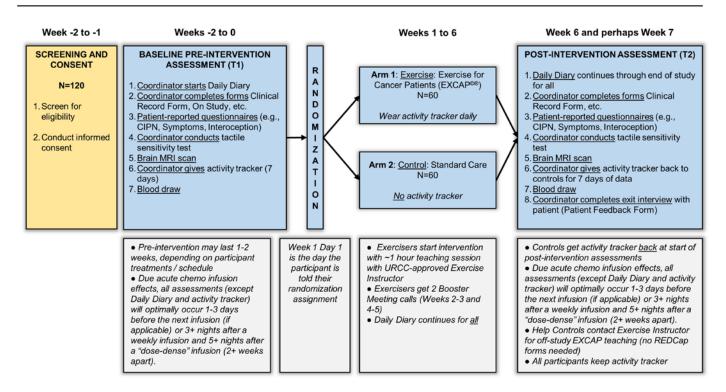
URCC-19075 Study schema



CIPN = chemotherapy-induced peripheral neuropathy. MRI = magnetic resonance imaging. The total study duration is approximately 7-8 weeks pre- and post-intervention assessments may take 1-2 weeks each surrounding the 6-week intervention.

3. Patient Selection and Enrollment

Inclusion Criteria (patients must...)

- 1. Have a diagnosis of cancer.
- 2. Be receiving neurotoxic chemotherapy or have completed neurotoxic chemotherapy in the past nine months (i.e., taxane-, platinum-, vinca alkaloid-, epothilone-, or proteasome inhibitor-based chemotherapy).
- 3. Report two or more symptoms of CIPN at a level of ≥4 on the CIPN symptom inventory on the Screening Form.
- 4. Have an ECOG Performance Status 0-1.
- 5. Have at least six months life expectancy.
- 6. Be at least 18 years of age.
- 7. Be able to read and understand English.
- 8. Be able to provide written informed consent.

Exclusion Criteria (patients must not...)

- 1. Have physical limitations (e.g., cardiorespiratory, orthopedic, central nervous system) that contraindicate participation in a low to moderate intensity home-based walking and progressive resistance exercise program, according to the patient's physician (e.g., oncologist, primary care) or physician's designee.
- 2. Be identified as in the active or maintenance stage of exercise behavior per the Exercise Stages of Change Question on the Screening Form.
- 3. Have planned surgery or radiation treatment during the course of the study (hormonal and biologic therapy is allowed).
- 4. Are pregnant of have plans to become pregnant during the course of the study. Documentation of pregnancy and use of contraception can be obtained from the medical record.
- 5. Have contraindications for MRI scanning, per the MRI scanning procedures and safety screening procedure of the facility that will be used in this study (approved by Dr. Kleckner or designee).
- 6. Have a current or prior cancer in the central nervous system (spine, brainstem, brain) as this would interfere with assessments of brain functional connectivity.

The patient's physician (e.g., oncologist, primary care) or physician's designee must confirm that the patient meets these eligibility criteria by signing the Eligibility Checklist prior to registration.

If a patient joins the study and cannot complete the brain MRI scan due to an unforeseen safety issue, unexpected claustrophobia, or pregnancy, the remainder of the study may be completed without the brain MRI scans.

Use of concurrent treatments for CIPN

Patients may use other potential treatments for CIPN during the course of this study (e.g., medications such as duloxetine or gabapentin, transcutaneous electrical nerve stimulation [TENS], acupuncture, cold gloves or stockings). However, we ask that patients maintain the dose of those treatments during the study period (e.g., maintain the dose of duloxetine or the use of TENS [or not using TENS] from pre-intervention assessments through the intervention period and the post-intervention assessments). We will ask patients about other potential CIPN treatments during the study and whether that dose has changed over time.

Inclusion of women and minorities

Our eligibility does not restrict our sample by sex, race, or ethnicity. We will make every attempt to include women (except for women who are pregnant or planning to become pregnant) and minorities in our sample, and we expect distributions of approximately 66% women, 88% Caucasian, and 12% minority, based on accrual to prior URCC NCORP studies.