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

Eligibility Criteria

1. The participant must provide study-specific informed consent prior to any study specific procedures and authorization permitting release of personal health information.
2. The participant must be ≥ 18 years of age.
3. The participant must have a first-time diagnosis of non-metastatic breast cancer which is Stage I-III.
4. The participant must have a score of < 12 on the PROMIS Adult v2.0 - Cognitive Function 4a.
5. Participants must be at least 6 months and no more than 5 years after completion of initial surgery +/- adjuvant chemotherapy/radiation therapy, and targeted therapies (e.g., PARP inhibitors, CDK4/6, or immunotherapy). Participants may still be taking endocrine therapy and/or trastuzumab.
6. The participant must be able to understand, speak, read, and write in English or Spanish.

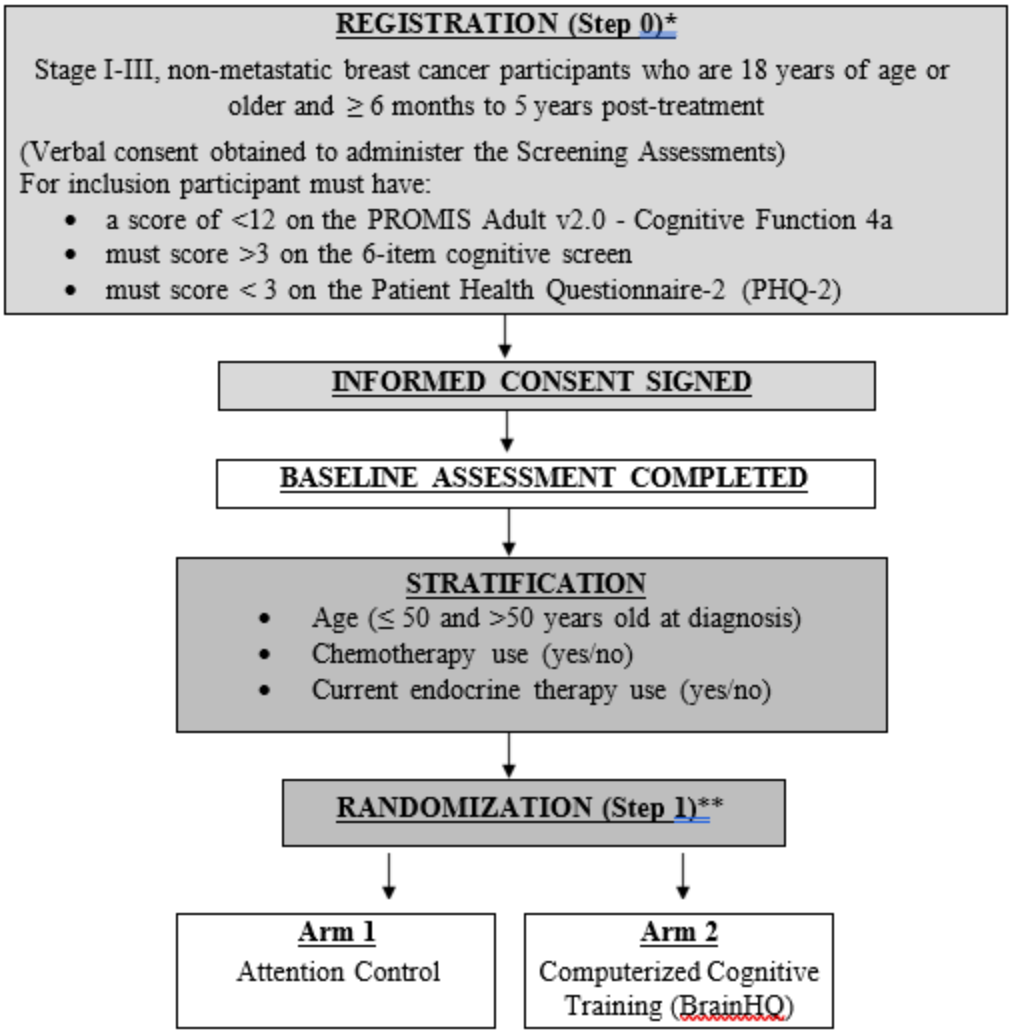
Ineligibility Criteria

1. Scoring ≤ 3 on the 6-item cognitive screen.
2. Patient Health Questionnaire-2 item (PHQ-2) score of ≥ 3.
3. Definitive clinical or radiologic evidence of metastatic disease.
4. Current or past history of another cancer. Patients with history of only non-melanoma skin cancer or in situ cervical cancer without chemotherapy treatment would be eligible.
5. Previous exposure to chemotherapy treatment for another cancer or due to other medical condition (e.g., methotrexate exposure for treatment of rheumatoid arthritis).
6. Previous CNS radiation, intrathecal therapy or CNS-involved surgery.
7. Participants with history of stroke, traumatic brain injury, brain surgery, Alzheimer's disease or other dementia.
8. Participants with active substance abuse and/or in treatment for substance abuse, or history of bipolar disorder, psychosis, schizophrenia, ADHD, ADD, or learning disability.
9. Participants who are enrolled in an active behavioral intervention (e.g.,

occupational therapy, physical therapy, etc.) or pharmaceutical intervention or who are in the follow- up phase of a cancer control trial or therapeutic trial that has extensive PRO follow-up after treatment ends. Participants who are enrolled in a therapeutic trial in which they have completed active treatment and require only minimal follow-up monitoring of toxicity and/or survival analysis (cancer-related mortality or all-cause mortality) would be eligible.

10. Hearing impairment unless adequately corrected with hearing aids to be able to hear over the phone for the neuropsychological testing.

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.