

# Optimizing Integrative Oncology Approaches to Address Chemotherapy-induced Peripheral Neuropathy in Gastrointestinal (GI) Cancer Patients: A SMART Pilot Study

NCT07501663

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<b>Status</b>	RECRUITING
<b>Phase</b>	Not Applicable
<b>Sponsor</b>	Sidney Kimmel Comprehensive Cancer Center at Thomas Jefferson University
<b>Enrollment</b>	60 participants

## Key Eligibility Criteria

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### Inclusion (5)

- Age 18 years or older,
- Self-reported moderate (e 2/4) numbness and tingling on the Patient-Reported Outcomes Version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE) Numbness and Tingling Severity Item in the previous week,
- At least three months since the last receipt of neurotoxic chemotherapy,
- Prior receipt of paclitaxel, docetaxel, cisplatin, oxaliplatin, nab-paclitaxel, or carboplatin for the treatment of stage I-III Gastrointestinal (GI) cancers,
- Speaking/reading English.

### Exclusion (8)

- An individual who meets any of the following criteria will be excluded from participation in this study:
- Prognosis of < 3 months,
- Documented neuropathy attributed to other causes (e.g., diabetic neuropathy),
- Intention to initiate a new prescription of duloxetine or other pain medications (i.e., first-line treatment for CIPN pain) during the study period; however, participants may continue on duloxetine or other pain medications if initiated at least 8 weeks before study enrollment, with no change in dose, and reporting unmanaged CIPN (i.e., e 2/4) PRO-CTCAE numbness/tingling severity in the last week,
- Currently using alcohol (ethyl), which means regular alcohol consumption (defined as e7 drinks/week for women, e14 drinks/week for men, or binge drinking >3 drinks per occasion at least weekly) within the past 3 months, or current alcohol use disorder or inability/unwillingness to abstain from alcohol during the study intervention period,
- ... and 3 more (see full listing online)

## Locations (1 total)

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Sidney Kimmel Cancer Center at Thomas Jefferson University, Philadelphia, Pennsylvania, United States

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<https://clinicaltrials.gov/study/NCT07501663>

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