

PREMIER Clinical Manual of Procedures

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Summary of Edits

Summary of changes between Version 1.0 and 1.1:

- Baseline waist circumference may be measured in the interim period or at the R/I visit (protocol change)

Summary of changes between Version 1.1 and 1.2:

- Diastolic BP escape criterion for this visit, p. 11-6 corrected from “sum of two > 199mmHg” to “sum of two > 219mmHg.”

Summary of changes between Version 1.2 and 1.3:

- Review the participant’s current health status to confirm that the participant is still cleared to continue. If health status has changed, assess whether or not it is still suitable to randomize the participant.

11. Randomization/Intervention Visit (R/I)

Overview

At the Randomization/Intervention visit, participants complete final baseline measurements, are randomized, and have their first intervention visit. Details of the latter are covered in the Intervention MOP. This chapter focuses on the clinic portion of the visit, including randomization.

Participant blood pressure, if collected at this visit, is not used to determine eligibility. However participants are still excluded for safety reasons if this blood pressure exceeds escape levels.

The Randomization/Intervention visit must occur no more than 6 months after the SV1 visit.

Setting

The randomization visit takes place at the clinical center and requires a quiet, private or semi-private setting where the required relaxed waiting time can occur before a random zero blood pressure (if needed) is taken, and an interviewing setting that permits privacy of response to the questions that are asked. Separate facilities must be provided to conduct the first intervention session, which also occurs as part of the R/I, in order to ensure that clinic staff remain blinded to intervention assignment.

Preparations for R/I Visit

If possible, complete and enter the Pre-Randomization Checklist (Form #19) prior to the randomization visit.

At least one day prior to the R/I visit, run the “Ready for Randomization” report, make sure all required forms have been entered, and confirm that the participant is eligible. Missing items must be completed (and if necessary entered) before a randomization assignment can be assigned. This chapter assumes that all of the discretionary activities covered in Chapter 10 (Interim Period Measures), with the exception of the 4th blood pressure measurement and the randomization consent, have been completed prior to the R/I visit.

The following materials are needed to conduct the R/I visit:

- Scale
- Tape Measure
- Randomization Checklist (Form #60)

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In addition, the following materials may also be required.

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)

Informed consent

- Consent materials for main trial

Miscellaneous

- Study charts for scheduled participants (if available)
- SV3 Activity Fact Sheet (Form #107)

The number of forms and pieces of equipment are determined by local staffing configurations and the anticipated participant flow. A spare sphygmomanometer should be available as backup.

Conducting the R/I Visit

Activities associated with the R/I visit are listed below.

- Confirm participant ID
- Confirm that the Pre-Randomization Checklist has been completed and entered
- Check visit window
- Review study and confirm interest
- Obtain consent for main trial (if not yet obtained)
- Measure fourth baseline blood pressure (if not yet obtained)
- Measure waist circumference (if not yet obtained)
- Weigh participant
- Record events and final eligibility status on the Randomization Checklist
- Randomize participant
- Conduct initial intervention session

Confirm participant ID

Check to be sure that the correct participant ID label has been attached to the Randomization Checklist and any other forms to be used at this visit.

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Confirm that the Pre-Randomization Checklist has been completed and entered

Make sure that the Pre-Randomization Checklist (Form #19) has been completed and entered. If it is not complete, finish the remaining items at this visit or reschedule a new randomization visit. All required items must be entered before the participant can be randomized.

Use the Ready for Randomization Report (MANAGE08) to confirm that all required data has been entered before proceeding with the randomization visit.

Check visit window

Make sure that the date of the Randomization/Intervention visit is within the window for the participant. The Ready for Randomization Report lists the date range appropriate for each participant. Since window is a maximum range (6 months) from SV1, this should be checked in advance of the visit. Once this visit window is exceeded it is too late to adjust the date.

Review study and confirm interest

Briefly describe PREMIER again, emphasizing the commitment required of participants. Give participant the SV3 Activity Fact Sheet (Form #107) as a visual reminder of the commitment she is being asked to make. Stress how important it is that those who enroll in the study follow through and complete the study, and confirm that participant thinks she would like to participate if eligible.

Review participant's current health status

Ask the participant whether there have been any important changes in their health status that may affect their ability to participate in the study. New injuries, surgeries, or recent major illnesses are examples of events that may influence the participant's ability to participate. If the answer is "Yes," a case conference should be conducted to assess whether the participant is a good candidate for randomization. If the case conference confirms that the participant should continue, check "Yes." If the participant is not cleared to continue, check "No," and complete Form #28 for the participant and do not enter Form #60.

Obtain consent for main trial (if not yet obtained)

Consent to participate in the main trial must be obtained sometime between the SV3 visit and prior to randomization. If this has not yet occurred, then it must be obtained now.

Measure fourth baseline blood pressure (if not yet obtained)

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In addition to the three eligibility blood pressure measurements taken at SV1, SV2, and SV3, all participants must provide a fourth, noneligibility baseline blood pressure measurement. This may be obtained any time after the SV3 visit and prior to randomization. If this has not yet occurred, then it must take place at the R/I visit and prior to randomization.

Take the participant's blood pressure using the random zero sphygmomanometer and the procedures described in MOP Chapter 17 (Blood Pressure Assessment). The cuff size must be the same as that used at SV1, except as noted in Chapter 17. If it is impossible to get an accurate measurement (e.g., if large cuff covers the antecubital fossa or arm circumference is >52 cm) the participant is excluded.

Although this blood pressure measurement is not intended as an eligibility measurement, participants with escape blood pressures at this visit are still excluded from the study and referred to a physician for further evaluation within one week. The escape blood pressure criteria for this visit is based only on the BP measurements taken at this visit, and not on the cumulative blood pressure measurements to date. The BP escape criterion for this visit is defined as either the sum of two systolic blood pressures exceeding 359 mm Hg or the sum of the two diastolic blood pressures exceeding 219 mm Hg. If an escape level is reached, the Blood Pressure Escape Form—Screening (Form #32) also needs to be completed, with one copy placed in the participant's chart at the site and one copy sent to the CC.

Measure waist circumference (if not yet obtained)

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.

Weigh participant

Measure the participant's weight per the protocol outlined in MOP Chapter 20. Note the weight on the Randomization Checklist (Form #60). All weights are measured and recorded in pounds to the nearest 0.25 pounds.

Record events and final eligibility status on the Randomization Checklist

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

Randomize participant

An unblinded staff member randomizes the participant and prints a report using the Intervention Application on the PREMIER computer workstation. The process is as follows:

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- (1) Open the Intervention Application and click on the Randomization button.
- (2) Select Enter Randomization Checklist
- (3) Enter the Randomization Checklist
- (4) Select Randomize Participant
- (5) Select the participant to randomize from the list of eligible participants.
- (6) Click Print Randomization Report
- (7) Deliver the printout to the interventionist who will be conducting the remainder of the R/I visit.

Participants are told to which group they have been assigned. Only unblinded staff have a level of computer access which allows them to perform the randomization procedure. Clinic personnel who perform follow-up participant measurements are blinded to intervention assignment.

Treatment allocation assignments are stratified by clinic and hypertensive status (yes/no), and within each strata are generated in blocks of varying sizes.

Ending the R/I Visit

To complete the R/I visit, do the following:

If the participant is ineligible

You may inform participants of their eligibility status and terminate the visit whenever it is clear that they are not eligible for PREMIER. Explain the reasons for ineligibility to the participant. Enter the visit outcome status onto the Randomization Checklist (Form #60).

If the participant is eligible

If participant is eligible, the clinic portion of the visit is ended when the participant is transferred to the intervention staff for randomization and the initial intervention visit.

Conduct initial intervention session

Once randomized, participants complete their initial intervention session. In order to assure blinding, this session should be conducted by a staff person who does not take post-randomization blood pressure measurements, and the session should be conducted in a setting separate from the routine clinical activities.

Details of how to conduct this session are included in the Intervention MOP.