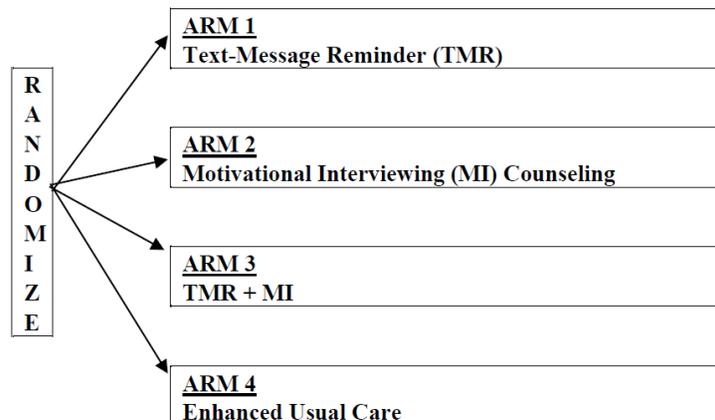


FAST FACTS

ALLIANCE A191901: OPTIMIZING ENDOCRINE THERAPY THROUGH MOTIVATIONAL INTERVIEWING AND TEXT INTERVENTIONS

Schema



Please refer to the full protocol text for a complete description of the eligibility criteria and intervention plan.

On-Study Guidelines

- 1. This clinical trial can fulfill its objectives only if patients appropriate for this trial are enrolled. All relevant medical and other considerations should be taken into account when deciding whether this protocol is appropriate for a particular patient. Physicians should consider the risks and benefits of any therapy, and therefore only enroll patients for whom this treatment is appropriate.**

Physicians should consider whether any of the following may render the patient inappropriate for this protocol:

- Patients with a contraindication to endocrine therapy medications, such as existing or planned pregnancy

Eligibility Criteria

Use the spaces provided to confirm a patient's eligibility by indicating Yes or No as appropriate. It is not required to complete or submit the following page(s).

When calculating days of tests and measurements, the day a test or measurement is done is considered Day 0. Therefore, if a test were done on a Monday, the Monday one week later would be considered Day 7.

1. Women with an initial pathologically confirmed diagnosis of stage I-III, hormone receptor positive, HER2-neu negative, invasive breast cancer within 18 months (i.e., <548 days) prior to registration

- If the patient has undergone neo-adjuvant chemotherapy and had no residual invasive disease at the time of surgery, eligibility can be based on clinical stage I-III prior to treatment and pathologic confirmation of receptor status from a diagnostic biopsy.

Hormone receptor positive is defined as estrogen receptor (ER), progesterone receptor (PR), or both of >1%

- HER2-neu negative is defined as 0-1+ by ImmunoHistoChemical (IHC) analysis, or non-amplified by Fluorescence in situ Hybridization (FISH) analysis. If HER2-neu status is unknown due to insufficient tissue for evaluation, the patient is eligible.
- Patients with synchronous primary tumor foci of different receptor phenotypes, whether in the same or contralateral breast, may be enrolled as long as one tumor focus meets thereceptor criteria and the patient is otherwise eligible.

2. Prior Treatment:

- Patients must have completed all planned cancer-directed surgery (except reconstruction surgery or oophorectomy).
- Patients must have completed all other adjuvant therapy (e.g., radiation and IV or oralchemotherapy) prior to registration (see [Section 3.2.3](#) regarding adjuvant endocrine therapy).
- Patients who will be taking a CDK4/6 inhibitor (e.g., abemaciclib, palbociclib, or ribociclib) during endocrine therapy are NOT permitted to enroll as this is consideredongoing adjuvant therapy.
- Patients who have previously been on ET drug outside the 6-month window for any reason, including breast cancer prevention or high-risk non-malignant lesions (e.g., ADH, LCIS) are ineligible.

3. Patients must be taking a once daily endocrine therapy drug initiated within the 6 months (i.e., <183 days) prior to registration, OR have received a prescription for a once daily ET medication with stated intent to initiate within 6 weeks (i.e., <42 days) after registration.

- Patients who switch ET drugs prior to enrollment remain eligible as long as the total time since initiation of the first ET drug does not exceed 6 months prior to registration.
- Patients who have stopped their ET drug prior to enrollment and not started another ET drug are ineligible.

4. No history of previous cancer as follows:

- Invasive or non-invasive breast cancer at any time
- Non-breast cancer, within the past 5 years, excluding non-melanoma skin cancer
- Patients with a history of high-risk breast lesions (e.g., atypical ductal hyperplasia – ADH, lobular carcinoma in situ—LCIS) are eligible as long as they have not previously taken an endocrine therapy drug (see [Section 3.2.2](#)).

5. Patients must be willing to use a smart phone for study activities

- Patient is NOT to be deemed ineligible during the recruitment process if they do not have a smart phone.
- A smart phone and service can be provided to the participant at no cost for the duration of the study activities if the participant meets at least one of the following criteria: (1) does not own a smart phone, (2) has a limited data, minutes, or texting plan, or (3) their smart phone cannot support the Alliance ePRO survey app. Study-provided smart phones will be provided through the Ohio State University partnership with Verizon Wireless.
- The Clinical Research Professional (CRP) is ONLY to discuss this option with those patients who self-identify a phone-related barrier to participation, including: lack of a smart phone, insufficient phone plan (minutes/text/data), or a smart phone incompatible with the Alliance ePRO app.

6. Patients must be willing to use a Pillsy medication event monitoring system for the duration of study participation

- Patients must be willing to use a pill bottle (provided by either the study or the patient's pharmacy) in combination with the Pillsy medication event monitoring system each time ET drug is taken. Use of any other container (e.g., pill box, etc.) for ET drug during study period is not permitted.

7. Age \geq 18 years**8. Language: In order to complete the mandatory patient-completed measures, participants must be able to speak and read English.**

- 9. Co-enrollment is allowed with the permission of the Alliance Executive Officer and both studies' Study Chairs**