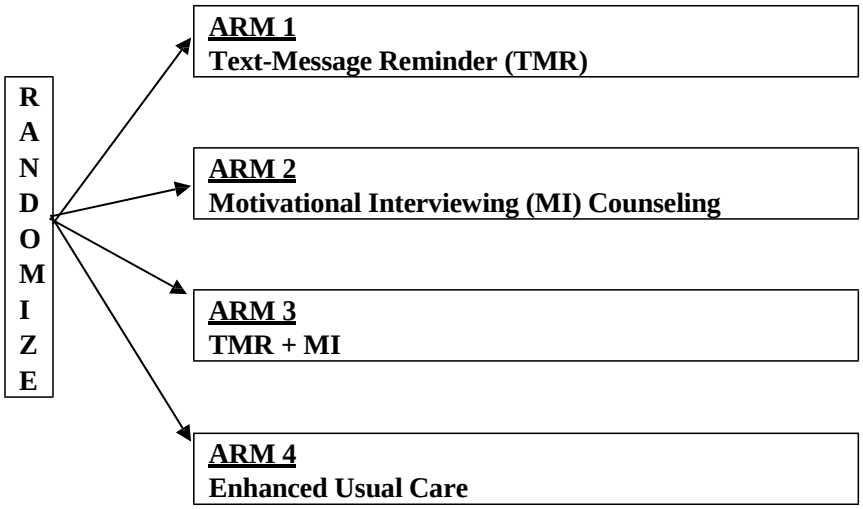
OPTIMIZING ENDOCRINE THERAPY THROUGH MOTIVATIONAL INTERVIEWING AND TEXT INTERVENTIONS

Eligibility Criteria (see Section 3.0)

Required Initial Laboratory Values
None

- Women with pathologically confirmed initial diagnosis of stage I-III, hormone receptor positive, HER2-neu negative invasive breast cancer within 18 months prior to registration (See §3.2.1).
- Patients must have received cancer-directed surgery, and/or completed all other adjuvant therapy, except reconstruction (See §3.2.2).
- Patients must have initiated an endocrine therapy drug within the 6 months prior to registration or have received a prescription with stated intent to initiate within 6 weeks after registration (See §3.2.3).
- Patients must have no history of cancer as follows: invasive or non-invasive breast cancer at any time, and/or no history of non-breast cancer within the last 5 years, excluding non-melanoma skin cancer (See §3.2.4).
- Patients must be willing to use a smart phone for study activities (See §3.2.5).
- Patients must be willing to use a Pillsy medication event monitoring system for study activities (See §3.2.6).
- Age ≥ 18 years
- Patients must be able to speak and read English

Schema



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

3.1 PATIENT SELECTION

For questions regarding eligibility criteria, see the Study Resources page. Please note that the Study Chair cannot grant waivers to eligibility requirements.

3.2 On-Study Guidelines

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 who have previously taken ET at any point during their cancer care, either for preventative or disease treatment measures
- Patients with a contraindication to endocrine therapy medications, such as existing or planned pregnancy

3.3 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.

___ 3.2.1 Women with an initial pathologically confirmed diagnosis of stage I-III, hormone receptor positive, HER2-neu negative, invasive breast cancer within 18 months prior to enrollment

- Women who have undergone neo-adjuvant chemotherapy who have no residual invasive disease post-surgery are eligible based on an initial pathologically confirmed diagnosis
- Hormone receptor positive is defined as estrogen receptor (ER) and/or progesterone receptor (PR) of >1%
- HER2-neu negative is defined as 0-1+ by ImmunoHistoChemical (IHC) analysis, or non-amplified by Fluorescence in situ Hybridization (FISH) analysis

___ **3.2.2 Prior Treatment:**

Patients must have received cancer-directed surgery, and/or completed all other adjuvant therapy, except reconstruction.

___ **3.2.3 Patients must have initiated an endocrine therapy drug within the 6 months prior to registration, OR have received a prescription with stated intent to initiate within 6 weeks after registration.**

___ **3.2.4 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

___ **3.2.5 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.
- If a participant does not own a smart phone or has limited data or texting capabilities or their smart phone cannot support the Alliance ePRO survey app, a smart phone and service can be provided to the participant at no cost through the Ohio State University partnership with Verizon Wireless for the duration of the study activities.
- The 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.
- For OSU-provided phones, charges will be paid by the grant through the intervention period. At the end of the 12-month intervention period, patients will be responsible for paying monthly fees, if continued service is desired. The physical phones will belong to the patients at the end of their study activities.

___ **3.2.6 Patients must be willing to use a Pillsy medication event monitoring system for the duration of study participation**

___ **3.2.7 Age ≥ 18 years**

___ **3.2.8 Language: In order to complete the mandatory patient-completed measures, participants must be able to speak and read English.**