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Summary of Edits

Summary of changes between Version 1.0 and 1.1:

- Corrected reference to fasting blood to state that a 12 hour fast is required.

Summary of changes between Version 1.1 and 1.2:

- Titles of Forms #104 and #105 changed to "Food Interview" from "Diet Recall"
- 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:

- For cohorts 2-4, additional baseline blood samples are drawn to be analysed at CDC for folate, carotenoids, and Vitamin B-12
- Title of Form #16 changed to "Baseline Symptoms Questionnaire"
- PAR may be collected either at SV3 or during the interim period

9. Screening Visit 3 (SV3)

Overview

Screening Visit 3, which must occur at least 7 days after SV2, is the third visit at which participants are screened to determine eligibility for PREMIER. Activities include BP measurement, completion of the 7-Day Physical Activity Recall and Symptoms Questionnaire, a review of the Food Record and the SV3 Activity Fact Sheet, and a motivational session with a staff interventionist.

The SV3 Blood Pressure eligibility is determined by summing up six total BPs, the two BPs from SV1, the two BPs from SV2, and the two BPs from SV3. Participants who are found to be eligible for the trial at the end of SV3 are provided with instructions to prepare them to complete the 24-hour food interviews to be administered by telephone by the Pennsylvania State University Diet Assessment Center.

Other measurements

The visit may also be used to perform the fasting blood draw and to receive and process the 24-hour urine specimen, both of which must occur at some time between SV1 and randomization. The blood draw, which requires an 12-hour fast, is processed centrally for analysis of lipids, insulin, glucose, and homocysteine. For cohorts 2 – 4, blood is also drawn to be analysed at CDC for folate, carotenoids, and vitamin B-12. The 24-hour urine collection is analyzed centrally for sodium, potassium, phosphorus, creatinine, and urea nitrogen (See Chapter 21, Central Laboratory Procedures, for details). The instructions for processing the fasting blood and urine collections should be followed no matter when the specimen is returned. The Central Lab Collection Form—Fasting Blood (Form #21) and the Central Lab Collection Form—24-hour Urine (Form #20) are used for processing the blood and urine samples.

A number of questionnaires may also be completed at any time during the screening period. These include the Patient History Questionnaire and a number of psychosocial questionnaires. These can be completed at any time prior to randomization. However it is suggested that they not be given to participants until after they complete the SV2 visit and are found eligible to continue to SV3. Although these forms do not have to be entered prior to randomization, it is strongly recommended that the entry be done prior to the randomization/intervention visit so that ample time is available to resolve data edits. Record the completion of these questionnaires on Form #19.

The Eligibility Review Questionnaire (Form #17, which must be done within 30 days of randomization) may be done at this visit.

Setting

The SV3 visit takes place at the clinical center. It requires a quiet, private setting where participants can wait prior to the blood pressure measurement. Questionnaires also need to be administered and reviewed in a setting that permits privacy for the participant.

Preparations for SV3

The exact number of forms and pieces of equipment needed for the SV3 visit is determined by local staffing configurations and the anticipated participant flow. If available, a spare sphygmomanometer should be available as backup. At a minimum, the following materials are needed to conduct the SV3.

- Study charts for scheduled participants
- Consent materials (if required by local IRB. See Chapter 4, Human Subjects)
- Random zero sphygmomanometer, standard sphygmomanometer and stethoscope
- SV3 Visit Form (Form #15)
- SV3 Blood Pressure Form (Form #14)
- Baseline Symptoms Questionnaire (Form #16)
- 7-Day Physical Activity Recall (Form #18)
- SV3 Activity Fact Sheet (Form #107)
- Screening Motivational Session Notes (Form #41)
- Diet and Physical Activity Change Questionnaire (Form #40)
- Food Interview Instruction Sheet (Form #104)
- Food Interview Informational Poster
- Food Interview Convenient Time Schedule (Form #105)
- Food Record and Instructions (Form #200) [if needs to be repeated]
- Eligibility Review Questionnaire (Form #17) [if Eligibility Questionnaire is not within 30 days of randomization, and SV3 visit is within 30 days of randomization)

Conducting SV3

In general, performing the SV3 activities in the order listed below should provide the most efficient identification of ineligible subjects. The visit may be politely concluded at any point after an exclusionary condition or situation has been identified.

- Confirm participant ID, check visit window, and obtain informed consent
- Take participant's random zero blood pressure readings and note eligibility on SV3 Visit Form
- Administer Baseline Symptoms Questionnaire
- Review Food Record or give new one if Food Record needs to be repeated
- Assess willingness to participate

- Review SV3 Activity Fact Sheet
- Conduct screening motivational session
- Administer Diet and Physical Activity Change Questionnaire
- Administer 7-Day Physical Activity Questionnaire
- Review Food Interview instructions, complete Convenient Time Schedule, and fax Food Interview Convenient Time Schedule to Pennsylvania State University Diet Assessment Center

Confirm ID, Check Visit Window, and Obtain Informed Consent

Generate pre-printed labels from the data management system and place the labels on all appropriate SV3 forms. Confirm that at least seven days have elapsed since the SV2 visit.

If necessary, obtain informed consent for the visit.

Measure Blood Pressure

Take the participant's blood pressure using the random zero device and the procedures described in Chapter 17 (Blood Pressure Assessment). **Be sure to use the same cuff size as was used at SV1, except as noted in Chapter 17, (Blood Pressure Assessment).** If the participant cuff size is found to differ from that used during SV1 (except as noted in Chapter 17) 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. Record the measurements on the SV3 Blood Pressure Form (Form #14). If the cumulative sum of the SV1, SV2, and SV3 systolic blood pressure measurements is between 717 and 956 and the cumulative sum of the SV1, SV2, and SV3 diastolic blood pressure measurements is between 477 and 572 mm Hg, the participant is blood pressure-eligible for randomization.

Participants who are excluded based on blood pressure readings outside these limits need to be referred to a physician for further evaluation. The timing of the referral, within one week or within one month, depends on the threshold level that is reached (see Chapter 23, Safety Monitoring). These threshold levels are also shown on the SV3 Blood Pressure Form. If the thresholds are exceeded, the Blood Pressure Escape Form – Screening (Form #32) also needs to be completed, with one copy placed in the participant's study chart and one copy sent to the CC. The participant may also be referred to a physician if deemed appropriate based on symptoms and clinical judgment even if the BP is lower than the above limits.

Administer the Baseline Symptoms Questionnaire

Ask the participant to complete the Baseline Symptoms Questionnaire (Form #16). A study clinician must sign the form. Check the appropriate box on the SV3 Visit Form to indicate the Baseline Symptoms Questionnaire has been completed.

Review the One-Day Food Record Screening Form

The One-Day Food Record Screening Form (#200) can be reviewed by any staff member. Make sure the Food Record is returned and completed by the participant. The Food Record is considered acceptable if the participant lists at least 4 food items with an attempt to indicate amounts for each food item. If these minimum requirements are not met, the participant is asked to repeat the food record. Indicate on the SV3 Visit Form whether the food record was complete, or whether it needed to be repeated.

Assess the Participant's Willingness to Participate in the Study

The next three forms in this section must be administered by an interventionist. Go over with the participant the SV3 Activity Fact Sheet (Form #107) to once again review the requirements of the study and conduct the Screening Motivation Session (Form #41) to explore the participant's interest and potential ambivalence. Administer the Diet and Physical Activity Change Questionnaire (Form #40) to ask whether the participant is willing and able to participate in the study activities and procedures. If the participant answers yes to the global question on Form #40, he is eligible to continue. Check the appropriate boxes on the SV3 Visit Form to indicate the SV3 Activity Fact Sheet was reviewed, the motivational session was delivered, and the eligibility status regarding the Diet and Physical Activity Change Questionnaire.

Administer 7-Day Physical Activity Recall

This must be administered by staff certified in PAR technique. Because of the potential for this interview to unblind the interviewer to the participant's treatment status during follow up, staff need to be carefully selected for PAR training. The ideal solution is to use a blinded person who is not taking BP measurements. The other option is an unblinded person, as long as they are not involved in delivering the intervention and do not take BP measurements. Sites can each find their best possible solution given staffing limitations.

See Chapter 22, Physical Activity Assessment, for more details on administering the recall. Complete the 7-Day Physical Activity Recall (Form #18). Check the appropriate box on the SV3 Visit Form indicating the recall was completed.

The PAR may be completed either at SV3 or during the interim period.

Give Instructions for the 24-Hour Food Interview

Give and review with the participant the instructions for the 24-hour food interview (Form #104). Have the participant complete the Food Interview Convenient Time Schedule (Form #105). This form has three pages, one for each time zone. Make sure to use the page with the appropriate time zone. Fax this form to the Pennsylvania State University Diet Assessment Center. Check the appropriate boxes on the SV3 Visit Form indicating the instructions were

given, the schedule was completed, and was faxed to Pennsylvania State University Diet Assessment Center. See Chapter 19 for more details on the 24-hour food interview.

Ending SV3

To complete the SV3 visit, do the following:

- Review the SV3 Visit Form and all other visit forms to make sure the visit is complete.
- Inform the participant of their eligibility status. You may terminate the visit at any point that it is clear that the individual is not eligible for PREMIER. Explain the reasons for ineligibility to the participant.
- If the participant is eligible thus far, remind participant that final eligibility will depend on the completion of the fitness test, fasting blood draw, 24-hour urine collection, pending questionnaires, and two 24-hour food interviews (and food record if not yet completed).
- If the participant was excluded due to escape-level blood pressure criteria, refer him to his physician and complete the BP Escape Form —Screening (Form #32).
- Enter the visit outcome status on the SV3 Visit Form (Form #15).
- Enter all questionnaires and the SV3 BP Form (Form #14) into the data entry application. After those forms have been entered, enter the SV3 Visit Form. All of this data entry should be completed within two weeks of the visit; preferably within one week.