Cancer Research Consortium of West Michigan
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FAST FACTS

S2010, A RANDOMIZED PHASE III TRIAL COMPARING ACTIVE SYMPTOM MONITORING PLUS PATIENT EDUCATION VERSUS PATIENT EDUCATION ALONE TO IMPROVE PERSISTENCE WITH ENDOCRINE THERAPY IN YOUNG WOMEN WITH STAGE I-III BREAST CANCER (ASPEN)

ELIGIBILITY CRITERIA

Disease Related Criteria

a. Participants must be female and have Stage I, II, or III hormone receptor positive breast cancer based on clinical or pathologic evaluation (See Section 4.0).
b. Participants must have been pre- or peri-menopausal at the time of breast cancer diagnosis by satisfying one of the following:

    1. had a menstrual period (by self-report) within the 12 months before breast cancer diagnosis, or
    2. had a serum or plasma estradiol and/or FSH concentration consistent with premenopausal status (based on institutional standards) within the 12 months before breast cancer diagnosis or when checked after breast cancer diagnosis.

c. Participants must not have distant metastatic breast cancer.

Prior/Concurrent Therapy Criteria

a. Participants must have started initial treatment with standard care oral endocrine therapy (ET) (i.e., tamoxifen, anastrozole, exemestane, or letrozole; see Section 7.1 for details) within 14 days prior to randomization or be planning to start initial treatment with standard of care oral ET (+/- GnRHa injection) within 14 days after randomization.

    NOTES:
    1. For participants who will be starting GnRHa injection followed by initiation of oral ET after achieving ovarian suppression, participants must be planning to start initial treatment with standard of care GnRHa therapy within 14 days after randomization.
    2. For participants who have already started receiving GnRHa injection, they must have started initial treatment with standard of care oral endocrine therapy (ET) (i.e., tamoxifen, anastrozole, exemestane, or letrozole; see Section 7.1 for details) within **14 days** prior to randomization or be planning to start initial treatment with standard ofcare oral ET within **14 days** after randomization.
    3. At the time of study enrollment, there should not be a pre-determined plan to change participant's oral endocrine therapy during study participation.

b. Participants who currently have ovarian function (recent menses within the past90 days or estradiol above the postmenopausal range) must be planning to undergo ovarian suppression or ablation (see Section 7.1) concomitantly with oral ET medication, starting before or at the same time as oral ET initiation. Participants with chemotherapy induced amenorrhea or ovarian failure at time of registration must be planning to start ovarian suppression or ablation if they have recurrence of ovarian function during study participation (circulating estradiol concentration in the premenopausal range or recurrence of menses).

c. Participants must have completed surgery for treatment of breast cancer at least 14 days prior to randomization.

d. Participants who received chemotherapy must have finished it at least 14 days prior to randomization.
NOTES:
   1. At the time of study enrollment, the decision to administer or not administer adjuvant chemotherapy should already have been made.
   2. Concomitant maintenance targeted or biologic therapy (e.g., anti-HER2 therapy, PARP inhibitor therapy, CDK4/6 inhibitor therapy, osteoclast inhibitor therapy) at the time of randomization and/or during study participation is allowed.

e. Participants who have started or plan to start treatment with tamoxifen during study participation must not have received prior tamoxifen for treatment or prevention of breast cancer.

f. Participants who have started or plan to start treatment with an aromatase inhibitor during study participation must not have received prior aromatase inhibitor therapy for treatment or prevention of breast cancer.

   NOTES:
   1. Participants who start or plan to start treatment with an aromatase inhibitor may have previously received tamoxifen for prevention of breast cancer or treatment of a prior cancer.

   2. Participants may have received prior treatment with an aromatase inhibitor for infertility treatment.

g. Participants must not be taking or planning to take oral estrogen- or progesterone-containing treatments during study participation.

h. Participants must not receive additional anti-cancer treatments (i.e., experimental therapy, immunotherapy, biologics, etc.) as part of another clinical trial.

i. Participants must not co-enroll on this trial and other clinical trials with similar interventions or endpoints (eg., Alliance A191907).

5.3 Clinical/Laboratory Criteria

a. Participants must be ≥ 18 years of age.

b. Participants must have a complete medical history within 60 days prior to randomization.

c. Participants must be able to complete Patient-Reported Outcome (PRO) instruments in English or Spanish. Participants must: 1) agree to complete PROs at all scheduled assessments (per Section 7.4); and 2) complete the preregistration (baseline) PRO forms within 14 days prior to randomization.

d. Participants must be able to complete symptom questions on a web browser (on a smartphone, tablet, or computer) or respond via voice on a telephone in English or Spanish. Participants must agree to complete symptom questions at all scheduled assessments.

   NOTE: Participants who do not have access to the internet and who cannot receive telephone calls for interactive voice response system (IVRS) assessments are not eligible.

e. Participants must not have a non-breast malignancy for which they are currently receiving treatment.

f. Participants must not be planning to become pregnant during the 80 weeks of study participation.

5.4 Specimen Submission Criteria

a. Participants must be offered the opportunity to participate in specimen banking for translational medicine as outlined in Section 15.2. With participant consent, specimens must be collected and submitted via the SWOG Specimen Tracking System as outlined in Section 15.3.

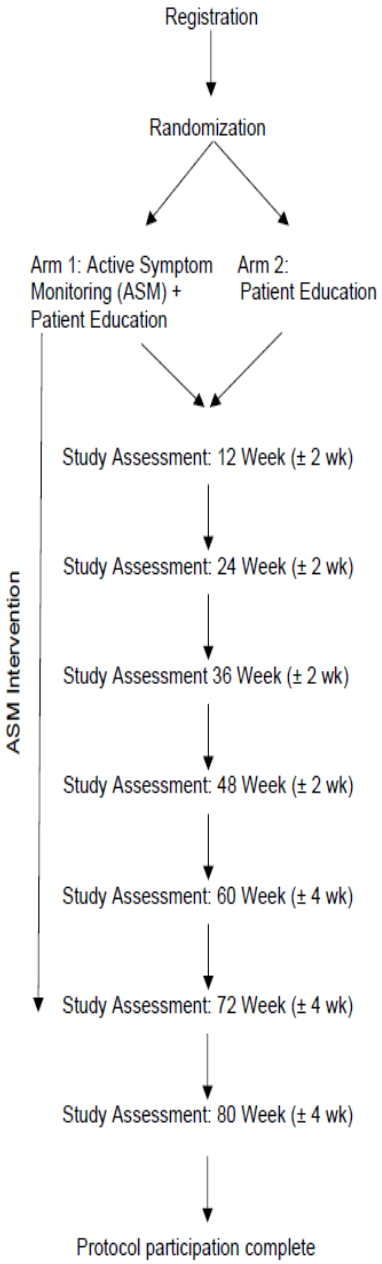
   NOTE: The optional specimen for banking collection is not required for sitesoutside of the US.

5.5 Regulatory Criteria

NOTE: As a part of the OPEN registration process (see Section 13.5 for OPEN access instructions) the treating institution's identity is provided in order to ensure that the current (within 365 days) date of institutional review board approval for this study has been entered in the system.

a. Participants must be informed of the investigational nature of this study and must sign and give informed consent in accordance with institutional and federal lines.

SCHEMA


Registration
Randomization
Arm 1: Active Symptom Monitoring (ASM) + Patient Education
Arm 2: Patient Education
ASM Intervention
Study Assessment: 12 Week (± 2 wk)
Study Assessment: 24 Week (± 2 wk)
Study Assessment 36 Week (± 2 wk)
Study Assessment: 48 Week (± 2 wk)
Study Assessment: 60 Week (± 4 wk)
Study Assessment: 72 Week (± 4 wk)
Study Assessment: 80 Week (± 4 wk)
Protocol participation complete