

Mobile Health for Adherence in Breast Cancer Patients

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is also accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* NON-PATIENT: Participants must be an oncology healthcare provider (i.e., oncologist, advanced practice provider, or oncology nurse) * NON-PATIENT: Participants must have taken care of at least one patient randomized to Arm B (CONCURxP) who had less than 85% adherence rate at 12 months as measured by the WiseBag * NON-PATIENT: Participant must speak English * NON-PATIENT: Participant must be employed at an National Cancer Institute Community Oncology Research Program (NCORP) site for at least 6 months * NON-PATIENT: Participant must be able to provide informed consent to participate in this study * PATIENT STEP 0: Patient must be \geq 18 years of age * PATIENT STEP 0: Patient must be fluent in written and spoken English OR patient must be fluent in written and spoken Spanish * PATIENT STEP 0: Patient must present with new or established pathologically proven hormone receptor (HR)+ HER2- metastatic breast cancer at the time of Step 0 * PATIENT STEP 0: Patient must have initiated any of the CDK4/6 inhibitors (palbociclib or Ibrance, ribociclib or Kisqali, abemaciclib or Verzenio) within 30 days prior to consenting to Step 0 or have received a prescription order with stated intent to initiate within 30 days following Step 0 consent * NOTE: Patients who have been treated previously with anticancer treatments other than CDK4/6 inhibitors are eligible * NOTE: CDK4/6 inhibitors must be provided/supplied as a single agent blister pack. If the medication is supplied as capsules in a pill bottle (e.g., Ibrance capsules), patient is not eligible * NOTE: Ribociclib (Kisqali) and abemaciclib (Verzenio) are only available in blister packs. Palbociclib (Ibrance) is the only CDK4/6 inhibitor that might be available in a capsule formulation. However, this is an outdated formulation and is rarely prescribed as a new start. The format of ordered palbociclib can be determined based on the prescription order * PATIENT STEP 0: Patients must not have been previously treated with any of the following CDK4/6 inhibitors: Palbociclib or Ibrance, ribociclib or Kisqali, and abemaciclib or Verzenio * PATIENT STEP 0: Patients must not already be enrolled in a therapeutic clinical trial that monitors CDK4/6 inhibitors * PATIENT STEP 0: Patient must confirm that they intend to receive their care or monitoring at an NCORP site * PATIENT STEP 0: Patient must have a personal mobile phone in which they are able and willing to send and receive text messages * NOTE: The restriction to those with mobile phone access with text messaging is based on the primary intention of the study which involves the use of text messaging to improve adherence * PATIENT STEP 0: Patient must have an email address * NOTE: The restriction to those with an email address is based on the primary intention of the study which involves patients responding to questions regarding their reasons for non-adherence after every missed dose to improve adherence * PATIENT STEP 0: Patient must have the ability to understand and the willingness to sign a written informed consent document * NOTE: Patients with impaired decision-making capacity (IDMC) who have a legally authorized representative (LAR) or caregiver and/or family member available are not eligible * PATIENT STEP 0: Patient must not have an Eastern Cooperative Oncology Group (ECOG) performance status \geq 3 OR patient must not be deemed medically unable to participate in the study by the study investigators or an oncology clinician (i.e., referral to hospice) * PATIENT STEP 0: Patient must not be enrolled in other trials offering financial assistance * NOTE: Gift cards for survey completion, parking passes, or free medication provided as part of therapeutic trials are not considered financial assistance * PATIENT STEP 1: Patient must meet all the eligibility criteria for Step 0 * PATIENT STEP 1: Patient must have signed a written informed consent form * PATIENT STEP 1: Patient must have completed baseline survey within 30 days of the date of Step 0 Registration * PATIENT STEP 1: Patients must have initiated their CDK 4/6 inhibitors within 30 days of the date of Step 0 registration

Conditions & Interventions

Interventions:

OTHER: Electronic Health Record Review, OTHER: Health Promotion and Education, PROCEDURE: Health Telemonitoring, OTHER: Interview, BEHAVIORAL: Patient Navigation, OTHER: Survey Administration, OTHER: Text Message-Based Navigation Intervention

Conditions:

Anatomic Stage IV Breast Cancer AJCC v8, Breast Carcinoma, HER2-Negative Breast Carcinoma, Hormone Receptor-Positive Breast Carcinoma

More Information

Contact(s): ctrrecruit@vcu.edu

Principal Investigator:

Phase: NA

IRB

Number:

System ID: NCT06112613

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