate on the preparation for one treatment group and be very experienced when conducting that particular group. Having the same interventionist always lead the same arm, however, would make it difficult to tease out the effects of the treatment arm from the interventionists' influence on enthusiasm. When there are overlapping cohorts, and one interventionist needs to lead both active treatment groups, delivery of appropriate intervention can be confused. Interventionists need to pay special attention while interacting with participants in or outside of sessions so the intervention materials can be followed closely.

There is no trial-wide policy regarding assignment of interventionist to treatment groups. However, it is recommended that the same interventionist leading the same active treatment group within one cohort to preserve continuity. Further, it is recommended that over the four cohorts, the interventionists lead all groups. The blinded staff should not know the assignment of which interventionist is leading which active treatment group. Participants are instructed to not share their interventionist's name to the clinic staff.

### ***Scheduling of intervention sessions***

From cohort to cohort, it is recommended that the intervention sessions be scheduled on a different day of the week (ie, if group B meets on Tuesday in cohort 1, group B of cohort 2 will meet on Thursday). This alternation of scheduling will further minimize the risk of unblinding

## **PREMIER Intervention Manual of Procedures**

staff. However, clinic sites have the discretion to schedule the sessions to suit their particular situations.

**PREMIER Intervention Manual of Procedures**

**40. NUTRITION SUPPLEMENTS 3**

**Introduction 3**

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**PREMIER Intervention Manual of Procedures**

**Summary of Edits**

## 40. Nutrition Supplements

### *Introduction*

PREMIER offers reliable and healthy eating recommendations to participants in all intervention groups. Nutrition guidelines for PREMIER C, which are based on the DASH study results, emphasize fruits, vegetables and dairy products. In general, following these guidelines/advice is the best way to get all the vitamins, minerals and other nutrients that a person may need for cardiovascular health. However, some participants may choose to take certain vitamin/mineral/herbal supplements on their own. PREMIER policies on supplement usage include:

1. Participants may continue to take vitamin/mineral/herbal supplements that they have been taking at entry to the study. Participants will be asked about their supplement usage at baseline, 6 month and 18 month using the Medication Use Questionnaire (Form #11).
2. PREMIER participants may request information regarding supplement usage. If such questions come up during intervention sessions, interventionists should gently point out to those participants in the intervention group C that the DASH diet was based on dietary patterns using various food groups and no one knows exactly which, if any, nutrients are the key to blood pressure reduction. For participants in all three groups, interventionists should emphasize the message that the best sources of nutrients are from foods, and eating a variety of foods is the best way to ensure adequate nutrition.
3. Since diet supplements are not the focus of the PREMIER intervention, interventionists should advise participants using guideline listed in #4 (below) and try to avoid extended discussion on this topic. Participants can be informed that written material about supplements is available and they can pick up the material at the end of session. Participants should also be encouraged to discuss use of supplements with their physicians.
4. Specific recommendations regarding supplements.
  - **Multiple vitamins/minerals (One a day, Centrum or Thera type), single vitamins/minerals (for example, vitamin C, vitamin E, folate, calcium, selenium, zinc or iron), and antioxidants supplements.**

These supplements may help certain populations meet their special nutritional needs. For example, osteoporosis patients that have difficulty getting adequate calcium from foods may need calcium supplements. Iron supplements are recommended for pregnant women or individuals with anemia. However, the effectiveness of using these supplements in preventing or treating chronic diseases such as heart disease and cancer is not known. In general, eating a wide variety of foods is the best way to obtain essential nutrients. The

## PREMIER Intervention Manual of Procedures

PREMIER study recognizes the interest of some participants in using supplements in promoting their health. Participants should be advised to use these supplements at or below the Recommended Dietary Allowances (RDA) and under their physician's supervision. It is possible that overdosage of these supplements may result in toxicity symptoms or negative outcomes.

- **Calcium fortified foods**

Calcium fortified foods are good sources of calcium. However, they do not contain other essential nutrients that are present in dairy products. For the PREMIER study, calcium fortified foods should not be used as a substitute for dairy products.

- Herbal and botanical supplements, energy supplements

These supplements have received very little scientific study regarding safety and effectiveness. They are not regulated by FOA and their quality during their manufacture is not checked. Furthermore, these products have frequently been associated with unfounded or misleading health claims on the label and in books. Participants should be advised to consult their physician before taking these supplements. Examples of common herbal and botanical supplements and their claimed functions are listed below:

Aloe vera	Cleansing/laxative
Chamomile	indigestion
Echinacea	Increase immunity
Ephedra (Ma Juang)	Weight loss/appetite control/Nasal decongestant/asthma/
Feverfew	Migrane
Garlic	Reduce cholesterol/arteriosclerosis
Ginkgo	Improve circulation
Ginseng	Tonic/reduce fatigue/increase stamina
Golden Seal Root	Increase immunity
Hawthorn	Congestive heart failure
Milk thistle	Hepatitis/cirrhosis
Saw Palmetto	Antiinflammatory
St. John's Wort	Antidepressant



## PREMIER Intervention Manual of Procedures

- **Non-prescription weight loss supplements/fat burners**

The display of these supplements always look extremely appealing—not much effort and quick results. Examples of such products include *hydroxycitric acid*, *chitosan*, *conjugated linoleic acid*, *ephedrine*, *pyruvate* and *cellasene*. Most of these products are claimed to increase weight loss, decrease fat absorption or formation. Very few human studies have been conducted to examine the effectiveness and safety of these products. In fact, about three dozen deaths have been linked to ephedra. Participants should be discouraged from taking them and be aware that the claims used for these products are not supported by scientific investigation. They should consult their physicians before taking them.

## PREMIER Intervention Manual of Procedures

<b>41. PREMIER A</b>	<b>3</b>
<b>Overview</b> _____	<b>3</b>
<b>Purpose</b> _____	<b>3</b>
<b>Description</b> _____	<b>3</b>
<b>Data Collection</b> _____	<b>3</b>
<b>Intervention Contacts</b> _____	<b>3</b>
<b>Randomization/intervention Visit</b> _____	<b>3</b>
<b>Setting</b> _____	<b>4</b>
Materials needed to conduct the R/I visit: _____	<b>4</b>
<b>Session Outline</b> _____	<b>4</b>
<b>6 Month Visit</b> _____	<b>5</b>
<b>Setting</b> _____	<b>5</b>
<b>Session Outline</b> _____	<b>6</b>
<b>18 Month Visit</b> _____	<b>6</b>
<b>Session Outline</b> _____	<b>6</b>

## **PREMIER Intervention Manual of Procedures**

### **Summary of Edits**

8/31/2000 Edits made to Version 1.0: 6 month visit window added

9/20/2000 Edits made to Version 1.1: 6 month visit window changed to be 5 ½ -9 months.

## **PREMIER Intervention Manual of Procedures**

### **41. PREMIER A**

#### *Overview*

#### *Purpose*

The purpose of this chapter is to standardize intervention for participants assigned to PREMIER A.

#### *Description*

Participants assigned to PREMIER A receive general lifestyle change advice consistent with the National High Blood Pressure Program (NHBPEP) and JNC guidelines for patients with above-optimal blood pressure and stage I hypertension. These recommendations include weight loss if overweight, no more than moderate alcohol intake, no tobacco use, regular physical activity, and a diet that is low in sodium, fat and cholesterol.

#### *Data Collection*

Participant attendance at each PREMIER A visit should be recorded on Form #42 and then entered in the study database. (See Chapter 45)

#### *Intervention Contacts*

PREMIER A participants receive three intervention contacts. The first occurs at randomization, the second after the 6-month clinic visit, and the third after the 18-month clinic visit. At the randomization and 6-month visits the participants receive advice along with educational materials, but no behavioral counseling. The final visit occurs after completion of the study data collection and may include behavioral counseling.

If the participant does not attend the 6 months intervention visit, no further attempts will be made to reschedule the visit. The final visit occurs at 18 months after the completion of the study. If a participant does not attend the 18 months group visit, an exit interview is attempted.

#### *Randomization/intervention Visit*

The initial PREMIER A intervention contact occurs at the end of the Randomization/Intervention Visit (R/I). This 30-minute visit is conducted by an interventionist. During this visit the participant is given his/her group assignment and is encouraged to discuss the value of the PREMIER A study arm. They will also receive advice reinforced by specific written materials. During this information only intervention session:

- Give advice on recommended lifestyle guidelines
- Answer participant questions regarding the recommended guidelines
- Do not provide detailed behavior change counseling

## **PREMIER Intervention Manual of Procedures**

### ***Setting***

The randomization visit can take place at any location that can ensure that the clinic staff remains blind to the participants' intervention assignment.

### ***Materials needed to conduct the R/T visit:***

- Guidelines for Better Control of Blood Pressure (two sided handout that has the Food Guide Pyramid on the other side)
- Resource List (each site will provide this list)
  - Community Resource list including local address and telephone number:
    - American Heart Association
    - USDA Food and Nutrition Field Office
    - City Library, health education section
  - Web Addresses
    - American Heart Association – [www.amhrt.org](http://www.amhrt.org)
    - American Dietetic Association – [www.eatright.org](http://www.eatright.org)
    - Blair's Quit Smoking Resources
    - Hypertension Network – [www.bloodpressure.com](http://www.bloodpressure.com)
    - National Heart, Lung & Blood Institute - [www.nhlbi.nih.gov](http://www.nhlbi.nih.gov)
    - World Hypertension League – [www.mco.edu/whl/know.html](http://www.mco.edu/whl/know.html)
  - National Organization Address
    - National High Blood Pressure Education Program
    - NHLBI Information Center
    - Bethesda, MD 20824-0105
- Education Pamphlets (given upon participant's request & provided by cc)
  - Achieving Your Healthy Weight: Information You Need to Lose or Control Weight (NIH, NHLBI, available from PREMIER website)
  - Exercise and Your Heart (NIH, NHLBI publication No. 93-1677)
  - Quit Smoking for Good (American Heart Association publication No. 501097)
  - Sensible Drinking (PREMIER Coordinating Center)
  - Spice Up Your Life! Eat Less Salt and Sodium (NIH, NHLBI, available from PREMIER website)
  - Cholesterol and Your Heart (American Heart Association publication No. 501059)
  - About High Blood Pressure (American Heart Association publication No. 501079)

### ***Session Outline***

- Give randomization assignment
- Discuss the value of PREMIER A to the trial
- Deal with disappointment (if necessary)
- Review clinic and session visit schedule

## **PREMIER Intervention Manual of Procedures**

- Present the PREMIER A advice guidelines using:  
Guidelines for Better Control of Blood Pressure/Food Guide Pyramid
- Handout the materials listed:  
Resource List  
(Optional individual pamphlets listed in the material list may also be used)
- Record attendance on Form #42

### ***6 Month Visit***

This visit should occur after collection of the 6-month clinic follow-up visit data and between 5 ½ and 9 months post randomization. The participant meets with the interventionist who reviews the PREMIER A advice guidelines (see PREMIER A handout) as previously discussed in R/I visit.

- Give advice on recommended lifestyle guidelines
- Answer participant questions regarding the recommended guidelines
- Do not provide detailed behavior change counseling

Educational materials previously distributed at the R/I visit may be reviewed and redistributed if necessary. Optional education pamphlets may be used at this time to help answer participant's questions. This visit should take about 15 to 20 minutes.

### ***Setting***

The 6-month visit can take place at the clinical center or any separate facility that can ensure that the clinic staff remains blinded to intervention assignments.

### **Materials needed to conduct the 6-Month visit:**

- Guidelines for Better Control of Blood Pressure (two sided handout that has the Food Guide Pyramid on the other side)
- Resource List (each site will provide this list)  
Community Resource list including local address and telephone number:  
American Heart Association  
USDA Food and Nutrition Field Office  
City Library, health education section  
Web Addresses  
American Heart Association – [www.amhrt.org](http://www.amhrt.org)  
American Dietetic Association – [www.eatright.org](http://www.eatright.org)  
Blair's Quit Smoking Resources  
Hypertension Network – [www.bloodpressure.com](http://www.bloodpressure.com)  
National Heart, Lung & Blood Institute - [www.nhlbi.nih.gov](http://www.nhlbi.nih.gov)  
World Hypertension League – [www.mco.edu/whl/know.html](http://www.mco.edu/whl/know.html)  
National Organization Address

## **PREMIER Intervention Manual of Procedures**

National High Blood Pressure Education Program  
NHLBI Information Center  
Bethesda, MD 20824-0105

- Education Pamphlets (given upon participant's request & provided by cc)
  - Achieving Your Healthy Weight: Information You Need to Lose or Control Weight (NIH, NHLBI, available from PREMIER website)
  - Exercise and Your Heart (NIH, NHLBI publication No. 93-1677)
  - Quit Smoking for Good (American Heart Association publication No. 501097)
  - Sensible Drinking (PREMIER Coordinating Center)
  - Spice Up Your Life! Eat Less Salt and Sodium (NIH, NHLBI, available from PREMIER website)
  - Cholesterol and Your Heart (American Heart Association publication No. 501059)
  - About High Blood Pressure (American Heart Association publication No. 501079)

### ***Session Outline***

- Review the PREMIER A advice guidelines
- Answer participant questions
- Distribute optional educational pamphlets on specific guidelines per participants need or request
- Review clinic and session visit schedule
- Record attendance on Form #42

### ***18 Month Visit***

The 18-month visit occurs after the study data collection is complete for each cohort. Each site has the discretion when to hold the group visit, but it must be within three months after the last data collection visit. If a participant is unable to attend the group visit, an exit interview is attempted. At this visit participants' questions will be answered and they will be given advice and some behavioral counseling to facilitate change.

### **Materials needed to conduct the 18-Month visit:**

- Materials listed in R/I and 6 Month visit (as needed)

### ***Session Outline***

- Welcome participants and thank them for participating in PREMIER study
- Answer participants questions
- Review optional educational pamphlets on specific blood pressure control guidelines and counsel per participants need or request
- Briefly present health education information (may use information developed for PREMIER C participant manual)

## **PREMIER Intervention Manual of Procedures**

- Record attendance on Form #42



**GUIDELINES**  
**FOR BETTER CONTROL OF BLOOD PRESSURE**

**HERE IS HOW TO DO IT:**

Lose weight if overweight	Limit alcohol
Increase daily physical activity	Eat less salt
Stop smoking	Reduce fat and cholesterol

**LOSE WEIGHT IF OVERWEIGHT**

- Eat a variety of healthy foods
- Use the Food Guide Pyramid
- Eat smaller servings
- Try not to skip meals

**STOP SMOKING**

- Talk to your doctor if you can't stop on your own

**INCREASE DAILY ACTIVITY**

- Check with your doctor before exercising
- Exercise for 30 minutes, 3 - 4 times a week

**LIMIT ALCOHOL**

- Limit of 1 - 2 drinks per day

**EAT LESS SALT**

- Use less salt in cooking and at the table
- Eat fewer salty foods
- Eat fewer ready-made and fast foods

**REDUCE FAT AND CHOLESTEROL**

- Eat low-fat poultry, meats, or fish
- Avoid fried foods and adding fat in cooking
- Trim off visible fat
- Drink skim or low-fat milk
- Eat less ice cream, cheese or other high-fat dairy food

**PREMIER Intervention Manual of Procedures**

<b>42. GROUP SESSIONS</b>	<b>3</b>
<b>Purpose</b> _____	<b>3</b>
<b>Description</b> _____	<b>3</b>
Guest Policy _____	3
<b>Format/Template</b> _____	<b>3</b>
<b>Taste It! / Check-in (10-15 minutes before the start of the sessions)</b> _____	<b>3</b>
Instructions for Taste-it Section _____	3
<b>Progress Check/Review (20-30 minutes)</b> _____	<b>4</b>
Instructions for Progress Check/ Review _____	4
<b>Try It! Activity/Demonstration/Discussion (45-60 minutes)</b> _____	<b>4</b>
<b>Next Steps: (20-30 minutes)</b> _____	<b>4</b>
Instructions _____	4
<b>Self-Monitoring</b> _____	<b>4</b>
Purpose _____	4
Instructions _____	5
<b>On Your Own</b> _____	<b>5</b>
Purpose _____	5
Instructions _____	5
<b>Attachment A</b> _____	<b>7</b>

## **PREMIER Intervention Manual of Procedures**

### **Summary of Edits**

#### **Change in version 1.0**

- Page 1 paragraph 2, Description. Delete the 1 hour time for Phase III.
- Page 5 paragraph 2, Instructions. Delete Encouraged self monitoring and recommend progression of self-monitoring.

## **PREMIER Intervention Manual of Procedures**

### **42. Group Sessions**

#### *Purpose*

The purpose of the Group Sessions is to facilitate the behavioral lifestyle interventions through an interactive group process and supportive group environment.

#### *Description*

Recommended group size is 8 to 15 participants. The meeting room should be ready for use at least 30 minutes prior to the start of the session and be easily accessible to participants. Chairs and tables should be provided including chairs without side arms for larger participants. The room should include an overhead projector, and a flip chart or a whiteboard. The session length is approximately 2 hours for Phase I and II sessions. The number and qualifications of the session facilitators may vary by site, but should be either two facilitators or one facilitator and one diet aide present at all sessions.

#### *Guest Policy*

Participants may bring guests with the permission of the Interventionist but are not encouraged to do so. Guests are not considered group members, but may participate in some group activities. They should adhere to the group rules.

#### *Format/Template*

See PREMIER Generic Group Session Description and general guidelines for debriefing and facilitating group discussions at the end this chapter.

#### *Taste It! / Check-in (10-15 minutes before the start of the sessions)*

The Taste-it portion of the group meeting should increase the participant's experience with, an awareness of, foods that meets the PREMIER guidelines, and encourage them to try new foods. The Taste-it portion of the session promotes an environment that is social and fun, thus contributing to retention. This format also allows an engaging activity to take place while the staff greet participants and collect data.

#### *Instructions for Taste-it Section*

1. Prepare selected food options ahead of time and have them available for tasting, at least 15 minutes before the start of the session. Have product labels displayed for participants to examine. Copies of recipes with appropriate nutrient analysis per serving (Calories, fat, sodium for PREMIER C) and (Calories and Sodium for PREMIER B) should be available for participants.

## **PREMIER Intervention Manual of Procedures**

2. Greet participants as they arrive, answering individual questions and inviting them to try the food samples. Participants should be weighed and data from food records entered onto the data form by the diet aide or second interventionist during this time.

### ***Progress Check/Review (20-30 minutes)***

The progress check allows participants an opportunity to discuss personal successes and challenges since the last meeting and to begin the process of problem solving in a supportive group environment. This part of the session allows the group facilitator an opportunity to listen and assess the participants' understanding of past topics and determine an appropriate pace for moving forward with new material and concepts.

#### *Instructions for Progress Check/ Review*

1. Have each participant report on the results of their action plan developed at the last meeting. Focus on record keeping, personal action plan outcomes and the "on your own" activities from the past week.
2. Summarize barriers and solutions experienced by the group members (Table 1).

### ***Try It! Activity/Demonstration/Discussion (45-60 minutes)***

The purpose of this section is to allow participants an opportunity to practice specific behavior-change strategies and skills in a participatory format. This portion of the session should include and address different learning styles through a variety of formats and activities. Activities, discussions, and worksheets vary and are detailed in each leader's guide.

### ***Next Steps: (20-30 minutes)***

The Next Steps part of the session allows the opportunity for participants to create a plan of action for the upcoming week and commit to that plan. The plan for the week is individualized so that participants focus on areas that they decide are important to them.

#### *Instructions*

1. Participants select areas to focus on for the coming week.
2. Each participant writes specific goals for the next week and a plan of action to achieve those goals.

### ***Self-Monitoring***

#### *Purpose*

Self-Monitoring increases the participants' awareness of food intake and provides feedback and potentially positive reinforcement for meeting study and personal goals. It also allows

## **PREMIER Intervention Manual of Procedures**

participants to monitor change (see also chapter \_\_\_\_, self-monitoring). Studies have shown that the number for food diaries kept is a strong predictor of short and long-term success.

### *Instructions*

1. Minimum self-monitoring: write down food intake and physical activity minutes and points.
2. Recommended self-monitoring: keeping food records for at least 3 days and 7-day Physical Activity records. Note that many previous studies have shown that the number for food diaries kept is a strong predictor of short and long-term success.

### *On Your Own*

#### *Purpose*

This portion of the session provides structure for the coming week with suggested activities to practice.

#### *Instructions*

Task list and suggested activities provided each week in the Participant Manual.

## PREMIER Intervention Manual of Procedures

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### General Guidelines for Debriefing and Facilitating Group Discussions

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Adapted from: *J. Am Diet Assoc.* 1999;99:72-76

1. Build the group from within. Assure participants that the group will be structured to fit their needs and concerns.
2. Have the group establish ground rules early on and stick to them.
3. Use icebreaker-type exercises to help participants start talking.
4. Ask open-ended questions: Ask questions that cannot be answered by “yes” or “no” and involve participants in describing their own experiences.
5. Ask for more information when clarity is needed, avoid making assumptions about what is not said.
6. Guide the discussion: Allow group participants to speak, keep discussion on track, and gently bring topics to a conclusion.
7. Avoid doing the problem solving for the participants.
8. Encourage full participation by making the group session a safe place: Encourage quiet participants to voice their ideas, listen intently to each participant, repeat comments when necessary, give positive feedback verbally and/or physically.
9. Focus the conversation: Clarify different views, restate the objectives of the session when necessary, summarize the important points of the discussion.
10. Correct misconceptions artfully: Avoid turning into the “lecturer”, emphasize the worth of participants’ experiences, use responses such as “I am glad this worked for you, what have other people found...”, and ask what other group participants think about the statement.
11. Create an atmosphere of acceptance: Accept and respect each participant’s feelings, even when you disagree with that viewpoint.
12. Summarize the discussion: Bring ideas together and repeat relevant information, strive to make the summary the result of the participants’ discussion, not your own analysis, and repeat and clarify the solution to any specific problem that participants discussed.
13. Be patient: Remember, it takes time for a group to grow and develop trust.
14. Have fun: Keep a smile and enjoy sharing and learning from the group.

**SAMPLE**  
**PREMIER Generic Group Session Description**  
**Phase I, G2-G8**

**Attachment A**

<b>Taste It!/Check-in</b>	10-15	Food that meets the PREMIER guidelines and is related to the theme of the session is available at the beginning of the session (preferable 15-30 minutes before the beginning of the session). Participants have time to socialize and check-in before the group gets started. Flexibility is given to the interventionist to have additional specific taste testing activities anytime during the session. For all food served, the product labels and/or the recipe are on display and available. Data collection and weigh-in occurs during the first few minutes of the session.
<b>Progress Check/Re-Cap</b>	20-30	Re-cap of last week's progress and discussion. Interventionist uses motivational interviewing skills to check on how the plans made last week are working, what might be in the way, what did not work, what problems were encountered, how barriers were overcome. The results of this discussion will help determine the pace for moving on to the planned materials for the session or spending time to allow participants to problem-solve around past material.
<b>Try It! Activity/Demo/Discussion:</b>	45-60	Try It! is designed to focus on and practice specific behavior-change strategies and skills. Applicable content is covered in a facilitated discussion format. A variety of group process formats (including small and large group activity and discussions) are used to address variations in learning style, motivation, culture, gender, age, and other differences. While several change strategies are applied during each Try It! activity, new strategies introduced or used during each activity are explicitly identified in the leader's guide instructions.
<b>Lifestyle Patterns:</b>	Part of the discussion in progress check, and Try It!	The focus of the session is based on the concept of lifestyle patterns (eating and physical activity). Individual participants start where they are at and progressively move at their own pace toward the PREMIER guidelines and goals.
<ul style="list-style-type: none"> <li>• <b>Eating</b></li> </ul>		The group session focuses on eating patterns as indicated by foods and meals most commonly eaten. Suggested progression for Phase I is: G1) introduction/overview G2) most common foods G3) daily/weekly eating patterns G4) eating patterns: a.m. meals-breakfast, G5) eating patterns: noontime meals-lunch, G6) eating patterns: p.m. meals-dinner, G7) snacking patterns, G8) eating out patterns. (Special occasions deferred to Phase II). Targeted nutrients are presented as a rationale for choosing certain types of foods, but specific nutrients are not typically the focus of each session.
<ul style="list-style-type: none"> <li>• <b>Physical Activity</b></li> </ul>		Physical activity component focuses on patterns of physical activity and inactivity in context to an entire week. Includes: patterns of activity related to time of day, patterns of building activity links, and patterns of social support related to activity.
<b>Change Strategies</b>		Key behavior change strategies are covered in Phase I with additional strategies introduced later. Initially, the change strategies are integrated as part of the activity without overt topical discussion (however identified in the leader's guide). Later, discussions occur around particular strategies. Specific strategies and implementation are described in the intervention MOP.
<b>Knowledge &amp; Skills:</b>		Specific content-rich information is presented for both nutrition and physical activity topics as applicable. Content is integrated into the progress check, Try It! activity, and facilitated discussions. The interventionist integrates the content into the session using a facilitated discussion format based on the direction and responses from the group.
<ul style="list-style-type: none"> <li>• <b>Nutrition</b></li> </ul>		Nutrition education occurs as it relates to the theme and focus of the eating pattern activity for the session.
<ul style="list-style-type: none"> <li>• <b>Physical Activity</b></li> </ul>		Physical activity topics are highlighted as they relate to the activity patterns discussion for the session.
<b>Next Steps:</b>		20-30
<b>Plan for the Week</b>		Logical follow-up from the Try It! activity for participants to identify personal action plans for the coming week(s).
<b>Tracking (self-monitoring)</b>		At minimum, participants are encouraged to write down what they eat and keep track of the physical activity. Ideally, by G3, participants are recording food, calories, sodium, and physical activity for Comp and food, calories, fat, sodium, servings fruits vegetables, servings dairy, and physical activity for Comp+DASH. Alternative formats for self-monitoring are introduced in later sessions.
<b>On Your Own</b>		Suggestions for new things to try during the upcoming week. May be recommended by PREMIER and/or recommended by other group members. Part of action planning, problem solving, and overcoming barriers.



**SAMPLE**  
**PREMIER Generic Group Session Description**  
**Phase I, G2-G8**

**PREMIER Intervention Manual of Procedures**

<b>43. PREMIER B AND C INDIVIDUAL VISITS</b>	<b>3</b>
<b>Overview and Purpose</b> _____	<b>3</b>
<b>Implementation</b> _____	<b>3</b>
Number of Contacts _____	3
Visit Objectives _____	3
Counseling Skills, Strategies and Style _____	4
Visit Tasks _____	5
<b>Materials</b> _____	<b>5</b>

**PREMIER Intervention Manual of Procedures**

**Summary of Edits**

## PREMIER Intervention Manual of Procedures

### 43. PREMIER B and C Individual Visits

#### *Overview and Purpose*

PREMIER B and C participants meet with the interventionist privately at scheduled times throughout the study to explore the participant's progress, identify challenges and barriers to making behavior changes, and develop individualized action plans. The participant's motivation, interests, experience, and personal situation are taken into account. The purpose of this chapter is to describe the counseling style and to outline the frequency of contact and materials used in the individual visits. Additional details on the individual visits are found in the Leaders Guide.

#### *Implementation*

##### *Number of Contacts*

PREMIER B and C participants have seven 45-minute individual visits during the 18-month intervention. These include the initial study contact, (R/I), and six other contacts dispersed throughout the intervention.

<b>Visit</b>	<b>Intervention Week</b>	<b>Session Placement</b>
I-1	Week 0	R/I
I-2	Weeks 5-6	Between G-4 and G-5
I-3	Weeks 11-12	Between G-8 and G-9
I-4	Weeks 18-19	Between G-11 and G-12
I-5	Month 8	Month of G-16
I-6	Month 11	Month of G-19
I-7	Month 14	Month of G-22

##### *Visit Objectives*

The purpose of the intervention contact is for the interventionist to use motivational enhancing counseling to help the participant explore and resolve ambivalence or feelings about the behavior changes that they are trying to make. The visit gives the interventionist an opportunity to:

1. Seek to understand the participant by asking open-ended questions and using reflective listening skills.
2. Provide the participant with individualized feedback on their progress and an opportunity to evaluate that feedback.
3. Provide the participant with the opportunity to choose a particular behavior on which to focus.

## **PREMIER Intervention Manual of Procedures**

4. Assess the participant's readiness to make further behavior changes.
5. Strengthen commitment to change, build motivation and help the participant tip the decisional balance in favor of change.
6. Problem solve around barriers for making changes
7. Negotiate an action plan for participants ready to make further changes.
8. Affirm and compliment; reinforce and support the participant for their progress, motivation and intentions.

### *Counseling Skills, Strategies and Style*

The PREMIER individual visit protocol is based on the principles of Motivational Interviewing as described in Motivational Interviewing; Preparing People to Change Addictive Behavior, by Miller and Rollnick. The methods include strategies, skills, and essential elements of a motivation-enhancing style of counseling.

The strategies include:

- Individualizing the intervention
- Assessing motivation and confidence
- Exploring ambivalence
- Negotiating action plans
- Problem solving
- Offering appropriate feedback, advice, and education
- Emphasizing freedom of choice.

The skills include:

- Reflective listening
- Asking open-ended questions
- Summarizing
- Affirming
- Supporting self-efficacy

The style is:

- Understanding
- Patient-Centered
- Collaborative
- Individualized
- Respectful and accepting

## **PREMIER Intervention Manual of Procedures**

### *Visit Tasks*

- Prepare a visit schedule

A couple of weeks prior to each visit, the interventionist prepares a schedule and has each participant sign-up for a visit time. It is suggested to schedule visits to last for an hour to have time to meet with the participant (30 to 45 minutes), document the outcome of the visit, and prepare for the next visit. The interventionist also assembles the session materials prior to the session. After the visit, the interventionist records the interaction in the participant's study record and records data on the intervention data collection form (form 42, 43, 44).

### *Materials*

The visit materials reinforce the participant's behavior change and provide feedback on their progress.

- Where Are You Now

This form helps the participant identify his/her motivation to adopt or continue with the PREMIER dietary and physical activity guidelines. The participant identifies progress towards goals by estimating what percent of the time he/she is adhering to the recommendations. He/she also completes a 1-10 scale showing relative motivation to adhere to the recommendations. This serves a basis for discussion.

- Action Planning Worksheet

This worksheet emphasizes the participant's responsibility and freedom of choice as they consider a personalized strategy for behavior change. It is used with the "Where Are You Now" form to facilitate empathetic discussion of problem solving around issues of behavior change, to assess confidence, and to reinforce self-efficacy.

- Lifestyle Options Tools

This tool helps the interventionist and participant set the agenda for the session.

- Individual Progress Report

This report is printed prior to each session from the PREMIER study computer and graphically outlines the participant's behavior change progress. The report compares the participant's progress with the PREMIER study goals.

- Document the discussion

Local sites determine additional documentation for the individual visit. Ongoing notes are kept to record participant motivation and confidence for discussion. Copy the Where Are You Now form and the Action Planning Worksheet for the participant's chart.

**PREMIER Intervention Manual of Procedures**

<b>44. INTERVENTION MONITORING: NUTRIENT ADEQUACY AND ATTENDANCE ALERTS</b>	<b>3</b>
<b>Purpose</b> _____	<b>3</b>
<b>Definition of Nutritional Inadequacy</b> _____	<b>3</b>
<b>Definition of Drop Out Risk</b> _____	<b>3</b>
<b>Procedures</b> _____	<b>3</b>
<b>References</b> _____	<b>4</b>

**PREMIER Intervention Manual of Procedures**

**Summary of Edits**



## **PREMIER Intervention Manual of Procedures**

### **44. Intervention Monitoring: Nutrient Adequacy and Attendance Alerts**

#### ***Purpose***

This chapter describes procedures for detecting possible nutritional adequacy problems and risk of dropping for participants assigned to the PREMIER B and PREMIER C interventions.

#### ***Definition of Nutritional Inadequacy***

Rapid weight loss may be an indication of inadequate nutrition. A mean weight loss of ½ to 2 pounds per week over 6 months, or 10 percent of body weight over 6 months, is considered reasonable (1). The working definition of too rapid weight loss in PREMIER will be a mean weight loss greater than 2 pounds per week for women and 3 pounds per week for men over a 4-week period. Weight loss greater than this amount will trigger a case review by the intervention staff. The only exception to this guideline will be the first two weeks of intervention in which a greater weight loss will be acceptable.

The initial target calorie level for weight loss in PREMIER is 1500 Kcal/day for women and 2000 Kcal for men. These values are based upon an estimated weight maintenance level of 2100 Kcal for women and 2600 Kcal/day for men (based on the DASH studies). A mean caloric intake of less than 1,000 Kcal/day for women and 1,500 Kcal/day for men over a four week period as documented by self-monitoring (i.e. FFD) will also trigger a case review by the intervention staff.

#### ***Definition of Drop Out Risk***

Participants who miss two consecutive intervention meetings without notifying the interventionists in advance, and for whom no follow-up contacts are recorded, will be considered at risk of dropping out of their intervention program.

#### ***Procedures***

1. Baseline weight is measured at the R/I visit, and attendance, weight, and dietary intake data are collected at each subsequent intervention session. These data will be monitored by the coordinating center, and the intervention director at each clinic will be notified when their participants reach alert levels for weight loss, caloric intake, or drop out risk.
2. When a participant reaches an alert level, the intervention director will be responsible for conducting a case review with the local intervention team and recording the results of that review in an alert log. The intervention team will be responsible for evaluating the case and developing a plan that might include an individual visit with the participant, a special plan for helping that participant in the context of the regularly scheduled group meetings, follow-up contacts by telephone, some other action, or taking no further action.
3. Nutrition and weight alerts – Case reviews should include all of the information available to the interventionists. In some cases the reported caloric intake may not be representative of the participants true mean intake (e.g., they are reporting eating 500 Kcal/day but are not losing weight). However, if a case review indicates that the participant may have a mean caloric intake below 1,000 Kcal/day for women or 1,500 Kcal/day for men, an individual

## **PREMIER Intervention Manual of Procedures**

visit with the participant should be scheduled. That visit may be conducted by any of the PREMIER interventionists familiar with the case. The purpose of the individual visit will be to review with the participant their recent food diaries and to discuss the importance of eating an adequate diet. Dietary recommendations will focus on a pattern including grains and cereals, fruits and vegetables, dairy, and meat and meat substitutes as noted in Dietary Guidelines for Americans (3) and consistent with the participant's PREMIER intervention group assignment.

4. Drop out alerts – A case review must be done within a week of the date a site receives the alert notice. Note that alerts for a given participant will continue to be issued as long as they are missing meetings. In the case of confirmed drop out, or a participant who cannot attend sessions for whatever reason, drop out alerts can be suppressed by sending a drop-out form (to be developed) to the coordinating center. This form will include the reason for non-attendance and must have the signature of both the intervention director and PI.
5. The disposition of each intervention alert should be recorded in a log. This log will be reviewed during the intervention site visits.

### ***References***

1. *Clinical Guidelines on the Identification, Evaluation and Treatment of Overweight and Obesity in Adults, The Evidence Report*, National Institutes of Health, National Heart, Lung, and Blood Institute. Obesity Research 1998;6(Supp2):515-2095.
2. *Position of the American Dietetic Association: Weight Management*, J Am Diet Assoc 1997;97:71-84
3. *Nutrition and Your health, Dietary Guidelines for Americans, 4<sup>th</sup> Ed.*, Washington, D.C., U.S. Department of Agriculture and Health and Human Services; 1995.

## PREMIER Intervention Manual of Procedures

<b>45. INTERVENTION DATA COLLECTION</b>	<b>3</b>
<b>Purpose</b> _____	<b>3</b>
<b>Description</b> _____	<b>3</b>
<b>Blinding Status</b> _____	<b>3</b>
<b>Intervention Adherence Self-Monitoring Data</b> _____	<b>3</b>
Intervention Data Collection (Form #42, 43, 44) _____	<b>3</b>
<b>Intervention Data Collection – Other Forms</b> _____	<b>3</b>
Vigorous Activity Worksheet (Form #36) _____	<b>3</b>
Participant-Reported Events (Form #31) _____	<b>4</b>
Premature Study Termination (Form #37) _____	<b>4</b>
Other Forms _____	<b>4</b>

**PREMIER Intervention Manual of Procedures**

**Summary of Edits**

## **PREMIER Intervention Manual of Procedures**

### **45. Intervention Data Collection**

#### ***Purpose***

This chapter describes intervention data collection responsibilities and is intended to be used in conjunction with data collection procedures as described in the coding instructions for each specific form.

#### ***Description***

Interventionists must collect adherence and self-monitoring data for all participants at each scheduled contact.

#### ***Blinding Status***

Intervention staff are unblinded and may not perform clinical outcome measurements. However, intervention adherence and self-monitoring data will be collected by unblinded interventionists, as described below.

#### ***Intervention Adherence Self-Monitoring Data***

##### ***Intervention Data Collection (Form #42, 43, 44)***

Complete the *session* and *self-monitoring* sections of the Intervention Data Collection Form (Form #42, 43, 44). See coding instructions for these forms for detailed steps on completing the forms correctly and for instruction regarding missed visits.

##### ***Intervention Data Collection – Other Forms***

Interventionists may complete the following forms as appropriate following randomization. Refer to the coding instructions included with each form for details on completing these forms correctly.

##### ***Vigorous Activity Worksheet (Form #36)***

Participants who enter the study already doing vigorous exercise may continue without further assessment or approval. Participants who wish to progress from low or moderate intensity to vigorous exercise must be assessed for the presence of cardiovascular risk factors using Form #36. The staff person completing this form must ask question 1 of the participant. The rest of the form is completed using information from the study chart. A participant who has 2 or more risk factors according to the JNC guidelines listed on Form #36 must provide a statement from his personal physician stating that the participant has had a negative exercise stress test within the

## **PREMIER Intervention Manual of Procedures**

last 6 months. In addition, both the participant's personal physician and the PREMIER clinician must give approval for the participant to engage in vigorous physical exercise.

### *Participant-Reported Events (Form #31)*

Form (#31) may be filled out by an interventionist if a participant calls in to report an adverse event, or mentions a potential adverse event at an intervention visit. This form is then reviewed by a clinician to determine whether an Adverse Events Form (#30) should be completed.

### *Premature Study Termination (Form #37)*

This form may be completed in consultation with unblinded clinic staff in the event that a randomized participant is excluded, or drops out and will not come in even for minimal measures.

### *Other Forms*

Participant Evaluation Form with ID (Form #XX - TBD)

Participant Evaluation Form (anonymous) (Form #XX - TBD)

**PREMIER Intervention Manual of Procedures**

<b>46. PARTICIPANT FOLLOW-UP</b>	<b>3</b>
<b>Purpose</b> _____	<b>3</b>
<b>Description</b> _____	<b>3</b>
<b>Participant Contacts/Missed Visits</b> _____	<b>3</b>
<b>Premature Study Termination</b> _____	<b>3</b>

**PREMIER Intervention Manual of Procedures**

**Summary of Edits**



## **PREMIER Intervention Manual of Procedures**

### **46. Participant Follow-up**

#### *Purpose*

This chapter describes intervention responsibilities for contacting participants who do not attend scheduled intervention sessions.

#### *Description*

Interventionists must collect compliance data for all participants at each scheduled contact. If a participant misses a group or individual session, interventionists must attempt to reach participants to schedule a make-up session to be held one-on-one, or by telephone. If unable to complete a make-up session in-person or by phone, materials for the missed session may be mailed to the participant.

#### *Participant Contacts/Missed Visits*

The participant should be contacted by phone as soon as possible after the missed session to discuss the reason for absence. If staff does not reach the participant right away, continue to make call attempts on different days and at different times of day until the participant is reached. If staff are unable to reach the participant within 7 days, check the “Unable to Contact” box on the Intervention Data Collection Form (#43 #44), and submit the form for data entry.

In case of a planned absence, enter the make-up session date. Participants may attend a make-up session of another group in the same randomization assignment in the same cohort. In this event, enter the date of the session actually attended under the make-up session date. See coding instructions for Form #43 or #44, Intervention Data Collection Forms PREMIER B or PREMIER C, for instructions on completing these forms correctly.

#### *Premature Study Termination*

Interventionists may work with clinic staff to complete documentation for randomized participants who terminate the study prior to completing the intervention and all follow-up measurements. For participants who terminate early, complete the following forms as indicated, in consultation with clinic staff:

- Form #37      Premature Study Termination Form
- Form #30      Adverse Events
- Form #31      Participant-Reported Events

Refer to Chapter 45 (Intervention Data Collection) and to the coding instructions included with each form for details on completing these forms correctly.

## PREMIER Intervention Manual of Procedures

<b>47. EXTERNAL RESOURCES POLICIES</b>	<b>3</b>
<b>Introduction</b> _____	<b>3</b>
<b>Policy on Using Cookbooks</b> _____	<b>3</b>
<b>Cookbooks listing</b> _____	<b>3</b>
<b>REGIONAL</b> _____	<b>4</b>
<b>LOW SODIUM and/or LOW FAT</b> _____	<b>5</b>
<b>LOW-FAT</b> _____	<b>6</b>
<b>Reference books list</b> _____	<b>10</b>
<b>Internet Resources List</b> _____	<b>13</b>
<b>Field Trips</b> _____	<b>15</b>
Policy on Field Trips _____	15
Examples of Field Trips _____	16
<b>Videos</b> _____	<b>16</b>
Policy on Using Videos _____	16
Examples of Videos _____	16
<b>Policy on Using Other Resources</b> _____	<b>17</b>

**PREMIER Intervention Manual of Procedures**

**Summary of Edits**

## PREMIER Intervention Manual of Procedures

### 47. External Resources Policies

#### *Introduction*

This chapter provides guidelines for using cookbooks, reference books, web sites, field trips, videos, etc., during the PREMIER intervention. Although these resources may enhance participants' adherence to the PREMIER lifestyle goals, clinic sites must follow these guidelines to assure that the same intervention is delivered to all sites. Resources listed in this chapter will be distributed to all participants, unless otherwise noted. The guidelines/policies for each area of resource is listed first, followed by a list of examples/actual resources.

#### *Policy on Using Cookbooks*

1. Cookbooks recommended to PREMIER participants should follow the PREMIER Lifestyle Guidelines for fat and sodium.
2. Participants should be encouraged to bring recipes/cookbooks to the intervention session for discussion/sharing.
3. Participants should be advised that even though the following cookbooks can be used in building a healthy eating pattern, the PREMIER study does not endorse all the information printed in the cookbooks.
4. Cookbooks should not be sold to participants.

#### *Cookbooks listing*

##### **For PREMIER C only:**

<b>Controlling Your Fat Tooth</b> By: Joseph C. Piscatella, Bernie Piscatella (1991)	\$15.95	0-894-80431-6	Specific, practical, usable advice on stripping fat from our diets by employing a special fat budget. With menus, tips, and over 200 delicious recipes
<b>Hot vegetables</b> By: Hugh Carpenter & Teri Sandison (1998)	\$17.95	0-89815-975-X	Fifty delicious vegetable dishes, plus tips on shopping and preparation techniques.
<b>Fresh from the Farmer's Market</b> By: Janet Fletcher (1997)	\$19.95	0-8118-1393-2	This book contains more than 75 mouthwatering recipes of fruits and vegetables.
<b>A cook's book of mushrooms</b> By: Jack Czarnecki (1998)	\$30.00	1-885183-07-0	One hundred delicious recipes for common and uncommon mushrooms.
<b>Gourmet's fresh-from the farmer's market to your kitchen</b> By: Lond'e Nast Books	\$27.50	0-375-50341-2	More than 200 very user-friendly fruits and vegetable recipes.

**PREMIER Intervention Manual of Procedures**

(1998)			
<b>Fresh from the garden</b> By: Perla Meyers (1997)	\$30.00	0-517-59357-2	Award winning author, Perla Meyers, will inspire you to put fruits and vegetables on your table. Great recipes and taste.
<b>Salad Days</b> By: Marcel Desaulniers (1998)	\$27.50	0-684-82261-X	Marcel presents many fun and delicious ways to include fruits and vegetables in a meal.

**For PREMIER B and C:**  
**REGIONAL**

<b>Title</b>	<b>Price</b>	<b>ISBN</b>	<b>Description</b>
<b>Cajun Healthy</b> By: Jude Theriot (1994)	\$22.95	1-565-54085-9	Theriot revamps the traditional canon of Cajun cooking with healthful versions of Shrimp and Okra Gumbo, Broiled Red Snapper with Sautéed Crabmeat, and Crawfish Etouffee. Theriot serves up mouth-watering, easy-to-follow suggestions for cutting fat and enhancing taste.
<b>Cajun Low Calorie Cooking</b> By: Enola Prudhomme (1991)	\$19.95	0-688-09255-1	For people who love the spice that Cajun food adds to their life but not what it adds to their waistline, one can eat authentic Southern-Style Oven-Fried Chicken, Blackened Catfish, Shrimp and Crabmeat Jambalaya, and many other dishes without worrying about calories.
<b>Louisiana Light: Low Fat, Low Cholesterol, Low-Salt, Cajun &amp; Creole Cookery</b> By: Roy F. Guste, Jr. (1990)	\$29.95	0-393-02714-7	For weight and health conscious people who love Louisiana cuisine, here is a marvelous cookbook designed to cut fat, salt and calories. The result is a pleasing array of wholesome dishes that don't sacrifice any of the rich Creole and Cajun tastes.
<b>River Roads III</b> By: The Junior League of Baton Rouge (1995)	\$17.95	0-961-30264-X	Was developed with both great taste and good health in mind. All of the original recipes have been modified into lighter versions to help people lower their intake of calories, fat, cholesterol, and sodium.

**PREMIER Intervention Manual of Procedures**

<b>Trim &amp; Terrific One-Dish Favorites : Over 200 Fast &amp; Easy Low-Fat Recipes</b> By: Holly Berkowitz Clegg (1997)	\$18.95	0-517-70258-4	Hundreds of new, fast, easy, and delicious low-fat recipes for contemporary one-dish meals and desserts.
<b>Low Fat Southern Style Cooking</b> By: Valissa Moore, (1996)	\$23.45	None	This Southern style, low fat cookbook provides you with savory recipes without all the fat. Recipes like low fat biscuits, nonfat gravy, southern style fried chicken, broccoli casserole and sweet potato pie are included. It will also teach you how to find the hidden fat and the percentage of fat in the foods you eat.
<b>A Trim and Terrific Louisiana Kitchen</b> By: Holly Berkowitz Clegg (1993)	\$18.95	0-961-08883-4	Easy, everyday recipes that can be prepared in about 30 minutes. Nutritional analysis is included for all 375 recipes. The cookbook also features a wonderful pasta section and great menu ideas

***LOW SODIUM and/or LOW FAT***

<b>Title</b>	<b>Price</b>	<b>ISBN</b>	<b>Description</b>
<b>American Heart Association Low-Salt Cookbook</b> By: Rodman D. Stroke, MD Mary Winston EdD, RD	\$23.00	0-812-918852-5	Featuring more than 175 all-new recipes and two diet plans--as well as tips on substituting ingredients, avoiding hidden sodium, dining out, and much more—this breakthrough guide offers information for people needing to control hypertension through diet.
<b>Cooking the Fat-Free, Salt-Free, Sugar-Free Flavor-Full Way</b> By: Marcia Sabate Williams (1997)	\$22.95	0-895-94858-3	To replace salt, the cookbook use fruit juices, wine, pepper, herbs and spices. To replace fats, non-stick pans, juices, stocks, wine, and watery vegetables and fruits are used. The result is great.
<b>Cooking Without a Grain of Salt</b> By: Elma W. Bagg, Susan Bagg Todd, Robert Ely	\$5.99	0-553-57951-7	Filled with useful tips on how to limit sodium without sacrificing flavor, as well as savory recipes that will help you put

## PREMIER Intervention Manual of Procedures

<b>Bagg</b> (1999)			your healthy, low-salt lifestyle into action.
<b>Get the Salt Out : 501 Simple Ways to Cut the Salt Out of Any Diet</b> By: Ann Louise Gittleman (1997)	\$11.00	0-517-88654-5	Presents 501 easy-to-follow suggestions for reducing salt consumption, discussing the dangers of excess salt intake and furnishing a selection of low-sodium foods; more than fifty delicious recipes and information on salt substitutes.

### *LOW-FAT*

<b>Title</b>	<b>Price</b>	<b>ISBN</b>	<b>Description</b>
<b>American Heart Association: Low-fat, Low Cholesterol Cookbook</b> By: Scott Grundy, MD PhD Mary Winston EdD, RD (1989)	\$15.00	0-812-91982-3	In addition to the 200+ recipes, the book includes a clear discussion of cholesterol, easy guidelines, alternative cholesterol-lowering drugs, and specific meal plans.
<b>Better Homes and Gardens Low-fat &amp; Luscious: Breakfast, Snacks, Main Dishes, Side Dishes, Desserts</b> By: Kristi Fuller (1996)	\$16.95	0-696-20373-1	A healthful and delectable assortment of low-fat, easy-to-prepare dishes. Furnishes ninety-eight recipes for breakfast, snacks, main dishes, meatless meals, and desserts, each of which comes complete with a breakdown of fat, food exchanges, and guidelines for determining fat allowances.
<b>The Black Family Dinner Quilt Cookbook: Health Conscious Recipes and Food Memories</b> By: Dorothy I. Height (1994)	\$12.00	0-671-79630-5	Offers recipes for wonderful dishes that capture all the down-home Southern flavor but provides only minimal salt and fat. Uplifting anecdotes by Mary McLeod Bethune, the founder of the National Council of Negro Women, complement the recipes.
<b>Cook Healthy : Cook Quick</b> By: Cathy A. Wesler (1995)	\$29.95	0-848-71424-5	Each of the 225 recipes makes a dish that's high in flavor, yet low in fat. Easy-to-follow instructions, nutritional analysis, and make-ahead hints make "eating right" a snap. Most recipes will take no more than 45 minutes to prepare.

**PREMIER Intervention Manual of Procedures**

<b>Cooking Light Light &amp; Easy Cookbook (1998)</b>	\$29.95	0848715977	Ingredients are readily available, simple, and best of all LIGHT.
<b>Don't Eat Your Heart Out Cookbook</b> By: Joseph C. Piscatella	\$17.95	1-563-05558-9	Updated to reflect the past decade's scientific discoveries, this cookbook by the author of Controlling Your Fat Tooth presents two hundred new and two hundred revised recipes for a heart-healthy diet.
<b>Down-Home Wholesome: 300 Low-fat Recipes from a New Soul Kitchen</b> By: Danella Carter (1998)	\$15.95	0-452-27325-0	The 300 recipes in this book conquer the seemingly impossible when it comes to a low-fat, low cholesterol yet full flavor diet: trimming the fat, sugar, and salt from popular soul recipes and offering a sparkling variety of taste alternatives to traditional dishes.
<b>Gone With the Fat : A Cookbook</b> By: Jen Bays Avis, Kathy F. Ward, James Kendricks (Illustrator) (1997)	\$17.95	0-962-86836-1	Several recipes in this book; extremely good and easy to make. Ingredients are very basic.
<b>The Healthy Soul Food Cookbook: How to Cut the Fat but Keep the Flavor</b> By: Wilbert Jones (1997)	\$12.95	0-806-51863-4	Features ninety-nine traditional African American dishes with emphasis on fresh ingredients and low-fat and no-fat ways to prepare such dishes as Mixed Greens, Red Beans and Rice, Unfried Chicken, and Mississippi Mud Cake.
<b>The Heart Smart Healthy Exchanges Cookbook</b> By: Joanna M. Lund (1999)	\$14.00	0-399-52474-6	Using ingredients available at most supermarkets--and recipes that save time and energy--readers can whip up tempting, meals that are "heart-smart" and that will please the entire family.
<b>Low-fat Cooking for Dummies</b> By: Lynn Fischer (1997)	\$19.99	0-764-55035-7	Features over 150 tasty, easy-to-prepare recipes for brown-bag lunches, Sunday brunches, dinner parties, and more.



## PREMIER Intervention Manual of Procedures

<b>Low-Fat Soul</b> <b>By: Jonell Nash</b> <b>(1998)</b>	\$14.00	0-345-41363-6	Features 100+ low-fat adaptations of favorite soul-food recipes from the Carolinas to the Texas coast, from the Caribbean to New Orleans. Easy to prepare meals for everyday, holiday fare, and elegant dinner parties- plus simple tips for stripping the fat from family recipes.
<b>Lean and Luscious Favorites</b> <b>By: Bobbie Hinman</b> <b>(1997)</b>	\$16.00	0-761-50644-6	Over 350 easy-to-prepare recipes from America's heartland, the Lean and Luscious authors deliver great food without fancy ingredients or cooking techniques.
<b>1,001 Low-Fat Recipes : Quick, Easy, Great Tasting Recipes for the Whole Family</b> <b>By: Sue Spitler with Linda Yoakam RD, MS</b> <b>(1998)</b>	\$15.96	1-572-84019-6	With an emphasis on the quick and easy, this updated edition of Spitler's encyclopedia of healthy cooking including 100 new recipes, 25 menus, and a schedule of steps for advance preparation. 20 illustrations.
<b>The Low-Fat Way to Cook</b> <b>By: Lisa A. Hooper</b> <b>(Editor)</b> <b>(1993)</b>	\$29.95	0-848-71125-4	This comprehensive cookbook/guide to healthy eating is a collection of recipes, menus, and helpful information designed to make low-fat cooking with everyday foods easier than ever. Features more than 450 kitchen-tested recipes, 30 menus, substitution chart, and more.
<b>The New American Diet</b> <b>By: Sonja L. Connor, William E. Connor</b> <b>(1986)</b>	\$14.00	0-671-66375-5	Lifetime family diet that can prevent heart disease, high blood pressure, diet-related cancers, and other degenerative diseases, and encourage easy, permanent weight reduction.
<b>No Salt, No Sugar, No Fat Cookbook (Nitty Gritty Cookbooks)</b> <b>By: Jacqueline Williams, Goldie Silverman, Carol Atherly</b> <b>(1993)</b>	\$8.95	1-558-67085-8	New information about delicious fat-free and sodium free products. Including how to find them, directions for adapting favorite recipes, nutritional analysis, and how to read the new food label.

**PREMIER Intervention Manual of Procedures**

<p><b>Quick &amp; Healthy Recipes and Ideas : For People Who Say They Don't Have Time to Cook Healthy Meals</b> By: Brenda J. Ponichtera, Janice Staver (1991)</p>	<p>\$16.95</p>	<p>0-962-91600-5</p>	<p>Includes low-fat recipes, nutrient analysis, diabetes exchanges, time-saving ideas, menus, and even a grocery list. Offers great time saving ideas, weight loss tips, nutritional analysis of recipes (including diabetes exchange), menus, and even a master grocery list.</p>
<p><b>Quick &amp; Healthy Volume II : More Help for People Who Say They Don't Have Time to Cook Healthy Meals</b> By: Brenda Ponichtera (1995)</p>	<p>\$16.95</p>	<p>0-962-91601-3</p>	<p>It features more delicious low-fat recipes that can be prepared in minutes. Also included are weekly menus with corresponding grocery lists, nutrient analysis, diabetes exchanges, and much more.</p>
<p><b>Ruby's Low-Fat Soul Food cookbook,</b> By: Ruby Baniks-Payne</p>	<p>\$12.95</p>	<p>0-8092-3153-0</p>	<p>Enjoy the best of American's traditional soul food cuisine made the healthy way. Each recipe is a delectable, satisfying celebration of rich African-American culinary heritage.</p>
<p><b>Six Ingredients or Less: Cooking Light &amp; Healthy</b> By: Carlean Johnson (1992)</p>	<p>\$12.95</p>	<p>0-942-87803-5</p>	<p>Always a pleasant surprise with so few ingredients and so few calories. Highly recommended for working people with little time and gourmet taste who are trying to eat healthy.</p>

(Information found: <http://www.amazon.com>)

**PREMIER Intervention Manual of Procedures**

**Policy on Using Reference books and internet resources**

1. The following reference book list can be shared with the PREMIER participants upon request. It should be made clear that these resources are optional for interest and they are not required by the PREMIER study.
2. PREMIER staff can provide the participants with the following list, but should not be involved in selling the books or videos.
3. Providing the list to the participants does not constitute an endorsement by the PREMIER study. Information presented in these resources may or may not help the participants in achieving their PREMIER goals.

*Reference books list*

<b>Title</b>	<b>Price</b>	<b>ISBN</b>	<b>Description</b>
<b>Good Health for African Americans</b> By: Barbara Dixon, Josleen Wilson (Contributor) 1995	\$14.00	0-517-88302-3	A guide to health for African Americans, examines the special health problems confronting African Americans, discusses health care options, and explains how, by adopting diet and lifestyle changes, people can reduce key risk factors.
<b>The Black Man’s Guide to Good Health: Essential Advice for the Special Concerns of African-American Men</b> By: James W. Reed et al 1994	\$12.00	0-399-52138-0	Thoroughly researched by a team of experts in African-American healthcare, this book addresses every condition—from sickle cell anemia to stroke. A comprehensive guide and an essential reference for black men and the people who care about them. This book also offers general health advice.
<b>Body &amp; Soul: The Black Women’s Guide to Physical Health and Emotional Well-Being</b> By Linda Villarosa (editor) 1994	\$20.00	0-060-95085-4	Written by black women for black women and sponsored by the National Black Women’s Health Project, here is an honest, straight-from-the-heart guide reminiscent of <i>Our Bodies, Ourselves</i> that addresses the physical, emotional, and spiritual health issues and concerns of black women today. Linda Villarosa is a senior editor at <i>Essence</i> magazine. 175 photos and illustrations.

**PREMIER Intervention Manual of Procedures**

<b>Title</b>	<b>Price</b>	<b>ISBN</b>	<b>Description</b>
<b>Natural Health for African Americans: The Physicians' Guide</b> By: Marcellus A. Walker, Kenneth B. Singleton 1999	\$14.99	0-446-67369-2	A realistic approach to good health, balancing the best that natural health methods have to offer with current methods of western medicine. The authors have a concern for black families that comes out in their encouragement to employ sound methods of preventing the diseases most common in black families.
<b>Eating on the Run</b> By: Evelyn Tribole, MS, RD 1992	\$14.95	0-880-11452-5	Nutritious eating—from airline meals to microwave zapping.
<b>Stealth Health</b> By: Evelyn Tribole, MS, RD 1998	\$24.95	0-670-87499-X	How to sneak nutrition painlessly into your diet; with more than 100 recipes and 1000 tips on how to eat right in spite of yourself.
<b>Strong Women Stay Young</b> By: Miriam E. Nelson, PhD 1998	\$12.95	0-553-37848-1	The scientifically proven strength training program that turns back the clock for women aged 35 and up—from the famed research labs of Tufts University.
<b>The American Dietetic Association's Complete Food and Nutrition Guide</b> By Roberta Larson Duyuff, Chronimed, 1998	\$24.95	1-565-61160-8	Written by a registered dietitian in an upbeat, personal style, this comprehensive guide offers quick access to timely advice on a multitude of food and nutrition topics. Scattered throughout are "nutrition check-ups," answers to common food and nutrition questions, and tips for reading food labels and planning meals.
<b>The American Dietetic Association Guide to Women's Nutrition for Healthy Living</b> By Susan Calvert Finn, Perigee/Berkley, 1997	\$14.00	0-399-52342-1	Written by ADA's chairperson for the Nutrition and Health Campaign for Women, this book offers advice on everything from basic nutrition and fitness to disease prevention throughout a woman's life.

**PREMIER Intervention Manual of Procedures**

<b>Title</b>	<b>Price</b>	<b>ISBN</b>	<b>Description</b>
<b>Monthly Nutrition Companion: 31 Days to a Healthier Lifestyle</b> By Registered dietitian Roberta Larson Duyff. Chronimed, 1997	\$10.95	0-471-34688-8	A pocket-size book which is part of the Nutrition Now Series. It tells readers how to create and carry out their own plan for better health.
<b>Carbohydrates: What You Need to Know</b> By The American Dietetic Association Chronimed, 1998	N/A	1-565-61144-6	Frequently asked questions about carbohydrates are covered by registered dietitian, Marsha Hudnall, who clears up the confusion about what are carbohydrates, who needs them, and how they affect our bodies.
<b>Snacking Habits for Healthy Living</b> By The American Dietetic Association. Chronimed, 1997	\$8.95	0-471-34704-3	In this book, part of the Nutrition Now Series, registered dietitian Jean Storlie shows how snacking can be a healthful part of anyone's diet. The appendix provides calorie, fat, and fiber values of snack foods.
<b>The Supermarket Guide</b> By The American Dietetic Association. Chronimed, 1997	\$8.95	0-473-34707-8	Written by registered dietitian Mary Abbott Hess and included in the Nutrition Now Series, this pocket-size book gives tips on reading labels, choosing foods that best fit a healthful eating plan, food safety, and stretching food dollars.
<b>The Tufts University Guide to Total Nutrition</b> By the Tufts University Diet & Nutrition Letter. 2nd edition. Harper Collins, 1996	N/A	0-060-15918-9	Updated to address current nutrition concerns, this comprehensive book explains difficult nutrition concepts in an easy-to-understand fashion. Some sample menus and recipes are provided.
<b>Bowes and Church's Food Values of Portions Commonly Used</b> By Jean AT Pennington. 17th edition. Lippincott, 1998	\$36.00	0-397-55435-4	Often used as a professional resource, this book is a spiral-bound compilation of nutritional values of foods in a form that allows quick and easy reference. More than 8,100 foods are listed, including brand-name and popular fast food restaurant items. Many supplementary tables provide difficult-to-find data, such as amino acid content, vitamin E, purines, and more.

**PREMIER Intervention Manual of Procedures**

<b>Vitamins, Minerals, and Food Supplements</b> By The American Dietetic Association. Chronimed, 1996	\$5.95	1-565-61092-X	Written by registered dietitian Marsha Hudnall for the Nutrition Now Series, this pocket guide identifies circumstances for which supplementation may be warranted, and gives information that is helpful in choosing supplements. Specific information for each vitamin and mineral appears in the appendices.
<b>Beyond Food Labels</b> By Roberta Schwartz Wennik. Berkeley Publishing Group, 1996	\$13.95	0-399-52201-8	Written by a registered dietitian, this approach to healthy eating uses information available on food labels, particularly the % Daily Values. An extensive food section covering over 350 pages lists serving size, calories, and % DV for fat, saturated fat, and cholesterol.
<b>The Complete Book of Food Counts</b> By Corrine T. Netzer. 4th edition. MJF Books, 1997	\$7.50	0-440-22110-2	This is a large compilation of nutrient data for basic generic foods, brand-name foods, and restaurant chains. Entries are listed alphabetically, with values for calories, protein, carbohydrates, fat, cholesterol, sodium, and fiber.
<b>Herbs of Choice</b> By Varro E. Tyler. Pharmaceutical Products Press, 1994	N/A	1-560-24894-7	An internationally renowned authority on herbs presents factual information about the therapeutic use of plant chemicals.
<b>The Nutrition Bible</b> By Jean Anderson and Barbara Deskins. Morrow, 1997	\$17.00	0-688-15559-6	Co-authored by a registered dietitian, this comprehensive book gives straight answers to food and nutrition questions. It is organized alphabetically, and contains extensive nutrient content information.
<b>The Vitamin Pushers</b> By Stephen Barrett and Victor Herbert. Prometheus Books, 1994	\$29.95	0-879-75909-7	This is a revealing book by two physicians who have devoted much of their professional lives to combating health quackery.

***Internet Resources List***

Below is a detailed list of web sites and what's found in each.

1. <http://www.fatfree.com>
  - Low fat/fat-free vegetarian recipes, books, USDA database, general info
2. <http://www.saltinfo.com/home.htm>
  - salt production, food, health, history

## PREMIER Intervention Manual of Procedures

3. <http://www.nih.gov>
  - health info from the National Institutes of Health
4. <http://www.westmont.edu/Ayoub/biolink/HealthLinks.html>
  - internet health resources
5. <http://www.healthfinder.gov>
  - links to more than 550 health web sites
6. <http://www.healthlines.com/fatab.htm>
  - weight loss, mgmt, dieting, sports & fitness, education
7. <http://www.medscape.com>
  - online resource for better patient care
8. <http://www.eatright.org>
  - American Dietetic Asso links to other web sites
9. <http://www.pueblo.gsa.gov>
  - Consumer info on publications of many topics (not just health related)
10. <http://www.fda.gov>
  - Info from the U.S. Food and Drug Administration
11. <http://www.ncahf.org>
  - National Council Against Health Fraud
12. <http://www.cancer.org>
  - American Cancer Society
13. <http://www.oncolink.com>
  - Cancer info and links
14. <http://www.amhrt.org>
  - American Heart Association
15. <http://www.ama-assn.org>
  - American Medical Association
16. <http://www.healthatoz.com>
  - Health-related search engine
17. <http://www.navigator.tufts.edu>
  - Tufts Univ. Nutrition Navigator
18. <http://www.ificinfo.health.org>
  - The International Food Information Council Foundation
19. <http://www.mayohealth.org>
  - Mayo Health Oasis (of the Mayo Clinic)
20. <http://www.fao.org>
  - Food & Agriculture Organization
21. <http://www.dole5aday>
  - Interactive and educational sites by Dole
22. <http://www.fwfs.com>
  - Four Winds Food Specialists Cultural diversity as it relates to food and nutrition
23. <http://www.shapeup.org>
  - Shape Up America! Dedicated to weight and nutrition issues
24. <http://www.wheatfoods.org>

## **PREMIER Intervention Manual of Procedures**

- Wheat Foods Council provides info on common food fads
- 25. <http://www.eatsmart.org>
  - Washington State Dairy Council
- 26. <http://www.cyberdiet.com> and [nutrition.miningco.com](http://www.nutrition.miningco.com)
  - Hosted by a registered dietitian with info on diet and nutrition
- 27. <http://www.cspinet.org>
  - Center for Science in the Public Interest/Nutrition Action newsletter
- 28. <http://www.mymenus.com>
  - Includes info on menus and recipes
- 29. <http://www.os.dhhs.gov>
  - U.S. Dept. of Health and Human Services
- 30. <http://www.cdc.gov>
  - The Centers for Disease Control
- 31. <http://www.cnn.com/health>
  - CNN Health
- 32. <http://www.healthgate.com>
  - HealthGate---includes free Medline access
- 33. <http://www.diabetes.org>
  - American Diabetes Association
- 34. <http://www.livingbetter.cary.com>

### ***Field Trips***

The purpose of conducting field trips is to increase variety and attractiveness of the intervention program, anticipating that it may enhance participants' adherence.

#### ***Policy on Field Trips***

1. Even though each site may have access to different types of activities within their communities, the following list of examples should be used when possible to assure consistency of intervention. New suggestions or additional options not included in the following list should be submitted to the intervention committee for prior approval.
2. Field trips are limited to roughly two hours each and to activities requiring minimal cost.
3. Field trips are led or supervised by PREMIER staff members.
4. Field trips are arranged between the PREMIER interventionist and the participants. It should be a group choice.
5. Sites should follow their institutions' specific policy regarding transporting participants.
6. Field trips do not replace scheduled group sessions during phase I and II. During phase III, field trips may replace group sessions. All field trips follow a standardized format predetermined by the intervention committee. Physical activity groups



## **PREMIER Intervention Manual of Procedures**

arranged by subset of participants, such as a walking group, are not considered a field trip.

### *Examples of Field Trips*

- Local supermarket tour
- Structured walks
- Restaurant excursion
- Hiking
- Canoeing
- Participate in a volleyball tournament
- Kayaking
- Berry picking
- Local marathons (charity walks)
- 20 mile biking expedition
- Visit to historical sites/zoos, etc.
- Participate in local dance festivals.
- Swing dancing, ballroom dancing, etc.
- Jazzercise
- Skiing
- Play a new game, racquetball, squash, badminton, table tennis, etc.
- Roller skating
- Strength and flexibility training
- Gourmet cooking session

### *Videos*

Videos may be used to demonstrate activities, illustrate principles, or provide role model behaviors.

#### *Policy on Using Videos*

1. Videos featuring healthy eating or regular physical activity that agrees with the PREMIER lifestyle guidelines can be recommended to the participants.
2. Videos do not replace PREMIER intervention sessions.
3. During phase III of the intervention, videos suggested by interventionists or participants and that has been approved by the intervention committee can be used in the group session.

#### *Examples of Videos*

All about fat (16 minutes), VHS, JG47084, Health Edco  
Shop smarter (19 minutes), VHS, JG46569, Health Edco  
High blood pressure (30 minutes), VHS, JG47516, Time Life Medical series  
Heart-Healthy Eating (W67-0017); 10-12 minutes, American Heart Assoc.

## **PREMIER Intervention Manual of Procedures**

Heart-Healthy Exercise (W67-0018); 10-12 minutes, American Heart Assoc.  
Heart-Healthy Shopping (W67-0015); 10-12 minutes, American Heart Asso

### ***Policy on Using Other Resources***

Any additional resource that is not listed in this chapter should be submitted to the PREMIER intervention committee for prior approval.

**PREMIER Intervention Manual of Procedures**

<b>48. ADHERENCE, COMPLIANCE, AND RETENTION</b>	<b>3</b>
<b>PREMIER Philosophy</b> _____	<b>3</b>
<b>PREMIER Screening and Intervention</b> _____	<b>3</b>
<b>Techniques and Strategies for Reinforcing Adherence of Randomized Participant</b>	<b>3</b>
<b>Specific Participant Problems</b> _____	<b>4</b>
<b>Early Detection of Problems</b> _____	<b>5</b>

**PREMIER Intervention Manual of Procedures**

**Summary of Edits**

## **48. Adherence, Compliance, and Retention**

### ***PREMIER Philosophy***

After randomization, participants formally remain in PREMIER regardless of adherence. Noncompliance with study requirements does not permit censure of their data and they cannot be replaced by another participant. This intention to treat design makes the adherence of every intervention participant critical to the success of the study.

Strategies for improving adherence in PREMIER B and C should be positive and focus on enhancing participant motivation for making lifestyle changes and eliminating root causes for nonattendance and other compliance issues.

### ***PREMIER Screening and Intervention***

PREMIER participants pass through several phases from first contact to final close out. Each phase requires somewhat different approaches to monitor and encourage compliance. The first of these is the screening visit (SV) cycle. In this phase, potential participants are, among other things, repeatedly measured to assure that blood pressure remains within specified limits. Assuming that the participant does not meet an exclusion criterion, the SV cycle entails at least 4 contacts primarily with clinic staff. In this case, compliance is essentially maintained through telephone and written contacts.

The second phase begins with the intervention sessions. At this point, adherence to divides into two components; the clinic and intervention session requirements. These exist largely independently of each other, and, due to blinding issues, adherence issues in one component will need to be addressed without knowledge of performance in the other. This necessitates independent monitoring and reward systems be in operation for clinic and intervention session requirements.

Within the intervention, there are initial more intensive contact schedules for the first 6 months and then a more relaxed set of contacts for the final 12 months. Adherence issues may function somewhat differently for these two time periods. Clinic contact schedules are more uniform throughout the intervention period.

### ***Techniques and Strategies for Reinforcing Adherence of Randomized Participant***

Attendance at intervention sessions is essential to the success of PREMIER. Failure to attend a scheduled session should trigger an immediate contact from intervention staff. This conversation, preferably via telephone, should gently probe the reason for nonattendance and, if possible, lead to participant commitment to attend the next session. In addition, a plan for reducing future non-adherence should be explored. Form 43 (for B) or form 44 (for C) is used to document these follow-up contacts as well as document attendance at scheduled sessions.

## **PREMIER Intervention Manual of Procedures**

Previous studies have shown that quick response to each unannounced absence decreases the risk of dropping out. In serious cases, special individual counseling sessions may be used for troubleshooting adherence barriers.

For most participants, social support of the group, and support from the interventionists will be the most powerful reinforcers for adherence. Additional incentives should also be used at clinical sites to recognize past and encourage future adherence. These could be rewards of nominal value such as t-shirts, coffee mugs, certificates of achievement, reduced price coupons at local stores, etc. In all cases, these incentives should be used to reinforce attendance and participation, rather than as rewards for achievement of study goals (e.g., weight loss, improved diet/physical activity, etc.). As noted, the incentive structure will need to function separately for the clinic and intervention components. It is recommended that a schedule of incentive administration be established prior to intervention, but this schedule can be altered to best-fit specific circumstances.

### ***Specific Participant Problems***

Inevitably, some cases of protracted non-adherence will occur. These will fall roughly into two categories: unforeseen and unavoidable conflicts for an otherwise willing participant (for example a major illness or moving out of town), or noncompliance with no apparent external cause. In the first instance, efforts to address and accommodate the participant should be explored to see if a satisfactory schedule of attendance or alternative intervention contacts could be devised. If not, with due notification of the local PI and the PREMIER CC, a participant may be excused from study activities until obstacles to participation have been removed. Hopefully these participants will be able to reenter intervention activities at a later date.

In the latter case, when participants report losing interest or “not having the time” to participate in intervention activities, contacts with the participant should focus on enhancing participant motivation to make lifestyle changes and helping them develop a plan for resuming intervention. These intervention contacts could be by telephone or in individual counseling sessions. If noncompliance continues, additional options include a complete case review by the local intervention team and consultations with senior PREMIER staff.

Note that participants who drop out of intervention may return at a later date. Although note to be used frequently, there may be situations in which a planned break from intervention participation may be negotiated with the interventionists. Special attention should be paid to punctual follow-up after these planned breaks.

Efforts to encourage the return of a non-compliant individual to the PREMIER program should continue in a fashion consistent with an informed assessment and the staff’s judgement of the likelihood of success. Randomized participants who unilaterally drop out of the program should also be informed that their return to study sessions is encouraged.

## **PREMIER Intervention Manual of Procedures**

### ***Early Detection of Problems***

It is, of course, desirable to identify and correct compliance issues as early as feasible. Every effort to identify potentially non-compliant individuals should be made before randomization. Effort should be made to fully inform potential participants as to study expectations and schedules frequently during the screening visit cycle. Staff judgement as to the reliability of potential participants should be also considered in the process of deciding whether to allow randomization.

Case conferencing of all participants should be a regular aspect of the PREMIER B and C interventions.

After randomization, ongoing monitoring and frequent evaluation of individual compliance is crucial and should be a routine element of staff meetings. Study wide conference calls and periodic face to face meetings should also address the issues of adherence.

**PREMIER INTERVENTION Manual of Procedures**

<b>49. INTERVENTION TRAINING</b>	<b>3</b>
<b>Introduction</b> _____	<b>3</b>
<b>Training Objectives and CE</b> _____	<b>3</b>
<b>Training Activities</b> _____	<b>3</b>
<b>Training Topics:</b> _____	<b>4</b>



## **PREMIER INTERVENTION Manual of Procedures**

### **Summary of Edits**

4/18 - Added five recommended elements for training new intervention staff. (Per Steering Committee Minutes #74)

5/1 - Page 3: Grammar edits in #5 of recommended training elements. Updated date and version to 1.2

## **PREMIER INTERVENTION Manual of Procedures**

### **49. Intervention Training**

#### ***Introduction***

The coordinating center is responsible for organizing and conducting intervention training activities including annual intervention training meetings for all PREMIER interventionists. Training is developed and delivered according to the needs identified during site visit reviews.

The Intervention Director at each site is responsible for the training of new staff hired during the course of the study. Local training of new Intervention staff should include but is not limited to the following elements.

1. Reading all related Intervention materials, including the study protocol.
2. Observing (using the observation checklist) an experienced PREMIER interventionist facilitating group sessions. Debrief with the interventionist after each observation.
3. Co-facilitate group sessions with an experienced PREMIER interventionist and debriefing after each session.
4. Be observed (using the observation checklist) facilitating group sessions by an experienced PREMIER interventionist. Debrief after each observation.
5. Participate in training that is focused on "Motivational Interviewing" including self-education by reading "Health Behavior Change, a Guide for Practitioners." Rollnick, Mason and Butler.

#### ***Training Objectives and CE***

Training conducted for the PREMIER Intervention will have stated training objectives. When appropriate, the coordinating center will apply for continuing education credits from the American Dietetic Association.

#### ***Training Activities***

Training activities include, but are not limited to the following.

- Conference calls
- Face to face meetings
- Recommended reading
- Recommended practice
- Individual observation and feedback

Trainers are knowledgeable about the PREMIER study and have expert knowledge in the area for which they are training. Trainers include, but are not limited to, Intervention Committee members with expertise in specific areas, study consultants and outside experts.

## **PREMIER INTERVENTION Manual of Procedures**

### ***Training Topics:***

Topics for training are determined on an “as needed” basis according to the needs identified from site visit review, interventionist request, and at the direction of the steering and intervention committees.

Topics will include but not be limited to the following:

Intervention Related Screening Activities

PREMIER A Intervention

PREMIER B and C Individual Visits

Group Session Implementation and Group Facilitation Skills

Motivational Enhancement Counseling

Behavior Change

Physical Activity

Minority Participants

Data Collection

**PREMIER Intervention Manual of Procedures**

<b>51. INTERVENTION QUALITY ASSURANCE</b>	<b>3</b>
<b>Overview</b> _____	<b>3</b>
<b>Written intervention materials</b> _____	<b>3</b>
<b>Intervention directors</b> _____	<b>3</b>
<b>Trial-wide training meetings</b> _____	<b>3</b>
<b>Telephone conference calls</b> _____	<b>3</b>
<b>Monthly review of intervention adherence data</b> _____	<b>4</b>
<b>Intervention site visits</b> _____	<b>4</b>
<b>Local quality control procedures</b> _____	<b>4</b>

**PREMIER Intervention Manual of Procedures**

**Summary of Edits**

## **PREMIER Intervention Manual of Procedures**

### **51. Intervention Quality Assurance**

#### *Overview*

This chapter describes the procedures that will insure that the PREMIER interventions are delivered using a standardized protocol. These quality control procedures are also used to help the interventionists and investigators monitor ongoing intervention progress and identify potential adherence problems. These procedures include:

- Use of written guidelines for each session
- Identification of an intervention director at each site
- Annual training meetings for all interventionists
- Frequent telephone conference calls for all interventionists
- Monthly review of key intervention adherence measures
- Annual intervention site visits at each clinical center by the CC
- Local quality control procedures

#### *Written intervention materials*

Written guidelines for each group and individual session are provided. Interventionists use these materials in providing the same intervention to participants at each clinical center. Separate sets of intervention materials are provided for participants in PREMIER A, PREMIER B, and PREMIER C. The materials are color coded to assure distribution to, and use for, the correct group. See IMOP Chapter 23, Leader's Guides, for more information about the procedures and use of the written leader's guides.

#### *Intervention directors*

Each clinical center PI identifies an intervention director for their site. The intervention directors are responsible for overseeing all intervention activities at their site and are responsible for insuring that the interventions are delivered according the PREMIER protocol and manual of procedures. Intervention directors should be knowledgeable and experienced in behavior change and group facilitation, as well as nutrition education.

#### *Trial-wide training meetings*

The coordinating center is responsible for organizing and conducting annual intervention training meetings for all PREMIER interventionists. The first intervention training meeting will be conducted in December, 1999.

#### *Telephone conference calls*

The coordinating center schedules regular conference calls for all PREMIER interventionists. The purpose of these calls is to review and answer questions regarding the written materials and

## **PREMIER Intervention Manual of Procedures**

plans for intervention sessions, discuss problems encountered in delivering the intervention, review intervention adherence reports, and help each other in developing plans for special intervention problems. For cohort 1, there will be weekly conference calls during phase 1. The schedule of conference calls for later cohorts will be determined based on experience with cohort 1. Additional conference calls may be scheduled as needed by the intervention committee chair.

### ***Monthly review of intervention adherence data***

The coordinating center prepares monthly reports on intervention adherence based on data obtained from intervention sessions and self-monitoring forms (overall and broken down by clinical center, race and gender). These reports are available to all project investigators and interventionists on the PREMIER Web site. Interventionists discuss these reports on their regularly scheduled conference calls. The adherence information on food intake comes from the food diaries and information on physical activity comes from the physical activity diaries. Both diaries are part of the Food and Fitness Diary. The content of these reports includes:

- Meeting attendance (PREMIER A, B, & C)
- Missed visits contacts (PREMIER B & C)
- Mean weight change (from randomization weight) (PREMIER B & C)
- Mean number of days per week of physical activity diaries (PREMIER B&C)
- Mean physical activity points per week from physical activity diaries (PREMIER B & C)
- Mean number of food diaries per week (PREMIER B & C)
- Kcal/day from food diaries (PREMIER B & C)
- mg sodium from food diaries (PREMIER B & C)
- Number of servings of F,V, & D from food diaries (PREMIER C)
- g total fat from food diaries (PREMIER C)

### ***Intervention site visits***

Each clinical center receives annual intervention site visits starting in project year 02. These site visits are led by an intervention expert from the coordinating center and also includes an interventionist from another clinical center. The site visitors review a number of procedures including record keeping, data collection and entry, and delivery of the intervention. Site visits are scheduled so that at least one group session can be observed by each interventionist. Written reports from the site visits are provided to the steering committee as well as the intervention director of the visited center.

### ***Local quality control procedures***

Each site is responsible for the development and implementation of local quality control procedures. These should include but not be limited to: interventionist observation of each other, regular observation by the site PI, observation and regular involvement by the site intervention director, behavior-change skills development, and regular access and consultation with a behavior change expert.

**PREMIER Intervention Manual of Procedures**

<b>52. INTERVENTION EVALUATION</b>	<b>3</b>
<b>Interventionist Session Process Evaluations (see attached)</b> _____	<b>3</b>
<b>Participant Evaluation</b> _____	<b>3</b>
<b>Focus Groups</b> _____	<b>4</b>
<b>Intervention Adherence Data</b> _____	<b>4</b>
<b>Cohort 1 Debriefing</b> _____	<b>4</b>
<b><u>PREMIER INTERVENTION SESSION EVALUATION</u></b>	<b>5</b>



**PREMIER Intervention Manual of Procedures**

**Summary of Edits**

## **PREMIER Intervention Manual of Procedures**

### **52. Intervention Evaluation**

Components of the evaluation include process, adherence and outcome. Evaluations are conducted at two levels: 1) trial wide: a) by treatment group and b) by treatment group for each cohort; 2) clinical center: a) by treatment group and b) by treatment group for each cohort.

Process evaluation includes information collected from the intervention staff and from participants for each cohort. Information is used to refine study process, and describe the intervention. Data is used in PREMIER manuscripts and reports to the Steering Committee.

#### ***Interventionist Session Process Evaluations (see attached)***

- During Cohort I, following each session – the interventionist who conducted the session completes the Intervention Session Evaluation form: The form is completed (typed) and forwarded electronically to the CC within 7 days after that session.
- These forms are completed for each session in Cohort 1. Following Phase 1 of Cohort 1, it is determined if these forms will be completed for subsequent cohorts. A condensed interventionist evaluation (covering several sessions at a time) may be developed for Phase II & III and for cohorts 2-4.
- The Evaluation Subcommittee (EC) reviews and prepares a summary of common themes and major issues. At the completion of Phase 1 for Cohort 1, a report is prepared by the IC Chair and EC for the Steering Committee. Similarly, a report follows Phase II and Phase III would be prepared.
- Intervention comments are discussed on IC conference calls. Questions and implementation/organizational issues are resolved as appropriate on these calls.

#### ***Participant Evaluation***

A written Participant Evaluation is completed by all participants in all cohorts at the end of Phase 1, and at the end of the study. These evaluations are used 1) to make general modifications study wide, or at a specific center; 2) in manuscripts to describe the intervention process evaluation; and 3) to guide planning for any follow-up, and to guide activities for each subsequent phases and cohorts.

Data summaries are prepared for each questionnaire for each cohort and each site. Additional summaries are prepared by gender and ethnicity.

Each site summarizes the open-ended questions and forwards an electronic copy of this summary to the CC.

## **PREMIER Intervention Manual of Procedures**

### ***Focus Groups***

Focus groups may be considered as ancillary study projects, or as individual field center options.

### ***Intervention Adherence Data***

These data include attendance, completion of self-monitoring records, self reported dietary intake [of calories, fat, sodium, fruits and vegetables, dairy (for Group C only)], physical activity, and weight.

These data are summarized by cohort, by phase, and by site. Summaries by gender, ethnicity and age may also be prepared. These data used by the IC Chair, IC and the EC to prepare reports for SC.

Procedures and processes regarding these data have been described in Chapters 45 and 51.

### ***Cohort 1 Debriefing***

A debriefing of each Phase of Cohort 1 prepared for the SC by the IC Chair and the EC, including information from IC calls, and intervention site visits.

**PREMIER Intervention Manual of Procedures**

**PREMIER Intervention Session Evaluation**

Date:_____
Site:_____
Group (B or C):_____
Session #:_____
Interventionist:_____

**1. How long did the entire session last?**

**How much time did it take to do follow-up after the session? (Contacting people, etc.)**

**Were there any attendance problems? If yes, how are you handling these?**

**2. How well did the participant check-in process work?**

**Any problems with completion of Data Collection Form and transferring data from *Food & Fitness Diary*?**

**3. How well did the Taste-It component work?**

**How long did it take to prepare for Taste-It?**

**What was served or demonstrated?**

**What were the participant questions and responses?**

**4. How well did the content, flow, and structure of the rest of the session work?**

**Debriefing?**

**Worksheets / Try-It?**

**Physical Activity?**

**Small group discussions?**

## **PREMIER Intervention Manual of Procedures**

**Next steps?**

**Did you have suggestions for improving the flow?**

**Were there things you did not get to cover?**

**What?**

**Why Not?**

**5. How well is the Self-Monitoring Component working for participants?**

**What problems are participants encountering?**

**How are participants using the action plan and goal setting?**

**6. How is increasing fruit and vegetable component going for participants?**

**7. How well is the Physical Activity Component working for participants?**

**8. Facilitation/Counseling – Are there any questions you have about how to handle specific participant questions, topics, or problems?**

**9. Leader’s Guide - Is there anything missing and what would you change?**

**10. Overall, what are participants’ responses to the program and what are the major questions raised by participants?**

**PREMIER Intervention Manual of Procedures**

<b>53. SITE SPECIFIC MATERIALS</b>	<b>3</b>
<b>Philosophy and purpose of site specific materials in PREMIER</b> _____	<b>3</b>
<b>Other site specific materials procedures</b> _____	<b>3</b>
<b>Criteria for developing site-specific materials</b> _____	<b>3</b>

**PREMIER Intervention Manual of Procedures**

**Summary of Edits**

## **53. Site Specific Materials**

### *Philosophy and purpose of site specific materials in PREMIER*

Locally developed materials must complement or enhance, and not replace, materials intended for use at all sites. No prior approval is necessary for providing additional materials, but they must be shared with other sites prior to use.

### *Other site specific materials procedures*

- Sites do not have to be consistent regarding locally provided incentives.
- Newsletters: clinical centers may use their own in-house procedures to develop and distribute participant newsletters.
- Recipes: just follow Taste-It! recipe guidelines, no prior approval needed.
- Caution: Review handout material carefully to make sure it is consistent with the PREMIER protocol. If there is any question, ask for review by the intervention committee.

### *Criteria for developing site-specific materials*

- Match PREMIER group content philosophy.
- Cannot decrease distinction between PREMIER B & C, ie., PREMIER C's fruit and vegetable and dairy emphasis is not given to PREMIER B.
- Meet an expressed need that is not met in existing materials.
- A copy of any locally developed material should be shared with all other sites AND the coordinating center.



**PREMIER Intervention Manual of Procedures**

<b>54. FOOD HANDLING</b>	<b>3</b>
<b>Description</b> _____	<b>3</b>
<b>Food Safety</b> _____	<b>3</b>
Safe Food Storage _____	3
Safe Food Handling _____	4
Safe Food Preparation and Serving _____	4

**PREMIER Intervention Manual of Procedures**

**Summary of Edits**

## **54. FOOD HANDLING**

### *Description*

Participants assigned to PREMIER B & PREMIER C study arms will be tasting and/or receiving foods that have been stored and/or prepared at each clinic site. The issues of food safety, storage and serving are important. To insure that all clinic sites follow proper procedures, participants are protected from any food-borne illness when being offered foods in conjunction with class participation.

### *Food Safety*

Food safety is a serious concern in any study that serves food to its participants. Each clinic site is responsible for implementing appropriate procedures to protect participants from any food-borne illness. Critical areas of control are in the flow of food production, from raw materials to finished products, where loss of control can result in an unacceptable food-safety risk. Critical areas to be addressed include treatment of foods, personal hygiene and health of the food handlers, and participants' handling of foods eaten on-site.

### *Safe Food Storage*

Once the procurement of fresh foods has taken place, the next step is to ensure proper storage. The following principles apply to the storage of all types of foods:

- Follow the First-in-First-Out rule (FIFO). Date new foods and place them behind existing products to help assure the use of the oldest product first.
- Use only designated areas for food storage space. Keep storage areas clean and dry.
- Store only food packages and wrappers that are clean, free from spills, and intact.

### Dry Food Storage

Store dry food goods in an area that is well ventilated, dry, clean, well lighted, and free from pests and excessive heat. The ideal temperature for extended shelf life of dry storage is 50 degrees F. Most dry products will remain safe at temperatures of 60 to 70 degrees F with a relative humidity of 50 – 60 percent. All food items should be stored off of the floor.

### Refrigeration Storage

To prevent food-borne illness outbreaks, store and maintain cold food items at 36 to 40 degrees F. To avoid cross-contamination, store raw foods below cooked foods and foods that will receive no further cooking. Cover all foods in the refrigerator. The refrigerator should not be

## **PREMIER Intervention Manual of Procedures**

overloaded to ensure proper holding temperatures and good air circulation. Monitor refrigeration temperatures in each unit used on-site.

### Freezer Storage

Freezer temperature must be maintained at or below 0 degrees F. Storage between minus 10 to 0 degrees F is strongly recommended to ensure high food quality. Only frozen or pre-chilled items should be placed in the freezer units. Adequate space in the freezer is necessary to provide proper air circulation. Monitor freezer temperature in each unit used on-site.

### *Safe Food Handling*

The food handler's good personal hygiene is a protective measure against food-borne illness.

### Hand Washing

Frequent and thorough hand washing is the most critical aspect of personal hygiene. Food handlers must wash their hands frequently using soap and warm water. They must dry their hands with paper towel and dispose.

### Health

Food handlers who have visible symptoms of illness (e.g., sore throat, colds) are a risk to food safety and should not engage in food production until symptoms are cleared.

### Uniform

Food handlers should use clean aprons and hair restraints should be worn at all times. These can include hair nets, headbands, barrettes, hats, or cap. The restraint should cover all hair.

### *Safe Food Preparation and Serving*

When food is being prepared, be sure the working surface area and utensils are clean and sanitized. When thawing frozen foods, the ideal way is to defrost frozen foods under refrigeration. When using cold food items for preparation, it is essential to check expiration dates and freshness. Use FIFO food rotation. Never use a food item when freshness and/or safety are in question: "When in doubt, throw it out."

**PREMIER Intervention Manual of Procedures**

<b>55. SIGNIFICANT OTHERS</b>	<b>3</b>
<b>Definition of significant others for PREMIER purposes</b> _____	<b>3</b>
<b>Background on role of significant other in counseling activities</b> _____	<b>3</b>
Advantages of inclusion of significant others _____	3
Disadvantages of inclusion of significant others _____	3
<b>Significant Others in PREMIER</b> _____	<b>3</b>

**PREMIER Intervention Manual of Procedures**

**Summary of Edits**

## **55. Significant Others**

### *Definition of significant others for PREMIER purposes*

A significant other is a family member, spouse, or close friend, who is intimately involved in the participants' day to day activities.

### *Background on role of significant other in counseling activities*

Wing and Jeffery (1999) studied 166 subjects either alone or with 3 friends/family members using standard behavioral treatment for weight loss and maintenance. Those with social support had greater weight losses at the 4-months and 10-month follow-ups. Those with social support completed 95% of the treatment, with 66% maintaining their weight loss. Among those without social support, 76% completed the treatment and 24% maintained their weight loss.

In light of data demonstrating the importance of social support, the general philosophy for PREMIER is to do whatever is appropriate to engage friends and families in supporting participants making lifestyle changes. In defining participant support systems, consideration should be given to defining these more broadly than a spouse or a "significant other." This is based on the observation that African Americans, and perhaps other minorities, utilize a greater variety of social support systems to conduct their daily lives than do European cultures (Resnicow et al. 1999).

### *Advantages of inclusion of significant others*

- a good social/family support system may help participants focus on their goals (weight loss/changing habits, etc.)
- the significant other may assure that the participant attends classes and fulfills other requirements of the protocol

### *Disadvantages of inclusion of significant others*

- participants may not take charge of their own health behaviors
- inclusion of significant others may dilute intervention resources for randomized participants

### *Significant Others in PREMIER*

Some sort of commitment needs to be procured from each significant other who wants to be involved in the study. PREMIER needs to be assured that involvement by the significant other will not in any way impede the success of the intervention. The inclusion of the significant other must be determined on an individual basis.

The significant other will not be required to attend group sessions, but may be allowed to attend sessions, provided the attendance is positive. If the attendance of any significant other proves to be disruptive to the sessions, they will be asked not to participate.

## **PREMIER Intervention Manual of Procedures**

We will not include significant others in individual sessions. Politely inform the significant other that you need to “talk to participant first” and arrange to speak with them later, if necessary

Activities to engage social support can be site-specific. It may be worthwhile to solicit ideas from participants on how best to engage their support systems. An example of an activity that engages participants support systems is a “family day.” This can be a festive invitation for families to learn about PREMIER. Participants may enjoy planning the family day with the PREMIER staff facilitating the process. Family days are best planned to coincide with the beginning, middle, and latter stages of the study. The beginning of the study explicitly solicits support from families. Latter meetings check on progress, share support ideas, and model target behaviors.



**PREMIER Intervention Manual of Procedures**

<b>56. MINORITY IMPLEMENTATION</b>	<b>3</b>
<b>Cultural Adaptation of the Intervention</b>	<b>3</b>

**PREMIER Intervention Manual of Procedures**

**Summary of Edits**

## **56. Minority Implementation**

### ***Cultural Adaptation of the Intervention***

There is a high priority placed on developing the PREMIER lifestyle intervention to be - appropriate for African Americans, a group at high risk for hypertension and obesity. To this end, a Minority Implementation Committee meets regularly and reviews all intervention plans and materials.

Previous studies have led to the identification of strategies that are incorporated into the design of the PREMIER lifestyle interventions. Most if not all of these strategies are effective and important for all study participants, but may require particular attention by the Minority Implementation Committee to ensure that interventions are not inadvertently biased toward the dominant culture. These strategies include: 1) adequate minority representation at all levels of implementation (i.e., interventionists, investigators, etc.); 2) social support systems for participants; 3) effective communication, including demonstrations; 4) involvement of family and community; 5) participant input into study procedures and identification with study goals (“ownership”); and 6) food guides and other intervention materials that are consonant with the various cultures represented among study participants. Additionally, centers attempt to include African-American staff as part of the intervention team.

**PREMIER Intervention Manual of Procedures**

<b><u>57. CLOSEOUT</u></b>	<b>3</b>
<u>Purpose</u>	3
<u>End of Data Collection</u>	3
<u>Directly at the 18-month visit</u>	3
<u>Subsequent to the 18-month visit</u>	3
<u>End of Trial</u>	3
<u>Future Studies</u>	3

**PREMIER Intervention Manual of Procedures**

**Summary of Edits**

## **PREMIER Intervention Manual of Procedures**

### **57. Closeout**

#### *Purpose*

Closeout marks the end of clinical trial participation. See also Clinical MOP Chapter 16.

#### *End of Data Collection*

At the conclusion of 18-month data collection for each individual, participants receive a summary of their blood pressure and weight data. The structure and content of closeout activities are left largely up to the individual sites, but in all cases include personalized feedback, a summary of blood pressure and other clinical measurements, and advice on heart disease prevention by qualified staff (e.g. dietitian, nurse, health educator). Closeout activities can take place in the context of either an individual exit interview or group counseling session. Both types of events occur after all 18-month data collection has ceased for the individual(s). Clinical centers can make alternative arrangements to provide this information to participants who are not able or willing to attend the exit interview.

#### *Directly at the 18-month visit*

The participant receives a report generated at the conclusion of their last 18-month cluster visit. This report contains a summary of blood pressure and weight data that have been collected and entered. A certificate of completion is also generated at that time and presented to the participant. Additional counseling, group session, and/or individual visits may be provided according to local site procedures.

#### *Subsequent to the 18-month visit*

The participant is provided with a summary report including the baseline, six and 18-month lab, fitness and selected dietary recall data.

#### *End of Trial*

After analysis of the full trial, study participants are informed about the overall findings of the trial. This may occur in the context of an individual interview, group meeting, or mailing according to local site procedure.

#### *Future Studies*

Closeout plans and procedures occur regardless of plans for participation in future studies.

## PREMIER Intervention Manual of Procedures

<b>58. OBESITY AND WEIGHT LOSS</b>	<b>4</b>
<b>PART I. PREMIER WEIGHT LOSS RECOMMENDATIONS</b>	<b>4</b>
<b>Body Mass Index (BMI, kg/m<sup>2</sup>)</b> _____	<b>4</b>
<b>PREMIER BMI Cutpoints and Recommendations</b> _____	<b>4</b>
BMI ≥25 _____	5
BMI 20 to <25 _____	5
BMI 18.5 to L20 _____	5
<b>Effective Approaches to Weight Loss</b> _____	<b>5</b>
Goals _____	5
Behavior Change _____	5
<b>Effective Approaches to Maintaining Weight Loss (Relapse Prevention)</b> _____	<b>6</b>
<b>Preventing Weight Gain</b> _____	<b>6</b>
<b>Weight Loss Drugs</b> _____	<b>6</b>
<b>Weight Loss Diets</b> _____	<b>7</b>
Very Low-Calorie Diets (VLCD) _____	7
Diet Supplements _____	8
<b>PART II. BACKGROUND INFORMATION ON OBESITY AND WEIGHT LOSS</b>	<b>8</b>
<b>Health Risks of Obesity</b> _____	<b>8</b>
<b>Body Fat Distribution</b> _____	<b>9</b>
<b>Health Benefits of Weight Loss</b> _____	<b>9</b>
<b>Potential Adverse Effects of Weight Loss</b> _____	<b>10</b>
Gallbladder disease _____	10
Bone mineral density _____	10
<b>Weight Loss and Mortality</b> _____	<b>10</b>
<b>Weight Cycling</b> _____	<b>11</b>
<b>PART III. PHYSIOLOGIC ASPECTS OF WEIGHT LOSS</b>	<b>11</b>
<b>Energy Metabolism</b> _____	<b>11</b>

## **PREMIER Intervention Manual of Procedures**

<b>Body Composition</b> _____	<b>12</b>
Composition of Weight Loss_____	12
Daily fluctuation in body weight_____	13
Daily Deficit of 500 Kcal _____	13
<b>References</b> _____	<b>14</b>



**PREMIER Intervention Manual of Procedures**

**Summary of Edits**

## **58. Obesity and Weight Loss**

### **Part I. PREMIER Weight Loss Recommendations**

In 1998 the first national clinical guidelines for overweight and obesity in adults were published (NHLBI, 1998) to address the clinical and public health need. It was noted that the prevalence of overweight or obesity in adults is at an all-time high, that obesity is the second leading cause of preventable death in the United States, and that it is affecting children and adolescents at increasingly higher rates.

PREMIER recommends weight loss of 15 lb (7 kg) or more for individuals who are overweight. Because of likely recidivism over 18 months, the weight loss goal at the end of the trial is 10 lb (4.5 kg). The PREMIER BMI cutpoints for weight loss were developed to be consistent with the Clinical Guidelines.

#### ***Body Mass Index (BMI, kg/m<sup>2</sup>)***

A BMI table will help the interventionist and participant see their current BMI level and what level of BMI a participant would achieve with a given amount of weight loss. BMI is calculated from weight (in kilograms) and height (in meters):

$$\text{BMI} = \text{weight (kg)} / \text{height (m)}^2$$

To calculate BMI from height in inches and weight in pounds, the formula is:

$$\text{BMI} = [\text{weight (lb)} / \text{height (inches)}^2] \times 704.5$$

#### ***PREMIER BMI Cutpoints and Recommendations***

The following table summarizes the PREMIER goals for PREMIER B & C based on BMI:

<u>BMI</u>	<u>PREMIER Recommendations</u>
≥25.0	Minimum of 15 lb (7 kg) weight loss is actively promoted and behavioral counseling is provided in the intervention.
20 to L25	Weight maintenance (weight control, or prevention of weight gain) is recommended; behavioral counseling for weight loss is provided only upon request.

## **PREMIER Intervention Manual of Procedures**

18.5 to L20                      Weight maintenance is recommended. No behavioral counseling for weight loss is provided.

### *BMI $\geq$ 25*

Weight loss goal of 15 lb (7 kg) is recommended for individuals with BMI  $\geq$ 25. In general, weight loss of 15 lb (7 kg) for an individual with a BMI of 25 would reduce their BMI to 22-23. For example, a woman who is 65 inches tall and weighs 150 lb has a BMI of 25. Weight loss of 15 lb would reduce her BMI to 22.5. A man who is 70 inches tall and weighs 174 lb has a BMI of 25. Weight loss of 15 lb (7 kg) would reduce his BMI to 23. After achieving a weight loss of 15 lb (7 kg), individuals with BMI  $\geq$ 25 may proceed to set larger weight loss goals if they wish.

### *BMI 20 to $<$ 25*

These individuals are not considered at increased risk of mortality, although they may still be above a weight that used to be called “desirable”, which was the weight at which the lowest level of mortality was observed in insured people (Metropolitan Life Insurance, 1983). The main goal for individuals in this group is to not gain any additional weight during the 18 month trial. Thus weight control and weight maintenance are the preferred message for individuals in this BMI range. However, some participants may still be interested in losing some weight. If a participant with BMI in the range of 20-24.9 asks for help in losing weight, interventionists may provide behavioral counseling to accommodate them. The weight loss goals for these participants should be whatever is necessary to achieve a BMI of no less than 20.

### *BMI 18.5 to L20*

The Clinical Guidelines classify as underweight individuals with BMI  $<$ 18.5, and thus the lower BMI cutpoint for eligibility into PREMIER is 18.5. For individuals with between 18.5 and  $<$ 20, the goal is to not gain any additional weight. Weight control and weight maintenance are the only message for individuals in this BMI range, and no behavioral counseling for weight loss should be provided by interventionists because weight loss could result in an individual achieving a BMI  $<$ 18.5, which is considered underweight.

## ***Effective Approaches to Weight Loss***

### *Goals*

The methods for weight loss are outlined in the Leader’s Guide, Participant Manual, and Intervention MOP Chapters on the dietary and physical activity interventions. The overall study goal (for those with BMI  $\geq$ 25 is 15 lb (7 kg) weight loss at 6 months. To achieve that weight loss, participants should set realistic short-term goals that will gradually get them to a 15 lb (7 kg) weight loss. Small, slow changes at a rate of 1-2 lb (.5-1.0 kg) per week are recommended.

### *Behavior Change*

A combination of calorie-reduced, lower fat diet and increased physical activity is recommended for weight loss (NHLBI, 1998). A review of the literature suggested that participants can lose

## **PREMIER Intervention Manual of Procedures**

about 8-10% of their body weight over 6 months (NHLBI, 1998). Behavioral strategies are used to promote change in eating and physical activity behaviors. The specifics are dealt with in other Intervention MOP chapters (Chapter 31. Behavioral Strategies), and in the Leaders Guide and Participant Manual.

### ***Effective Approaches to Maintaining Weight Loss (Relapse Prevention)***

Although many people are able to lose weight, the major difficulty is keeping it off. Designing interventions to promote maintenance of weight loss and prevention of relapse remain the greatest challenge in obesity research. Several studies have examined the factors related to maintenance of weight loss, which include the following (Kayman et al., 1990; Perri et al, 1993):

- engaging regularly in physical activity
- continuing in intervention contact and attendance
- being conscious of behaviors
- using social support
- confronting problems directly
- using personally developed strategies to help themselves
- viewing less TV

In PREMIER, the intervention will be maintained throughout the entire 18 months. The greater the weight loss that is achieved early on, within 6 months, the greater the likelihood of having a discernible difference in weight between the intervention and advice only groups at 18 months. Continued group and particularly individual sessions are used to sustain behavioral strategies for the maintenance of the weight loss.

### ***Preventing Weight Gain***

Little research has been conducted on obesity prevention. Most likely the same principles used for weight loss also apply to weight control. Although reduction in caloric intake is not needed; healthy eating behaviors and regular physical activity are necessary for weight control and prevention of weight gain. The beneficial effects of physical activity in weight control and in promoting and maintaining weight loss has been a frequent finding among several types of studies. Physical activity has been found to be:

- related to lower body weight
- related to lower weight gain with age and over time
- related to less weight gain after smoking cessation in women
- related to weight loss over two years
- a predictor of successful weight loss and its maintenance

### ***Weight Loss Drugs***

Typically, weight loss drugs are not given to patients unless their BMI is  $\geq 30$  with no risk factors or  $\geq 27$  with risk factors. The drugs tend to be only modestly effective (2-10 kg) in producing

## **PREMIER Intervention Manual of Procedures**

weight loss over and above what diet and physical activity can achieve and most of the weight loss usually occurs in the first 6 months of therapy. Recidivism and lack of compliance occurs with weight loss drug regimes. When drugs are discontinued, weight regain occurs.

Currently, only two prescription drugs are approved by FDA for weight loss: Sibutramine (Meridia) and Orlistat (Xenical). Sibutramine acts like a stimulant (inhibits reuptake of the neurotransmitters norepinephrine, dopamine, and serotonin) and increases heart rate and blood pressure. Therefore it is not recommended for people with high blood pressure and would not be appropriate for any PREMIER participant since the goal of the trial is to reduce blood pressure.

Orlistat inhibits fat digestion and absorption. It may decrease absorption of fat-soluble vitamins, and soft stools and anal leakage have been reported. There have also been some reports of breast cancer among women taking Orlistat.

Over-the-counter drugs include phenylpropanolamine (Acutrim, Dexatrim), which act like a stimulant, and have been shown in short-term studies to produce modest weight loss of 1.5 kg more than placebo after 8 weeks. Few long-term (>1 year) studies have been conducted on these over-the-counter drugs.

Taking weight loss drugs is an eligibility exclusion for PREMIER. However, if participants who are already entered into the trial ask about taking weight loss drugs, they should be discouraged, or if they begin taking these drugs, they should be asked to stop taking them.

The following points should be covered when participants ask about taking weight loss drugs to help them lose weight.

- Lifestyle (nonpharmacological) intervention should be the first step in treating obesity.
- Weight loss drugs have side effects.
- Weight loss drugs generally have been tested for safety and efficacy for only 1 to 2 years year.
- Weight loss drugs are effective for only as long as they are being taken and thus require life-long compliance.
- Weight loss drugs are only modestly more effective than diet and physical activity in producing weight loss.
- Weight loss drugs require medical follow-up with a physician.

### ***Weight Loss Diets***

#### *Very Low-Calorie Diets (VLCD)*

These diets typically provide 400-800 kcal/day, and should be taken only on a short-term basis. People on VLCDs should be medically supervised. While substantial and rapid weight loss occurs in the short-term, after 6-12 months weight loss tends to be only 1-10 kg better than on standard low-calorie diets. After 1 year, there is no difference in weight loss between VLCD and regular low-calorie diets. Also, increased risk of gallstones has been associated with VLCD.

## **PREMIER Intervention Manual of Procedures**

**PREMIER participants should not follow VLCDs because there is no overall benefit and there are risks.**

### *Diet Supplements*

Some diet supplements like Slim-Fast are liquid drinks packaged in cans. One can has 325 ml (about 11 fl oz) containing 220 kcal, 3 g fat, 1 g saturated fat, 220 mg sodium, 10 g protein, and 5 g fiber. Other products are powder to which 8 oz water is added (e.g., Pounds Off, Slim Fast), containing 210 kcal, 5 g fat, 2.5 g saturated fat, 150 mg sodium, 11 g protein, 3 g fiber. These products are marketed as meal replacements for 1-3 meals a day. They usually have added vitamins and minerals. Their long-term effectiveness in producing weight loss has not been tested. Since long-term weight loss and weight control require permanent lifestyle behaviors related to dietary choices and physical activity, use of supplements do not lend themselves to lifestyle changes. **PREMIER participants should not use supplements instead of meals to promote weight loss because behavioral theory underlying the intervention cannot be utilized and the supplements have not been shown to be effective long-term.**

## **Part II. Background Information on Obesity and Weight Loss**

### *Health Risks of Obesity*

Information on the health risks of obesity and the health benefits of weight loss is summarized in the NHLBI Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults (1998). The most recent National Health and Nutrition Examination Survey (NHANES III), 1988-94, reported that 59.4% of men and 50.7% of women in the U.S. are overweight (BMI 25.0-29.9) or obese (BMI  $\geq 30$ ), and the prevalence is much higher in African American women, at 66.0%. Moreover, the prevalence of overweight or obesity (BMI  $\geq 25.0$ ) has increased over the last decade (NHANES II, 1976-80) by 15% for men and 25% for women.

In most epidemiologic studies, mortality begins to increase at BMI of 25 kg/m<sup>2</sup>, and at BMI of 30 kg/m<sup>2</sup> or greater it begins to rise more sharply. Mortality rates, especially those from cardiovascular disease, increase by 50% to 100% at BMIs of 30 kg/m<sup>2</sup> compared to BMIs of 20-25 kg/m<sup>2</sup>. These mortality data are the basis for the Clinical Guidelines definitions for overweight (BMI  $\geq 25$ ) and obesity (BMI  $\geq 30$ ). There are fewer data available for African-Americans. Based on three small cohort studies, the increase in mortality begins at 1-3 kg/m<sup>2</sup> higher BMI for African Americans than Whites; however, the use of the cutpoints of BMI  $\geq 30$  kg/m<sup>2</sup> for defining obesity is applicable to African-Americans as well as to whites.

Cardiovascular disease risk factors increase with increasing obesity: blood pressure, total cholesterol, LDL-C, HDL-C (inverse), triglycerides, glucose, and insulin. Above BMI of 20 kg/m<sup>2</sup>, several health conditions increase with increasing BMI. Most striking is the progressive increase in the prevalence of high blood pressure (SBP >140 mm Hg, DBP >90 mm Hg, or taking antihypertensive medications) with increasing BMI. Adults with a BMI  $\geq 30$  have double

## **PREMIER Intervention Manual of Procedures**

the risk of developing hypertension compared to adults with a BMI <25. The large international INTERSALT study conducted in over 10,000 adults observed that 10 kg (22 lb) higher weight is associated with 3.0 mm higher SBP and 2.3 mm higher DBP, resulting in an estimated 12% increased risk for coronary heart disease and 24% increased risk for stroke.

Higher prevalence of dyslipidemia occurs with higher BMI in men and women. Thus, compared to BMI <25, there is increased prevalence of high total cholesterol ( $\geq 240$  mg/dL), high LDL-cholesterol ( $\geq 160$  mg/dL), low HDL-cholesterol (<35 mg/dL for men and <45 mg/dL for women), and higher triglycerides in adults with BMI >30. A 10 kg/m<sup>2</sup> higher BMI has been associated with 10-20 mg/dL higher LDL-cholesterol, which in turn is associated with a 10% increased risk in coronary heart disease over a period of 5 to 10 years.

Higher BMI has been associated with increased risk of diabetes (25% increased risk for each additional BMI unit > 22 kg/m<sup>2</sup>), coronary heart disease (double risk at BMI of 25-28.9 compared to BMI < 21), congestive heart failure, stroke (75% increased stroke risk in women at BMI >27 compared to BMI <21), gallstones (from 50% up to 7-fold increased risk at BMI 26-45+ compared to BMI <24), osteoarthritis (9%-13% increased risk for every kg higher weight in women), sleep apnea, and certain cancers such as colon cancer, postmenopausal breast cancer, endometrial cancer, and gallbladder cancer.

Obesity has also been related to adverse psychosocial outcomes. Social stigmatism and discrimination, psychopathology and emotional distress, binge eating disorder, and disturbances in body image have all been associated with obesity, particularly in women.

### ***Body Fat Distribution***

Evidence has accumulated that the location of body fat is an important disease risk factor, although the degree to which the risk is independent of overall obesity is still unclear. The first major longitudinal study, conducted in Sweden, showed that the waist-to-hip ratio (WHR), an indicator of central obesity, was directly associated with mortality in men and women, and that this relationship was true at all levels of BMI. Other studies subsequently found central obesity to be directly related to heart disease, diabetes, hypertension, and some forms of cancer (Bray, 1998). Weight reduction is usually accompanied by reduction in waist circumference, although not necessarily WHR. **PREMIER will not be focusing on body fat distribution, as there is no known way of differentially reducing body fat in specific locations.**

### ***Health Benefits of Weight Loss***

Randomized controlled trials of weight loss have demonstrated that disease risk factors are reduced with weight loss. By reducing risk factors, the likelihood of developing disease is reduced. The evidence for the beneficial effects of weight loss or risk factors is strongest and most consistent for blood pressure. Randomized, controlled trials have shown that weight loss is associated with reduction in blood pressure in both hypertensive individuals and individuals without hypertension. In the Trial of Antihypertensive Interventions and Management (TAIM) a

## **PREMIER Intervention Manual of Procedures**

mean 10-lb weight loss was associated with a reduction of 2.8 mm Hg SBP and 2.5 mm DBP in hypertensive individuals. In nonhypertensive individuals, the Trials of Hypertension Prevention (TOHP I and II) observed that 10 lb weight loss was associated with a reduction of 3 mm Hg SBP and 2.0-2.5 mm DBP. The greater the weight loss the greater the blood pressure reduction, and as long as weight loss was maintained, blood pressure remained reduced. Moreover, the incidence of hypertension over three years was reduced by 20% (TOHP II).

Randomized controlled trials have demonstrated that weight loss reduces total cholesterol, LDL-cholesterol, and triglycerides, and increases HDL-cholesterol. A mean 9% weight loss produced by diet (without particular attention to increasing physical activity) was associated with 5% reduction in total cholesterol, 9% reduction in LDL-C, 25% reduction in triglycerides, and 8% increase in HDL-C.

Fasting glucose and insulin are reduced with weight loss even among individuals with normal glucose levels. Among diabetic individuals, weight loss decreases hemoglobin A1C, which is a measure of long-term blood sugar control. In a study conducted in China, weight loss among overweight individuals with impaired glucose tolerance was shown to reduce the incidence of diabetes.

### ***Potential Adverse Effects of Weight Loss***

#### ***Gallbladder disease***

Some adverse health effects have been observed with weight loss. Weight loss, especially rapid weight loss, has been associated with an increased risk for gallstone formation. This has been observed most notably in women on very low calorie diets (Lee, 1996). However, in the Nurses' Health Study, it was noted that obesity posed a much greater risk of developing gallstones (7-fold increased risk at BMI  $\geq 45$  kg/m<sup>2</sup> than BMI  $< 24$  kg/m<sup>2</sup>) than did weight loss (2-fold greater risk of gallstones with  $\geq 10$  kg weight loss versus no weight loss).

#### ***Bone mineral density***

Lower weight has been associated with lower bone mineral density, and thinner women have a higher risk of osteoporosis than heavier women. Recent studies have noted that weight loss reduces bone mineral density. A recent report noted that even moderate weight loss of 3.6 kg resulted in greater reduction in bone mineral density in the hip and non-significantly in the spine than no weight loss in premenopausal women. Physical activity ( $> 1000$  kcal/week) attenuated the reduction in bone mineral density at the spine but had no significant effect on bone mineral density at the hip. The effect of this degree of bone mineral density reduction on osteoporosis and fracture risk in women is not known, and few studies have been conducted in men.

### ***Weight Loss and Mortality***

Many large epidemiologic studies have observed that weight loss is associated with all-cause mortality and cardiovascular disease mortality. Only several of these studies adjusted for



## **PREMIER Intervention Manual of Procedures**

smoking and excluded mortality occurring in the first several years of follow-up to eliminate those with pre-existing disease (sick individuals are likely to lose weight and then have higher mortality). The findings of increased mortality even with these adjustments generally remained. However, most of the studies were not able to discern whether the weight loss was intentional. Whether weight loss is intentional or unintentional is important in interpreting the results, as it has been observed that unintentional weight loss occurs more often in individuals who report poor health status, use medications for chronic health conditions, and smoke.

Only two studies have reported on mortality and intentional weight loss. One was a randomized intervention study of a “cardioprotective” diet delivered to patients who were recently diagnosed with myocardial infarction. In secondary analyses, the study reported that those participants who lost weight had reduced cardiac events and mortality compared to those who did not lose weight. In a large observational study of overweight women, intentional weight loss was associated with reduced mortality in women with obesity-related conditions. No effect of intentional weight loss on mortality was found in women without obesity-related condition. In the ongoing non-randomized Swedish Obesity Study, surgically-induced weight loss was associated with 97% lower incidence of diabetes, 67% lower incidence of hypertension, 74% lower incidence of high triglycerides, and 69% lower incidence of low HDL-C over two years. These results suggest that voluntary weight loss will have beneficial effects on disease and ultimately mortality. However, observational studies, because of their limitations, have not been able to provide a clear picture of the effect of intentional weight loss on mortality. A randomized trial directly examining the effects of weight loss on mortality has not been conducted. A study currently under way is examining the effects of intentional weight loss on heart disease occurrence in overweight diabetics (Study of Health Outcomes of Weight Loss, SHOW).

### ***Weight Cycling***

Weight cycling refers to repeated periods of weight change, i.e., weight loss and weight regain. The definition of weight loss has varied greatly among studies, including relative amounts (i.e., 20% regain of weight loss), absolute amounts (i.e., bouts of loss and regain of 4.5-10 kg) and statistical values (i.e., coefficient of variation of body weight). Although most observational studies have shown a direct relationship between weight change and total mortality and cardiovascular disease mortality, these studies suffer from limitations that make interpretation of results difficult and their relevance to weight cycling questionable. The studies of weight change measure weight many years apart, which is quite different than the concept of weight cycling. Also, whether or not the bouts of weight loss were intentional is not known. In secondary analyses of weight loss studies, no adverse effects were generally found on blood pressure, blood lipids, and body fat distribution in individuals who regained their weight compared to those who never lost weight (Jeffery, 1996; National Task Force, 1994).

## **Part III. Physiologic Aspects of Weight Loss**

### ***Energy Metabolism***

## **PREMIER Intervention Manual of Procedures**

Total energy expenditure is composed of:

- resting metabolism—the energy required to carry out all metabolic processes to sustain life when the body is at rest and fasting
- physical activity—energy required for muscular work
- thermogenesis
  - thermic effect of food*: energy required for transport, digestion, and assimilation of consumed food; each macronutrient has a different thermic effect, with the largest being protein and the smallest being fat
  - facultative thermogenesis*: energy expenditure that is influenced by a variety of factors, including cold, stress, and drugs. Although debatable, it also could be considered the energy expended in adaptation to over- and under-nutrition

Resting metabolism comprises the greatest proportion of total energy expenditure, about 70% for a sedentary person. It is directly related to the amount of lean body mass (primarily muscle), as fat tissue is relatively inactive metabolically. Thermogenesis accounts for about 15% of total energy expenditure for a sedentary person. Physical activity is the most variable component of total energy expenditure, and accounts for about 15% of total energy expenditure for a sedentary person.

### ***Body Composition***

There are several models that can describe body composition. The simple tissue-based model describes the body as consisting primarily of lean body mass (muscle, bone, organs, blood), and adipose (fat) tissue. Fat tissue is approximately 80% fat, 2% protein, and the remainder water. The body also contains a glycogen pool weighing about .5 kg. Water is associated with the glycogen (3-4 g water per g glycogen), so together the glycogen-water pool weighs about 1.5-2.0 kg. The average non-obese man contains 12%-20% body fat and the average nonobese woman about 20-30% body fat. Fat mass serves as the primary energy storage depot, used by most tissues of the body for sustained energy utilization, with the exception of several organs, most notably the brain, which uses glucose, glycogen, and ketone bodies, but not fat.

### ***Composition of Weight Loss***

Precise estimates of the composition of weight loss during caloric reduction are not available, although some estimates have suggested 6000-6500 kcal/kg. If the weight loss were pure fat, the energy content would have been 9100-9400 kcal/kg. What has been observed consistently is that during the first few days of calorie-reduced diets, weight loss is rapid because the energy content of the weight loss is low; i.e., it consists of glycogen, water, and protein, with lower amounts of fat. As caloric reduction and weight loss continues, more of the weight loss is due to fat. Because the energy content of adipose tissue is high, it takes a larger energy deficit to produce 1 lb of weight loss than during the early period of weight loss. One study observed that after 2 months of low-calorie diets (650-800 kcal/day), about 90% of the weight loss is due to body fat (Wynn et al, 1985).

## **PREMIER Intervention Manual of Procedures**

Precise estimates of the composition of weight loss are difficult to obtain because of a number of factors: measures of body composition need to be highly accurate; the degree of caloric reduction affects the composition of weight loss (the greater the caloric reduction the greater the relative loss in lean body mass compared to fat mass); and the degree of obesity at the start affects the composition of weight loss (the greater the initial body fat, the greater the relative loss in fat mass in relation to lean body mass). Altering the composition of the diet during caloric reduction does not preserve lean body mass (i.e., high protein diets do not prevent loss of lean body mass). During caloric reduction and weight loss, physical activity reduces but does not completely prevent loss in lean body mass.

The loss of lean body mass along with weight loss accounts for much of the decrease in resting metabolic rate that is observed with weight loss. Physical activity generally does not prevent the reduction in resting metabolic rate during caloric reduction and weight loss.

### *Daily fluctuation in body weight*

Large changes in body weight from day-to-day (>.5 lb/day) can be attributed primarily to changes in water and glycogen stores. These changes can occur because of variations in salt and carbohydrate intake, variation in physical activity, and fluid retention due to a number of reasons, including the menstrual cycle. Weight loss has no energy value if it is due entirely to water loss and has a maximum energy value of 9400 kcal/kg if 100% of the weight loss is due to fat.

### *Daily Deficit of 500 Kcal*

Assume that 1 lb of weight loss consists of 70% fat and 30% lean body mass. This lb of weight loss contains 320 g fat, worth 2880 kcal (9 kcal/g), and 135 g, lean tissue, worth 540 kcal (4 kcal/g), for a total energy content of 3420 kcal (note this is similar to the 3500 kcal/lb rule of thumb). To lose 1 lb of weight that is not due to primarily changes in water or glycogen stores, a 3420 kcal deficit is required, or 490 kcal per day for 7 days. This deficit is best obtained by both lowering calorie intake and increasing calorie expenditure.

For simplicity, a 500-1000 kcal daily deficit has been used as the rule of thumb for weight loss regimes and is still a good guideline.

## **PREMIER Intervention Manual of Procedures**

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**PREMIER Intervention Manual of Procedures**

<b>59. INTERVENTION TOOLS/PRODUCTS</b>	<b>3</b>
<b>Donations</b> _____	<b>3</b>
<b>Guidelines for soliciting/receiving/distributing donations</b> _____	<b>3</b>
<b>Policies and guidelines</b> _____	<b>4</b>
<b>Appendix</b> _____	<b>5</b>

**PREMIER Intervention Manual of Procedures**

**Summary of Edits**

## **PREMIER Intervention Manual of Procedures**

### **59. Intervention Tools/Products**

#### *Donations*

Donations may be solicited for the PREMIER study to help with the overall conduct and participants' involvement in the study. The coordinating center may identify staff member(s) to seek donations for the entire trial following the study guidelines listed below. Individual sites may also seek donations for their site using the same guidelines. The intention for using donated products is to acknowledge general participation in the study, and to facilitate participation in the intervention programs.

#### *Guidelines for soliciting/receiving/distributing donations*

1. The project office at NHLBI should be kept informed of all donation-seeking efforts. A list of the staffs/sites who are asking for donations, from whom donations are being solicited, and the type of donations should be compiled and given to the project office. Donations must conform to the NHLBI policy regarding industry and other third party involvement in NHLBI studies. (see Appendix)
2. Fruits, vegetables and dairy products should be given to participants in group C only.
3. Donations should be solicited for items pertaining to the intervention program only. For example, food items, seasonings, t-shirt, pens, measuring cups, etc. All donated items should be approved by the Intervention committee prior to distribution to participants.
4. Receipt of donation in no way indicates endorsement of the products by the PREMIER study or the NHLBI. Companies who donate may not have earlier access to study results than the rest of the scientific community and general public. Donor companies may note the study results in their advertising, but not emphasize their relationship with NHLBI.
5. Food donations should follow the PREMIER nutrition guidelines. Specifically, fat content of the products needs to follow fat gram guidelines (see Food & Fitness Guide). Products high in sodium such as vegetables canned with salt, pickled vegetables, salted and cured meats, salted condiments and snack foods are not appropriate for distribution to the PREMIER participants.
6. Donated products should be distributed to the participants in small [sample size] portions or used in the Taste-It activities and should not be used as their main supply.
7. Donations should be presented to the participants as options only, with no obligation to use the products.

## **PREMIER Intervention Manual of Procedures**

8. Companies who donate may not have access to personal information concerning study participants, including name, address, phone number, etc. Company representatives may not be on site to meet with participants when participants come for study visits or for any other reason.

### ***Policies and guidelines***

1. Value limitation. Products that cost less than about \$10 each can be given to participants, and should not exceed \$100 per participant over the entire period of intervention.
2. Contingencies. Non-contingent products can be provided to all participants. Products also can be used for Group A, B and C participants based on their attendance to clinical measurement visits or intervention sessions. However, products should not be contingent on performance toward intervention lifestyle guidelines.
3. Blinding. Products related to intervention should be distributed by the intervention staff during intervention sessions. Participants should be advised to keep these products in their tote bags or at home and not share them with the blinded clinic staff. Blinded clinic staff should not be informed about the particular intervention products provided to the participants.

Clinic staff may provide other products/reminders to all the participants regardless of group assignment for their compliance to the clinic measurement demands.

4. Examples of intervention tools/products.  
For overall study participants, possible intervention tools/products could be: t-shirts, calendars, coffee mugs, pens and phone cards.
5. For active intervention groups only, possible tools/products might include: calculators, food-related magnets with fruit/vegetables/dairy pictures, discount coupon for athletic stores, discount membership at health clubs, water bottles, food containers and insulated lunch bags



## **PREMIER Intervention Manual of Procedures**

### *Appendix*

May 7, 1993

#### NHLBI Statement on

#### PRIVATE SECTOR PARTICIPATION IN A CLINICAL TRIAL

The primary factors influencing an NHLBI decision to undertake a clinical trial (or the selection of a drug in a clinical trial) are the scientific and clinical need, opportunity, and feasibility of the study. The availability of private sector funds may increase the feasibility of a study. Although, it may make one study (or drug) more feasible and more desirable than another, need, opportunity, and feasibility - i.e., scientific merit - must all be met and remain as the primary factors in arriving at any decision.

The control of the clinical trial must reside entirely with the Institute and the scientific participants of the trial.

Private sector cooperating institutions may have limited participatory roles in planning the study, in the development of its protocol, and in planning the ultimate analysis of the data. However, definitive decisions on these matters reside with the Institute and the scientific participants of the trial.

Once the trial is started, data confidentiality must ordinarily be maintained within the Institute and the data and safety monitoring board. Except under special circumstances and by specific prior arrangement, private sector cooperating institutions will not have earlier access to any scientific data than the rest of the scientific community and the general public.\* Immediately prior to their release, results will be made available to the cooperating private sector institutions. (During the conduct of the trial, general information will be provided dealing with the overall progress of the operational aspects of the study, such as the rate of recruitment, but this will not be the detailed data on performance that goes to the data and safety monitoring board.)

In the event that any adverse effects are encountered which, for legal or ethical reasons, may require communication with the FDA, the relevant private sector institutions will be notified.

The detailed results of a study are ultimately to be available to the private sector institution to be used for such purposes as applications to the FDA, and in its advertising. The advertising might, for example, emphasize the scientific results of studies, and note, but not emphasize, the relationship with NHLBI. Similarly, neither the conduct of the trial nor the results should be represented as a NHLBI endorsement of the drug or product under study.

## **PREMIER Intervention Manual of Procedures**

Appropriate recognition will be given to the private sector institution's contributory role in the clinical trial.

\*For example, in some situations, arrangements might be made for the private sector cooperating institution to appoint a physician or other scientist (who may be an employee) to review and provide written comment on the near final major manuscript(s) for consideration of the writing committee. The institution must have in place a policy and process for treating such manuscripts and their findings as highly confidential by the reviewer and any few necessary consultants of the reviewer, including no or minimum communication of such findings "vertically" to higher management within the organization and none "laterally" outside the "scientific" management path.