URCC 10055 - Assessment of Cognitive Function in Breast Cancer and Lymphoma Patients Receiving Chemotherapy at Pre-Treatment, Post-Treatment, and at Six Month Follow-Up

Fast Facts

Inclusion Criteria, Subjects Receiving Chemotherapy:

1. Have a diagnosis of invasive breast cancer (stage I-IIIC) or intermediate or high-grade* lymphoma (*defined by the treating physician)
2. Be scheduled to begin a course of chemotherapy
    a. Oral chemotherapy is acceptable
    b. Previous or concurrent treatment with hormones or biological response modifiers is acceptable. (Subjects receiving biological response modifiers only are not eligible).
3. Be chemotherapy naïve
4. Life expectancy greater than 10 months
5. Be able to speak and read English
6. Be 21 years old or older
7. Give written informed consent

Exclusion Criteria, Subjects Receiving Chemotherapy:

1. Must not be currently hospitalized or have been hospitalized within the last year for a psychiatric illness
2. Must not be diagnosed with a neurodegenerative disease (eg Alzheimer's disease or Parkinson's disease)
3. Must not have any CNS disease (eg movement disorder, multiple sclerosis)
    a. Subjects could have had a TIA or stroke in the past if the TIA or stroke was greater than one year ago and subject does not have any remaining symptoms
4. Must not have received chemotherapy in the past
5. Must not be scheduled to receive concurrent radiation treatment while receiving chemotherapy
6. Must not have (or have had) metastatic disease (subjects with breast cancer)
7. Must not be pregnant
8. Must not be colorblind

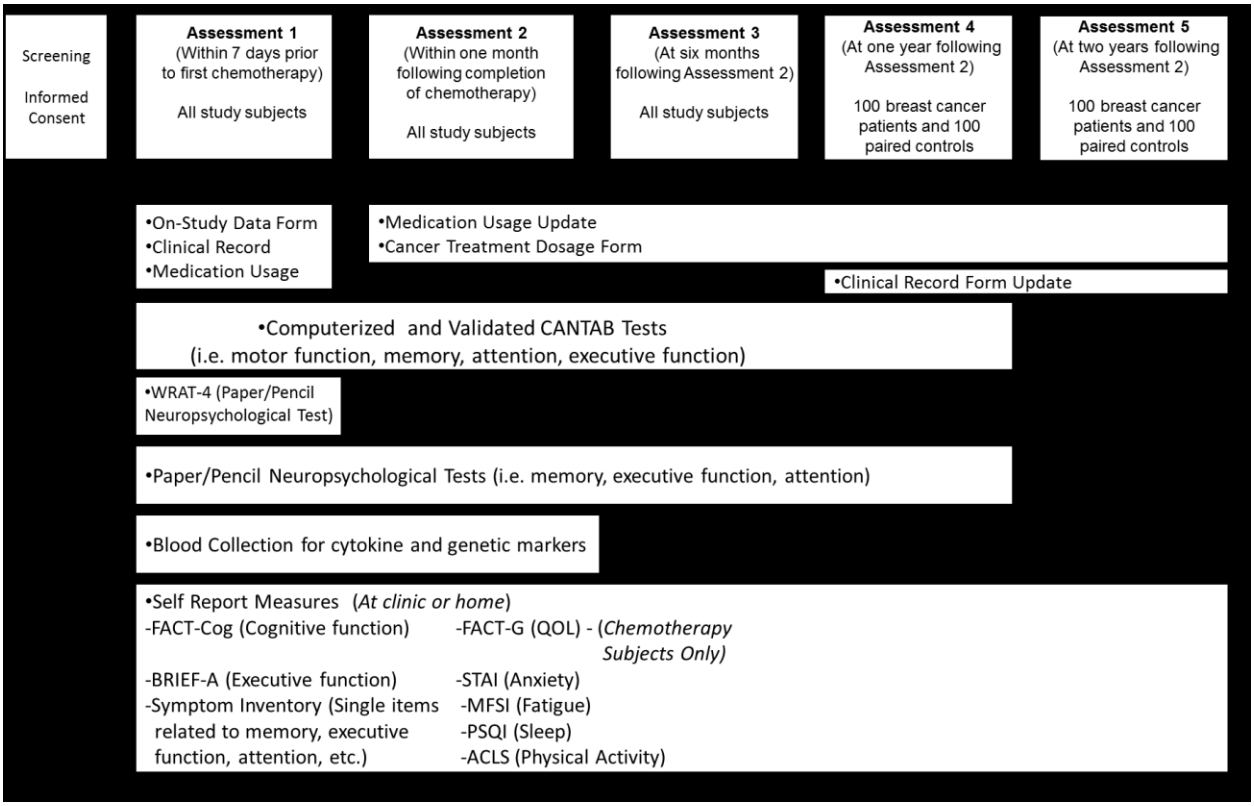
Inclusion Criteria, Controls:

1. Must be the same gender as the subject receiving chemotherapy
2. Must be within 5 years of the age of the subject receiving chemotherapy
3. Life expectancy greater than 10 months
4. Be able to speak and read English
5. Be 21 years old or older
6. Give written informed consent
7. Must be willing to participate in the study for the entire period

Exclusion Criteria, Controls:

1. Must not be currently hospitalized or have been hospitalized within the last year for a psychiatric illness
2. Must not be diagnosed with a neurodegenerative disease (eg Alzheimer's disease or Parkinson's disease)
3. Must not have any CNS disease (eg movement disorder, multiple sclerosis)
    a. Subjects could have had a TIA or stroke in the past if the TIA or stroke was greater than one year ago and subject does not have any remaining symptoms
4. Must not have been diagnosed with cancer or previously have received chemotherapy
5. Must not be pregnant or plan on becoming pregnant during the study period
6. Must not be colorblind

Schema


Screening
Informed Consent
Assessment 1 (Within 7 days prior to first chemotherapy) All study subjects
Assessment 2 (Within one month following completion of chemotherapy) All study subjects
Assessment 3 (At six months following Assessment 2) All study subjects
Assessment 4 (At one year following Assessment 2) 100 breast cancer patients and 100 paired controls
Assessment 5 (At two years following Assessment 2) 100 breast cancer patients and 100 paired controls
•On-Study Data Form
•Clinical Record
•Medication Usage
•Medication Usage Update
•Cancer Treatment Dosage Form
•Clinical Record Form Update
•Computerized and Validated CANTAB Tests (i.e. motor function, memory, attention, executive function)
•WRAT-4 (Paper/Pencil Neuropsychological Test)
•Paper/Pencil Neuropsychological Tests (i.e. memory, executive function, attention)
•Blood Collection for cytokine and genetic markers
•Self Report Measures (At clinic or home)
-FACT-Cog (Cognitive function)
-FACT-G (QOL) - (Chemotherapy Subjects Only)
-BRIEF-A (Executive function)
-STAI (Anxiety)
-Symptom Inventory (Single items related to memory, executive function, attention, etc.)
-MFSI (Fatigue)
-PSQI (Sleep)
-ACLS (Physical Activity)