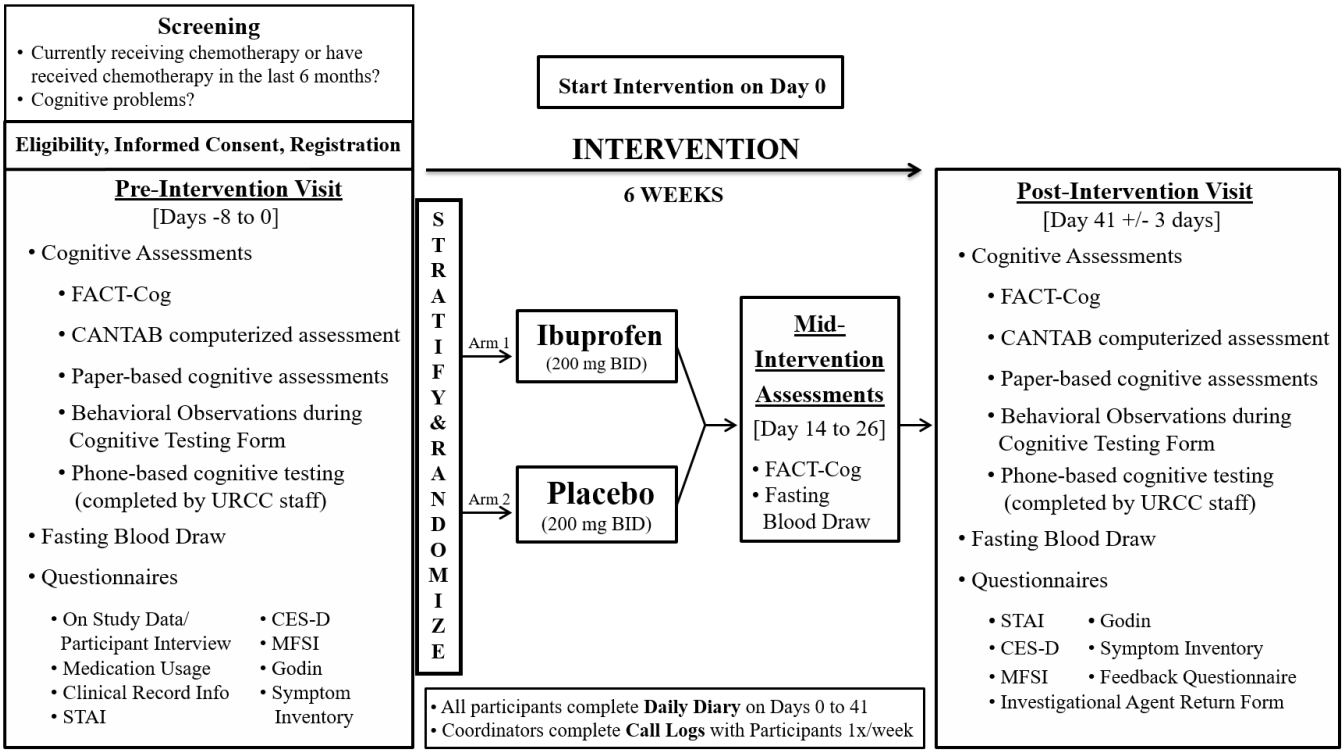
Schema


Screening
• Currently receiving chemotherapy or have received chemotherapy in the last 6 months?
• Cognitive problems?
Eligibility, Informed Consent, Registration
Pre-Intervention Visit
[Days -8 to 0]
• Cognitive Assessments
• FACT-Cog
• CANTAB computerized assessment
• Paper-based cognitive assessments
• Behavioral Observations during Cognitive Testing Form
• Phone-based cognitive testing (completed by URCC staff)
• Fasting Blood Draw
• Questionnaires
• On Study Data/ Participant Interview
• Medication Usage
• Clinical Record Info
• STAI
• CES-D
• MFSI
• Godin
• Symptom Inventory
STRATIFY&RANDOMIZE
Start Intervention on Day 0
INTERVENTION
6 WEEKS
Arm 1
Ibuprofen
(200 mg BID)
Arm 2
Placebo
(200 mg BID)
Mid-Intervention Assessments
[Day 14 to 26]
• FACT-Cog
• Fasting Blood Draw
• All participants complete Daily Diary on Days 0 to 41
• Coordinators complete Call Logs with Participants 1x/week
Post-Intervention Visit
[Day 41 +/- 3 days]
• Cognitive Assessments
• FACT-Cog
• CANTAB computerized assessment
• Paper-based cognitive assessments
• Behavioral Observations during Cognitive Testing Form
• Phone-based cognitive testing (completed by URCC staff)
• Fasting Blood Draw
• Questionnaires
• STAI
• CES-D
• MFSI
• Godin
• Symptom Inventory
• Feedback Questionnaire
• Investigational Agent Return Form

2.1. Primary Objective

2.1.1. To provide preliminary data on the effect of ibuprofen on alleviating CRCI in cancer patients receiving chemotherapy or who have received chemotherapy within the last 6 months compared to a placebo control, as assessed by the Functional Assessment of Cancer Therapy-Cognitive Function (FACT-Cog).

2.2. Exploratory Objectives

2.2.1. To provide preliminary data on the effect of ibuprofen on alleviating CRCI in cancer patients receiving chemotherapy or who have received chemotherapy within the last 6 months compared to a placebo control by objective assessments of cognitive function. These are measured by validated neuropsychological assessment of verbal memory, attention, and executive function via CANTAB (computerized DMS, VRM, and RVP) and paper-based measures (CTMT and COWA).

2.2.2. To provide preliminary data on the effect of ibuprofen on alleviating CRCI in cancer patients receiving chemotherapy or who have received chemotherapy within the last 6 months compared to a placebo control on phone-based cognitive function measures (digit span, word recall, digits backward, CALVT, category fluency; all from BTACT).

2.2.3. To provide preliminary data on the effect of ibuprofen on alleviating CRCI in cancer patients receiving chemotherapy or who have received chemotherapy within the last 6 months compared to a placebo control on serum pro-inflammatory (MCP-1, IL-6, IL-8, TNF-α, sTNFR2, sTNFR1, IL-1β) and anti-inflammatory (sIL-1Ra, IL-10) cytokines/receptors in cancer patients receiving chemotherapy.

2.2.4. To provide preliminary data on the mediating effects of cytokine/receptor concentrations on the CRCI changes due to ibuprofen in cancer patients receiving chemotherapy or who have received chemotherapy within the last 6 months compared to placebo control.

3. CHARACTERISTICS OF STUDY POPULATION

3.1. Inclusion Criteria

Study participants must:

3.1.1. Be ≥ 18 years of age

3.1.2. Have a diagnosis of cancer and are now receiving cytotoxic chemotherapy or have received cytotoxic chemotherapy within the last 6 months (i.e. are within a 6 month window of completion of chemotherapy).

3.1.3. Report cognitive difficulties or respond YES to the question: "Have you noticed any problems in your memory, attention, concentration, multi-tasking, or other cognitive functions?"

NOTE: If a participant does not report cognitive difficulties or answers NO, they should be re-approached multiple times. Patients should be re-screened at all subsequent chemotherapy treatments and multiple times during the six months following completion of chemotherapy via phone and in person.

3.1.4. Be able to swallow medication.

3.1.5. Be able to read English.

3.1.6. Be able to give written informed consent.

3.2. Exclusion Criteria

Study participants must not:

3.2.1. Have a confirmed brain tumor or confirmed brain metastases.

3.2.2. Be taking regular daily doses of an NSAID. Note: Daily doses of 81 mg aspirin are permitted and higher doses of an NSAID on an 'as needed' basis are permitted.

3.2.3. Be diagnosed with dementia or severe neurodegenerative disease that would prohibit the ability to complete cognitive testing.

3.2.4. Have a contraindication to ibuprofen per physician or physician's designee (e.g., allergy, worsening of ongoing medical problem due to NSAID, very low platelet count from chemotherapy, full-dose anti-coagulation/high risk of bleeding, as well as uncontrolled conditions such as hypertension, asthma, or peptic ulcer disease).

3.2.5. Have a hospitalization for treatment of a major psychiatric illness within the last five years.

3.2.6. Be pregnant.

3.2.7. Have a serum creatinine above 1.5 ULN. ULN is per institutional definition. If currently receiving chemotherapy, lab test must be collected within the 4 weeks prior to study enrollment. If not currently receiving chemotherapy, most recent labs tests may be used.

3.2.8. Be colorblind.

3.2.9. Have active substance abuse (e.g. alcohol, drugs) that would interfere with participation in this study per self-report or medical record.

3.3. Source of Study Participants

Data will be gathered from patients, 18 years of age or older, undergoing chemotherapy treatment for cancer or have received chemotherapy within the last 6 months at participating sites. Pediatric patients will be excluded from this study. Women and members of minority groups and their subpopulations will be included in the study.