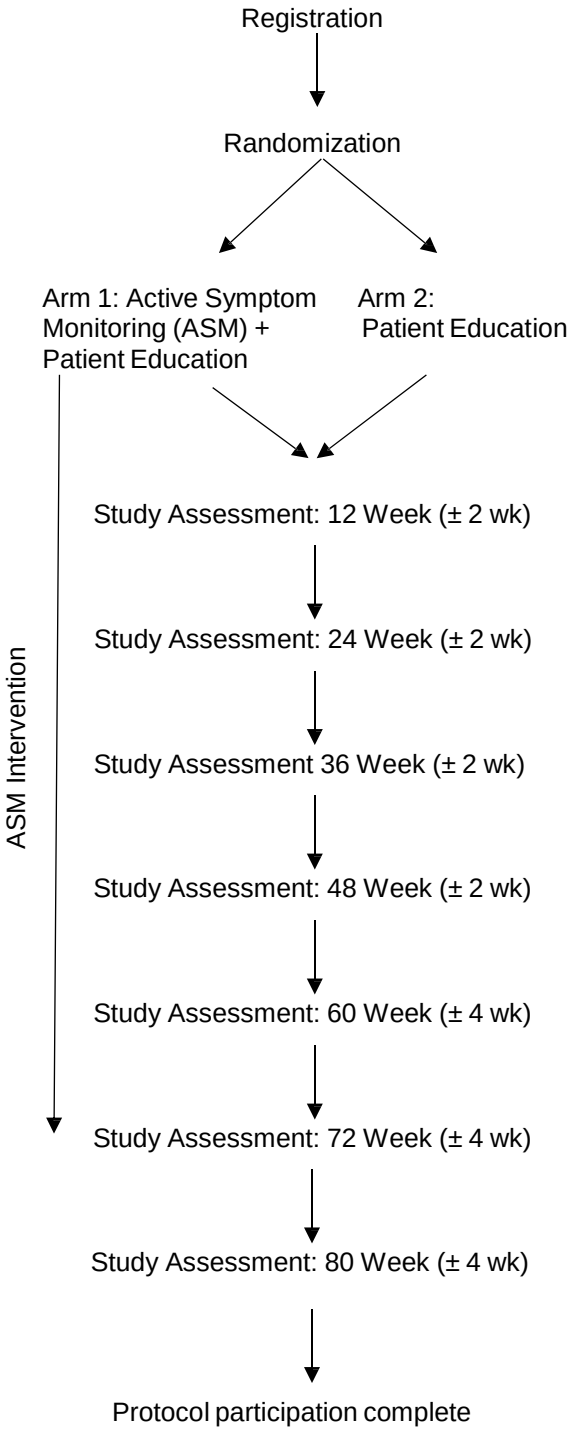
SWOG S2010 SCHEMA



5.0 ELIGIBILITY CRITERIA

Each of the criteria in the following section must be met in order for a participant to be considered eligible for registration in OPEN. Section 5 may be printed and used to by the site, but is not to be uploaded in RAVE (unless specially stated). For each criterion requiring test results and dates, please record this information on the Onstudy Form and submit via Medidata Rave® (see Section 14.4). Any potential eligibility issues should be addressed to the SWOG SDMC in Seattle at 206/652-2267 or cancercontrolquestion@crab.org prior to registration. **NCI policy does not allow for waiver of any eligibility criterion (http://ctep.cancer.gov/protocolDevelopment/policies_deviations.htm).**

In calculating days of tests and measurements, the day a test or measurement is done is considered Day 0. Therefore, if a test is done on a Monday, the Monday 4 weeks later would be considered Day 28. This allows for efficient participant scheduling without exceeding the guidelines. **If any of the days mentioned in Section 5 fall on a weekend or holiday, the limit may be extended to the next working day.**

NOTE: Sites that routinely use symptom assessments between scheduled clinic visits for clinical care may not register participants on this study.

5.1 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.

5.2 Prior/Concurrent Therapy Criteria

a. Participants 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 of care oral ET (+/- GnRHa injection) within **14 days** after randomization.

   NOTE: 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.

b. Participants who currently have ovarian function (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.

NOTE: Concomitant radiotherapy at the time of randomization and/or during study participation is allowed.

d. Participants who received chemotherapy must have finished it at least **14 days** prior to randomization.

NOTE: 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.

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 pre-registration (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.

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 guidelines.