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Summary of Edits

Summary of changes between Version 1.0 and 1.1:

- Re-organization of bulleted list on page 14-3 to be consistent with 13-3.
- Added form numbers throughout when title of form is mentioned and corrected form titles when incorrect
- Changed +/- to \pm
- Study clinician does not sign Form #16. Deleted from *Administer Symptoms Questionnaire*
- AE form is filled out if Form #16, Question #17 is “yes” (not question #14)
- AE form is filled out if Form #6, Question #8 is “positive”

Summary of changes between Version 1.1 and 1.2:

- Participants with a newly positive Rose Angina Questionnaire at this visit must refrain from exercise until they have a stress test and approval from both their personal physician and a PREMIER clinician.
- Participants with a positive Rose Angina Questionnaire at this visit who had any previous positive Rose Angina Questionnaire refrain from exercise until they have approval from both their personal physician and a PREMIER clinician. The decision to require a repeat stress test in this case is left to the discretion of the participant’s personal physician.

Summary of changes between Version 1.2 and 1.3:

- Form #34, Brief Medication Use Questionnaire, is no longer in use. Use Form #79, Follow-Up Medication Use Questionnaire.
- Use Form #201, Weight Loss Medications that Affect Blood Pressure, when completing Form #79, Follow-Up Medication Use Questionnaire
- If Follow-Up Symptoms Questionnaire (Form #78) Question #15 = yes, an AE Form (330) is required.

Summary of changes between Version 1.3 and 1.4:

- Form #84 is completed for 12-month BP escape tracking.

14. 12-Month Visit

Overview

This chapter describes the sequence of activities that comprise the 12-month visit. The purpose of the 12-month visit is to collect information regarding blood pressure, weight, medication use and symptoms and intervention side effects reported by participants. The blood pressure measures act as a safety check required periodically throughout the study.

Setting

All of the 12-month measurements take place at the clinical center and require a quiet, private or semi-private setting where the participant can wait relaxed prior to the random zero blood pressure measurement. Questionnaires also need to be administered and reviewed in a setting that permits privacy for the participant.

Required Materials

- 12-Month Visit Form (#58)
- Study charts for scheduled participants
- Scale

Questionnaires

- Rose Angina Questionnaire (Form #6)
- Follow-Up Symptoms Questionnaire (Form #78)
- Follow-Up Medication Use Questionnaire (Form #79)
- Weight Loss Medications that Affect Blood Pressure (Form #201)

Blood pressure assessment

- Random zero sphygmomanometer and stethoscope
- Standard mercury sphygmomanometer
- 12 month visit blood pressure form (Form #54)
- Blood Pressure Escape Form –12 month visits (Form #84)

Preprinted ID labels should be available to use on the forms. The number of forms and pieces of equipment are determined by local staffing configurations and the anticipated participant flow. If available, a spare (back up) sphygmomanometer should be available.

Conducting the 12-Month Visit

As noted previously, the following activities should be completed between 11 and 13 months post randomization. The exact sequence for the activities, however, as well as the content of any given visit, are left to the discretion of the individual clinical centers. The only requirement is that the visits fall within the windows shown in table 14-1. For most activities, the separate target, allowable, and adjudication windows are listed. In addition, a Visit Windows Report for each participant can be printed from the Data Management System. This gives exact calendar dates for each of the windows based on the participant’s randomization date. Staff should always attempt to schedule activities to occur within the target windows, and the CC will report on the success of each site in achieving these target ranges. However measurements may still be collected outside of the target window provided that they fall within the allowable window range. Measurements taken outside of the allowable windows are evaluated by the adjudication committee to determine if and how they can be used. It is critical that staff make every possible effort to make sure all of the three month activities occur within the allowable window.

- Confirm participant ID
- Complete the Rose Questionnaire – Angina (Form #6)
- Measure Blood Pressure (two measurements on a single collection day) (Form #54)
- Measure Weight (Form #58)
- Complete the Follow-Up Symptoms Questionnaire (Form #78)
- Complete the Follow-Up Medication Use Questionnaire (Form #79)
- Record events on the 12-Month Visit Form (#58)

<p>Table 14-1. 12 Month Visit Measurement Targets and Windows <i>(exact visit windows vary by participant, print Visit Window Report in Data Management System to get participant-specific dates)</i></p>
<p>RZ BP (2 times on a single collection day) Questionnaires Weight</p>
<p><i>Target</i></p> <ul style="list-style-type: none"> • 12 months from randomization date \pm 2 weeks. <p><i>Allowable Window</i></p> <ul style="list-style-type: none"> • 12 months from randomization date \pm 4 weeks <p><i>Adjudication Window*</i></p> <ul style="list-style-type: none"> • between 7 ½ months and 15 ½ months.
<p><i>*If outside allowed range, collect data, enter forms, and adjudication committee will determine if/how to use. If outside adjudication range, collect but do not enter. Adjudication committee will review.</i></p>

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Confirm participant ID

Make sure that the participant's ID is on the 12-Month Visit Checklist and any other forms to be completed as part of the 12-month visit. Clinical center staff should confirm the accuracy of all IDs. Use of preprinted ID labels is recommended.

Complete Rose Angina Questionnaire (Form #6)

Administer the Rose Angina Questionnaire (Form #6) to the participant. Individuals with a positive Rose Angina Questionnaire (question #8 answered "positive") are immediately referred to their personal physician for evaluation.

If **all previous** Rose Angina Questionnaires were negative, the participant is asked to refrain from further exercise until they have a stress test, and approval from both their personal physician and the PREMIER clinician.

If **any previous** Rose Angina Questionnaire was positive, the participant is asked to refrain from further exercise until they have approval from both their personal physician and a PREMIER clinician. A repeat stress test is not automatically required in this case; the decision to perform one is left to the discretion of the participant's personal physician. If the participant does not have a personal physician, she is given a referral to a physician whom she is advised to consult.

In either case, if angina is confirmed, they are advised to follow their physician's advice regarding exercise. Otherwise, they can restart exercise per PREMIER recommendations.

An AE form is to be completed if the answer to question #8 is "positive." Check the appropriate box on the 18 Month Visit Form (#58) to indicate that the Rose Angina Questionnaire was administered. Use the worksheets attached to the Rose Questionnaire to document the follow-up process.

Measure blood pressure (Form #54)

Two blood pressure measurements must be obtained on a single collection day between 11 and 13 months after the randomization visit. Take the participant's blood pressure using the random zero sphygmomanometer and the procedures described in MOP Chapter 17 (Blood Pressure Assessment). **Be sure to re-measure the cuff size.** Record the outcome of the measures on the 12 Month Visit Blood Pressure Form (#54).

If the mean blood pressure from these two readings is \geq either SBP of 160 mmHg or DBP of 100 mmHg, one additional set of RZ measurements must be obtained within one week. If the cumulative mean from the two visits is \geq SBP 180 or DBP 110, the participant is referred to his/her personal

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physician for further evaluation within one week. If the cumulative mean from the two visits is \geq SBP 160 or DBP 100, then the participant is referred to his/her personal physician within one month.

If the cumulative mean blood pressure recorded at the 12 month visit is \geq either a SBP of 140 mmHg or a DBP of 90 mmHg, one additional set of RZ blood pressure measurements must be obtained within one week. If the cumulative mean from the two visits is \geq SBP 160 or DBP 100, the participant is referred to his/her personal physician within one month. If the cumulative mean from the two visits is \geq SBP140 or DBP 90, the participant is referred to a physician for further evaluation within two months.

The timing of the referral, within one week, within one month, or within two months, depends on the threshold level that is reached (see Chapter 23, Safety Monitoring). These threshold levels are also shown on the 12 Month Visit Blood Pressure Form. If the threshold levels are exceeded, the Blood Pressure Escape Form –12 Month Visits (Form #84) 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.

The clinical centers should endeavor to obtain four sets of end-of-intervention blood pressure measurements on all participants who meet one of the BP escape criteria. Care should be taken that this does not delay or otherwise interfere with appropriate clinical care. Regardless of the outcome of the referral, all participants continue in the trial and get all study measurements.

Measure weight

Measure the participant's weight according to the procedures in Chapter 20. Record on the 12 Month Visit Form (#58).

Administer the Follow-Up Symptoms Questionnaire (Form #78)

Ask the participant to complete the Follow-Up Symptoms Questionnaire (Form #78). If the participant answers "yes" to question #15, an Adverse Events Form (Form #30) is required. Check the appropriate box on the 12 Month Visit Form to indicate that the Follow-Up Symptoms Questionnaire was administered.

Complete the Follow-Up Medication Use Questionnaire (Form #79)

Confirm that the participant has brought in all medications, over-the-counter products, or nutritional supplements that they are currently using. Check the participant's medication containers and complete the Follow-Up Medication Use Questionnaire. If the participant has started taking any exclusionary medications, or any medications for which the category is unclear, a PREMIER clinician must review the form. If the participant fails to bring her current medications, it will be necessary to call the participant at home to review her medications. Use Form #201, Weight Loss Medications that Affect Blood Pressure, to check weight loss medications.

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Record events and final eligibility status on the 12 Month Visit Form (#58)

Review the 12 Month Visit Form and all other forms to make sure the data collection is complete and each item has been checked off on the checklist.

Ending the 12 Month Visit

Once all items on the 12 Month Visit Form are complete, enter the following items. Be sure to enter the 12 Month Visit Form last.

- BP Escape Form—12 Month Visits (#84) (if any)
- Follow-Up Symptoms Questionnaire (Form #78)
- Participant Closeout Form (#28) (if any)
- Adverse Events Form (#30) (if any)
- Follow-Up Medication Use Questionnaire (Form #79)
- 12 Month Visit Form (#58)