

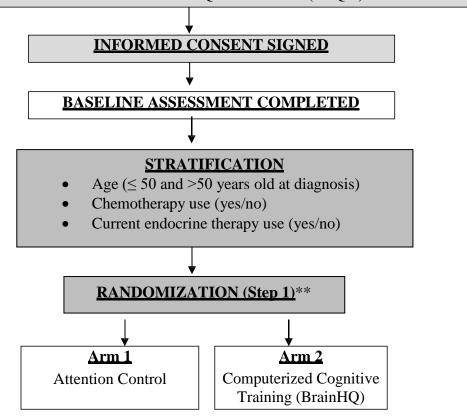
## Figure 1. NRG-CC011 SCHEMA

## **REGISTRATION** (Step 0)\*

Stage I-III, non-metastatic breast cancer participants who are 18 years of age or older and  $\geq$  6 months to 5 years post-treatment

(Verbal consent obtained to administer the Screening Assessments) For inclusion participant must have:

- a score of <12 on the PROMIS Adult v2.0 Cognitive Function 4a
- must score >3 on the 6-item cognitive screen
- must score < 3 on the Patient Health Questionnaire-2 (PHQ-2)



<sup>\*</sup>All potential participants will be registered in Step 0.

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.

<sup>\*\*</sup>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.

<sup>\*\*</sup>Randomization is 1:1

## 3.2 Eligibility Criteria

A participant cannot be considered eligible for this study unless ALL of the following conditions are met. (Specifically, all criteria must be met at Step 0-Registration)

- 3.2.1 The participant must provide study-specific informed consent prior to any study specific procedures and authorization permitting release of personal health information.
- 3.2.2 The participant must be  $\geq 18$  years of age.
- 3.2.3 The participant must have a first time diagnosis of non-metastatic breast cancer which is Stage I-III.
- 3.2.4 The participant must have a score of < 12 on the PROMIS Adult v2.0 Cognitive Function 4a.
- 3.2.5 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.
- 3.2.6 The participant must be able to understand, speak, read, and write in English or Spanish.

## 3.3 Ineligibility Criteria

Participants with any of the following conditions are NOT eligible for this study.

- 3.3.1 Scoring  $\leq$  3 on the 6-item cognitive screen.
- 3.3.2 Patient Health Questionnaire-2 item (PHQ-2) score of  $\geq$  3.
- 3.3.3 Definitive clinical or radiologic evidence of metastatic disease.
- 3.3.4 Prior history of past or current other cancer, except for non-melanoma skin cancer or in situ cervical cancer within the past 5 years.
- 3.3.5 Previous exposure to chemotherapy treatment for another cancer or due to other medical condition (e.g. methotrexate exposure for treatment of rheumatoid arthritis).
- 3.3.6 Previous CNS radiation, intrathecal therapy or CNS-involved surgery.
- 3.3.7 Participants with history of stroke, traumatic brain injury, brain surgery, Alzheimer's disease or other dementia.
- 3.3.8 Participants with active substance abuse and/or in treatment for substance abuse, or history of bipolar disorder, psychosis, schizophrenia, ADHD, or learning disability.
- 3.3.9 Participants who are enrolled in other therapeutic trials and/or quality of life trials.