Additional Support Program Via Text Messaging and Telephone-Based Counseling for Breast Cancer Patients Receiving Hormonal Therapy

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

* 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 * Patients must have received cancer-directed surgery, and/or completed all other adjuvant therapy, except reconstruction * 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 * 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 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 electronic patient reported outcomes (ePRO) survey application (app), a smart phone and service can be provided to the participant at no cost through the Ohio State University (OSU) 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 * Patients must be willing to use a Pillsy medication event monitoring system for the duration of study participation * In order to complete the mandatory patient-completed measures, participants must be able to speak and read English

Conditions & Interventions

Interventions:

OTHER: Educational Intervention, OTHER: Text Message-based Navigation Intervention, BEHAVIORAL: Motivational Interviewing, OTHER: Best Practice, OTHER: Questionnaire Administration, OTHER: Quality-of-Life Assessment

Conditions:

Anatomic Stage I Breast Cancer AJCC v8, Anatomic Stage II Breast Cancer AJCC v8, Anatomic Stage III Breast Cancer AJCC v8, HER2 Negative Breast Carcinoma, Hormone Receptor Positive Breast Carcinoma, Invasive Breast Carcinoma, Prognostic Stage I Breast Cancer AJCC v8, Prognostic Stage II Breast Cancer AJCC v8, Prognostic Stage III Breast Cancer AJCC v8

More Information

Contact(s): Katherine E. Reeder-Hayes, MD - kreeder@med.unc.edu
Principal Investigator: Thomson, Maria
Phase: PHASE3
IRB Number: HM20022273
System ID: NCT04379570