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Summary of Edits

Summary of changes between Version 1.0 and 1.1:

- p.4, added creatinine to 24-hr urine measurements

Summary of changes between Version 1.1 and 1.2:

- Titles of Forms #104, #105, and informational poster changed to “Food Interview” from “Diet Recall”
- Baseline waist circumference may be measured in the interim period *or* at the R/I visit (protocol change)
- Added note that for Cohort 1, PAR will be administered at the interim visit rather than at SV3

Summary of changes between Version 1.2 and 1.3:

- Added note to blood and urine sample collection instructions referring to Chapter 21 for details on sample handling, processing, acceptability, and requirements for repeat samples.

Summary of changes between Version 1.3 and 1.4:

- For cohorts 2-4, additional baseline blood samples are drawn to be analyzed at CDC for folate, carotenoids, and Vitamin B-12
- PAR may be collected either at SV3 or during the interim period

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- **10. Interim Period Measures**

Overview

Participants must complete a fitness assessment and two 24-hour food interviews between Screening Visit 3 and the Randomization/Intervention visit (R/I). Clinical centers should allow at least 3-4 weeks between SV3 and the R/I visit in order to complete these activities.

The interval between SV3 and the R/I visit also should be used to complete, if needed: follow-up of individuals who have a positive Rose Angina or PVD questionnaire; the 24-hour urine collection; the fasting blood draw; the Eligibility Review Questionnaire; the case conference; the fourth baseline blood pressure; and a number of noneligibility questions (see below) whose times of administration are flexible. The randomization consent may also be obtained during this interval.

The timing and order of all of these activities is flexible. However, with the exception of the fourth baseline blood pressure measurement and the randomization consent, clinical centers are strongly encouraged to complete all of the above activities, and enter the relevant data, prior to the R/I visit. This will enable data problems to be detected and resolved prior to randomization. Waiting to complete these activities until the R/I visit may cause delays in randomization, since several of the above forms/activities must be entered, and data edits resolved, before a randomization assignment can be issued.

Required Materials

The following materials are needed to complete the activities described above:

- Pre-Randomization Checklist (Form #19)

Food interview materials

- Food Interview Instruction Sheet (Form #104)
- Food Interview Informational Poster
- Food Interview Convenient Times Schedule (Form #105)

Non-eligibility baseline questionnaires

- Patient History Questionnaire (Form #24)
- Quality of Life Questionnaire (Form #23)
- Perceived Stress Questionnaire (Form #25)
- Exercise Confidence Questionnaire (Form #45)
- Eating Habits Confidence Questionnaire (Form #46)

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- Social Support and Eating Habits Questionnaire (Form #47)
- Social Support and Exercise Questionnaire (Form #48)
- Perceived Body Image Questionnaire (Form #49)

Treadmill Fitness Test

(Detailed information on conducting the fitness test is included in Chapter 18).

- Treadmill equipment and materials as specified in Chapter 18.
- Fitness Test Form (Form #26)

Central Lab Specimens Collection

(Detailed information on processing lab samples is included in Chapter 21).

- Fasting blood sample kit (analyzed centrally for total cholesterol, LDL-C, HDL-C, VLDL-C, triglycerides, insulin, glucose, and homocysteine)
- CDC kit for folate, carotenoids, and vitamin B12
- 24-hr urine processing materials (analyzed centrally for Na, K, phosphorus, creatinine, and nitrogen)
- Central Lab Collection Form – Baseline 24hr Urine (Form #20)
- Central Lab Collection Form – Baseline Fasting Blood (Form#21)
- CDC Lab Collection Form – Folate/Carotenoids/Vitamin B12 (Form #77)

Eligibility review

- Eligibility Review Questionnaire (Form #17)

Blood pressure assessment

- Random zero sphygmomanometer and stethoscope
- Standard mercury sphygmomanometer
- Fourth Baseline Blood Pressure Form (Form #27)
- Blood Pressure Escape Form – Screening (Form #32)

Other

- Randomization Checklist (Form #60)
- Participant Closeout Form (Form #28)
- PAR (Form #18)

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Conducting the Interim Data Collection Visit(s)

As noted previously, not all of the following activities may need to be completed between SV3 and the R/I visit. Some may either already have been done, or else may be done at the R/I visit. Except as noted, clinical centers are discouraged from using the latter (R/I) option. In addition, those activities that are done during this interval need not all be done as part of the same visit.

- Confirm participant ID
- Complete the Eligibility Review Questionnaire (if needed)
- Complete/review followup for positive Rose questionnaires (PVD and Angina, if needed)
- Complete/review the non-eligibility baseline questionnaires
- Completion of two 24-hour food interviews
- Collect and process the fasting blood sample
- Collect and process the 24-hour urine specimen
- Conduct the treadmill fitness test and record the results
- Conduct a case conference and determine whether the participant will continue in the study
- Measure 4th Baseline Blood Pressure
- Obtain randomization consent
- Record events and final interim eligibility status on the Pre-Randomization Checklist

Confirm participant ID

Make sure that the participant's ID is on the Pre-Randomization Checklist (Form #19) and any other forms to be completed during the interim period. Clinical center staff should confirm the accuracy of all IDs. Use of preprinted ID labels is recommended.

Complete the Eligibility Review Questionnaire

The Eligibility Questionnaire (Form #4) is asked as part of the SV1 visit and is primarily designed to identify persons who are ineligible for medical reasons. It also asks about a variety of other eligibility criteria. If more than 30 days will have elapsed between the date of the Eligibility Questionnaire (Form #4) and the scheduled R/I visit, complete the Eligibility Review Questionnaire (Form #17) to ensure that no major eligibility criteria have changed. This form, if needed, can be administered at any time within 30 days of the R/I visit. To determine which participants need to have the Eligibility Review Questionnaire administered, run the Ready for Randomization Report (MANAGE08). Some sites may find it easier to complete Form #17 for all participants to avoid computing the 30-day window.

This questionnaire can be sent to the participant to complete at home prior to the visit, or simply given to the participant to complete during the visit. Inform participants that, when they have questions or are unsure about the answer to an item, they should leave it blank and write a comment or question in the comment section for that item so that it can be reviewed with a staff

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person later. Regardless of when the form is completed, a clinical center staff person should review it with the participant to verify its completeness and to attempt to resolve any items with comments. Be sure to place a label with the participant's study ID on each page of the form. Any positive response to an eligibility question (see form for explanation of which questions determine eligibility) makes the participant ineligible for randomization. Questions must be resolved, with a clinician if necessary, before a participant can be randomized. For this reason the form should ideally be administered prior to the R/I visit.

The questionnaire must be completed **and entered** prior to randomization.

Complete/review follow-up for positive Rose Questionnaires

If either of the Rose Questionnaires administered at SV1 had a positive outcome, the follow-up with the participant's physician and the study clinician must be completed and noted on the Pre-Randomization Checklist (Form #19) before randomization can occur. Use the worksheets attached to each Rose Questionnaire to document the follow-up process.

Complete/review the non-eligibility baseline questionnaires

A number of questionnaires may optionally occur during the interim period. These include a variety of baseline measures such as the Patient History Questionnaire and various psychosocial questionnaires.

These can be completed at any time prior to randomization, and do not have to be entered prior to randomization. However it is recommended that they be completed prior to the randomization visit so that ample time is available to resolve data edits. Record the completion of these questionnaires on Form #19.

Administer 7-Day Physical Activity Recall

The 7-Day Physical Activity Recall (Form #18) may be completed during the interim period or at SV3. See Chapter 9, SV3, and Chapter 22, Physical Activity Assessment, for more details on administering the recall.

Completion of two 24-hour food interviews

Two unannounced 24-hour food interviews occur during the interim period to establish baseline diet status. These recalls, conducted by telephone by the Diet Assessment Center of Pennsylvania State University, must take place within a 3-week period on nonconsecutive days. Completion of the 2 recalls is a requirement for randomization. The procedure for administration of the interviews is presented in Chapter 19. Penn State will notify the clinical centers once the two interviews have been completed so that this information can be noted in the data management system using Form #19.

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Collect and process the 12-hour fasting blood sample and the 24-hour urine specimen

Central lab specimens may be collected at any time between SV3 and randomization if they have not already been obtained. Participants need to be made aware that they cannot be randomized until this specimen has been obtained. It is recommended that they be done at least a few days prior to the randomization visit in case the collection is not successful and needs to be repeated. (See Chapter 21, Central Lab Procedures, regarding requirements for acceptability and repeat samples. Details on handling of samples and processing are also covered in Chapter 21.)

The central lab forms (Forms #20 and #21) and the CDC Lab Collection Form (#77) must be completed prior to randomization, but do not have to be entered prior to randomization. However the relevant boxes on Form #19 must be checked to indicate that acceptable samples were collected.

Conduct the treadmill fitness test and record the results

Baseline cardiorespiratory fitness is determined by submaximal treadmill stress testing. This procedure is described in Chapter 18. Participants must complete the fitness test between SV3 and the R/I visit. Note the completed test on Form #19.

Conduct a case conference

Before scheduling a Randomization/Intervention Visit, sites should plan a brief case conference to discuss each participant. This is a chance for clinical staff to voice any safety or compliance issues they may have with particular participants. The PI at each site is responsible for making a final eligibility decision about each participant for whom there are any questions or concerns.

The outcome of the case conference is entered on the Pre-Randomization Checklist. Participants declared to be ineligible during the case conference are automatically closed out when their checklist is entered.

Measure 4th Baseline Blood Pressure

The 4th baseline blood pressure must be measured at least seven days after SV3 and prior to randomization (including at the R/I visit). Record the outcome of the measure on the Randomization Checklist (Form #60), not the Pre-Randomization Checklist, even if it is taken prior to the R/I visit. Be sure to use the same cuff size as that used at SV1, except as noted in Chapter 17. If the participant cuff size is found to differ from that used during SV1 and the cuff size is not appropriate for the participant, a replacement blood pressure should be taken using the proper cuff if participant has not left the clinic. Otherwise the original measurement stands.

If the participant's blood pressure hits an escape level on this measurement, the participant is excluded from further participation. Enter the 4th Baseline Blood Pressure Form (Form #27), a

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BP Escape Form—Screening (Form #32), and then complete the Participant Closeout Form (Form #28). In this case, staff do not need to enter the Pre-Randomization Checklist or any other interim forms.

Measure waist circumference

Measure the participant's waist circumference per the protocol outlined in MOP Chapter 20. Note the measurements on the Randomization Checklist (Form #60) in centimeters to the nearest 0.1 cm.

Obtain randomization consent

Consent to participate in the main trial must be obtained sometime between the SV3 visit and prior to randomization. Enter the outcome on the Randomization Checklist (Form #60). Participants who choose to drop out of the study at this point should be closed out immediately using the Participant Closeout Form (Form #28).

Record events and final eligibility status on the Pre-Randomization Checklist

Review the Pre-Randomization Checklist and all other forms to make sure the data collection is complete and each item has been checked off on the checklist.

Ending the Interim Data Collection Visit(s)

Inform the participant of her eligibility status. The visit may be terminated at any point that it is clear that the individual is not eligible for PREMIER. Explain the reasons for ineligibility to the participant. Enter the visit outcome status on the Pre-Randomization Checklist (Form # 19).

Once all items on the checklist are complete, or the participant is found to be ineligible, enter at least the following two items (in this order):

- Eligibility Review Questionnaire (if any)
- Pre-Randomization Checklist

In addition, any of the non-eligibility baseline forms can be entered (in any order) at this time.