

NSABP DMP-1: A Study to Evaluate Different Decision-Making Approaches Used by Women Known to be at Increased Risk for Breast Cancer

Fast Facts

Inclusion Criteria

1. The participant must have consented to participate and must have signed and dated an appropriate IRB-approved consent form.
Note regarding additional consent forms:
 - At selected NSABP sites participating in the video recording/interviewing components of DMP-1 (**GRCOP is not participating in the video recording**), the consent forms in Appendices C and D must be signed by the participant and her doctor/HCP, respectively. After the accrual of 30 participants for the video recording and interview component of the study has been reached, the participant consent form in Appendix B must be used.
 - The consent form in Appendix E will be completed online by participants who are invited to complete the optional online questionnaire, and who have given their consent to be contacted for this part of the study.
2. The participant must be female.
3. The participant must be ≥ 35 years of age.
4. The participant must be English-speaking.
5. The participant must have been identified as being at increased risk for breast cancer as determined by the doctor/HCP. (Increased risk for breast cancer does not have to be based on a Gail score.)
6. During the participant's counseling session, breast cancer risk and the use of SERMs for breast cancer risk reduction must have been discussed, as reported by the doctor/HCP who conducted the session. Note: This criterion does not apply to participants who are asked *before the counseling session* to participate in the video recording component of DMP-1 at the selected NSABP sites (see Section 5.3.1).

Exclusion Criteria

1. Previous invasive breast cancer of any type.
2. Previous history of DCIS.
3. Previous history of LCIS if treated with mastectomy, radiation therapy, or endocrine therapy.
4. Participation in any other cancer prevention study involving pharmacologic intervention(s) or osteoporosis prevention study involving pharmacologic intervention(s).
5. Any history of or current tamoxifen, raloxifene, or other SERM therapy for any reason. (Participants are eligible if SERM use has been discussed prior to the counseling session as long as SERMs were never used.)

TABLE 1. Study schedule for DMP-1 participants and doctors/HCPs **NOT** participating in video recording/interviews

Activity at Local Site (if applicable)	AFTER the Counseling Session		
	On the same day as the counseling session	At 3 months	At 6 months
Consent form signed by participant (Appendix B)	X		
Study enrollment	X		
Q1 must be completed by participant	X ^a (preferably on the same day)		
Questionnaire for Counseling Staff completed by doctor/HCP ^b	X (preferably on the same day)		
Check Q1 for decision made	X		
If decision made regarding SERM use, give participant Q2	X ^c (or mail Q2 within 1 week after counseling session)		
If decision not made regarding SERM use, call participant. If participant indicates during phone call that decision has been made, mail Q2.		X (mail Q2 within 1 week after phone contact)	
Q2 should be completed by participant and returned to site at this time		X ^d (within 2 weeks after participant receives Q2)	
If Q2 has not been sent to participant because a decision about SERM use has not yet been made, send Q2 to participant			X
If not completed previously, Q2 should be completed by participant and returned to site at this time			X ^d (within 2 weeks after participant receives Q2)
<p>a It is preferred that Q1 be completed by the participant before leaving the clinic/office, but it is not required. If Q1 is not completed before leaving the clinic/office, the participant should complete and return Q1 to the site within 2 weeks. If Q1 is not returned within 2 weeks, contact the participant to remind her to complete and return Q1. <i>If Q1 is not returned within 6 weeks of the counseling session, submit the missing data form (Form QMD). The participant must not be given Q2.</i></p> <p>b Doctor/HCP who discussed breast cancer risk and SERM use with the participant.</p> <p>c If Q1 is completed and returned to the site, Q2 should be mailed to the participant within 2 weeks after receipt of Q1.</p> <p>d If Q2 is not returned within 3 weeks, send reminder postcard to the participant. If Q2 is not returned within 2 weeks after anticipated receipt of the postcard, send a replacement Q2. If Q2 is not returned within 4 weeks, submit Form QMD.</p>			