Cancer Research Consortium of West Michigan
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FAST FACTS

NRG-CC011: COGNITIVE TRAINING FOR CANCER RELATED COGNITIVE IMPAIRMENT IN BREAST CANCER SURVIVORS: A MULTI-CENTER RANDOMIZED DOUBLE- BLINDED CONTROLLED TRIAL

1.0 Eligibility Criteria

1.1 The participant must provide study-specific informed consent prior to any study specific procedures and authorization permitting release of personal health information.

1.2 The participant must be ≥ 18 years of age.

1.3 The participant must have a first time diagnosis of non-metastatic breast cancer which is Stage I-III.

1.4 The participant must have a score of < 12 on the PROMIS Adult v2.0 - Cognitive Function 4a.

1.5 Participants with ≥ 6 months to 5 years post-treatment (completion of initial surgery +/-adjuvant chemotherapy/radiation therapy) except may still be taking endocrine therapy or HER2-directed adjuvant therapy.

1.6 The participant must be able to understand, speak, read, and write in English or Spanish.

2.0 Ineligibility Criteria

2.1 Scoring ≤ 3 on the 6-item cognitive screen.

2.2 Patient Health Questionnaire-2 item (PHQ-2) score of ≥ 3.

2.3 Definitive clinical or radiologic evidence of metastatic disease.

2.4 Prior history of past or current other cancer, except for non-melanoma skin cancer or in situ cervical cancer within the past 5 years.

2.5 Previous exposure to chemotherapy treatment for another cancer or due to other medical condition (e.g. methotrexate exposure for treatment of rheumatoid arthritis).

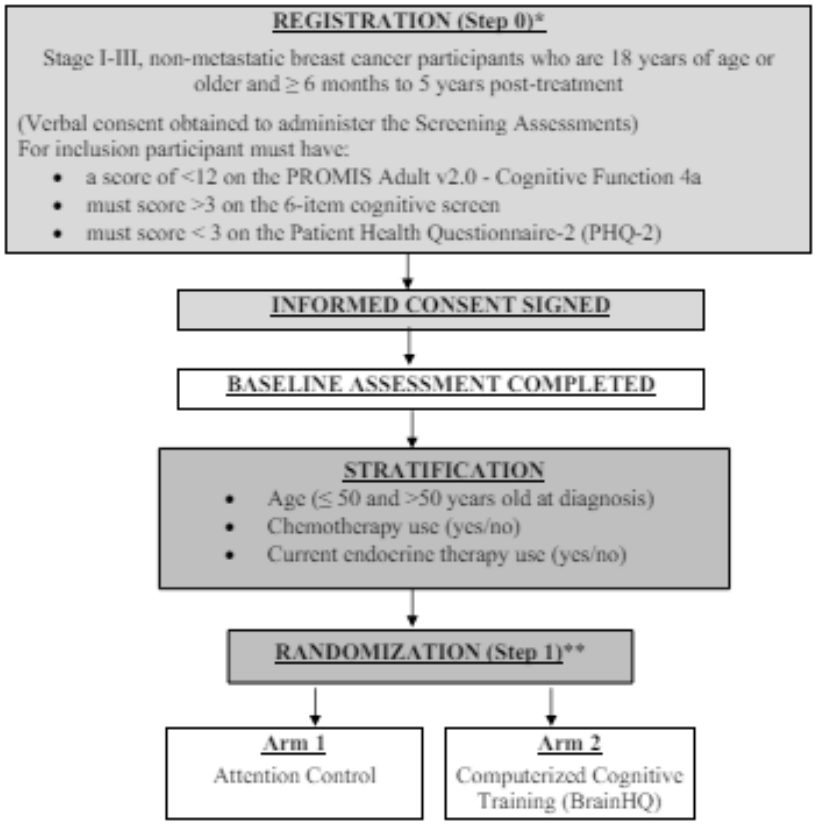
2.6 Previous CNS radiation, intrathecal therapy or CNS-involved surgery.

2.7 Participants with history of stroke, traumatic brain injury, brain surgery, Alzheimer's disease or other dementia.

2.8 Participants with active substance abuse and/or in treatment for substance abuse, or history of bipolar disorder, psychosis, schizophrenia, ADHD, or learning disability.

2.9 Participants who are enrolled in other therapeutic trials and/or quality of life trials.

NRG-CC011 SCHEMA



All potential participants will be registered in Step 0.
*If a participant meets all eligibility requirements, provides written informed consent, and completes the baseline assessment (both surveys via VTOC tool and neuropsychological assessment), the participant will be randomized in Step 1.
**Randomization is 1:1
Registration (Step 0) and Randomization (Step 1) are a collaboration of NRG Oncology sites, NRG SDMC, and Ohio State University (shading represents the steps where sites are involved).
The baseline assessment is a function of the NRG Oncology SDMC and Ohio State University only.