



# **Challenges to Implementing Recommended Chemotherapy- Induced Peripheral Neuropathy Assessment and Management Strategies into Clinical Practice**

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Assistant Professor

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# Disclosures

- **I have the following financial relationship:**
  - Personal fees (Consulting)
    - Fors Marsh Group
    - Osmol Therapeutics, Inc.
    - Comprehensive and Integrative Medicine Institute



**M** 2021



2020



2023



2019

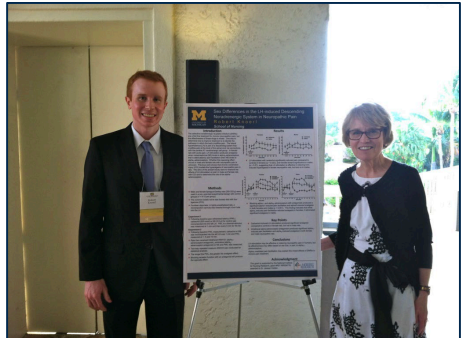


2017

 Dana-Farber  
Cancer Institute

**M** 2014

**M** 2010



# Outline

- What is chemotherapy-induced peripheral neuropathy (CIPN) and why is it a problem?
- Why are strategies needed to increase communication and the uptake of recommended CIPN management strategies?
- Exemplar of intervention to increase use of recommended CIPN assessment and management strategies
- What are clinicians' views on CIPN assessment and management and future directions for this area?

# Why is CIPN a Problem?

# Neuropathy Diminishes Quality of Life

## Incidence

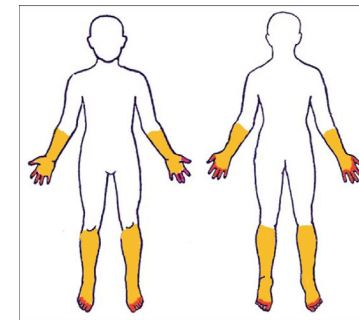
Paclitaxel, vincristine, oxaliplatin, bortezomib are first line treatments for many types of cancer



**68%**



## Symptoms and Impact

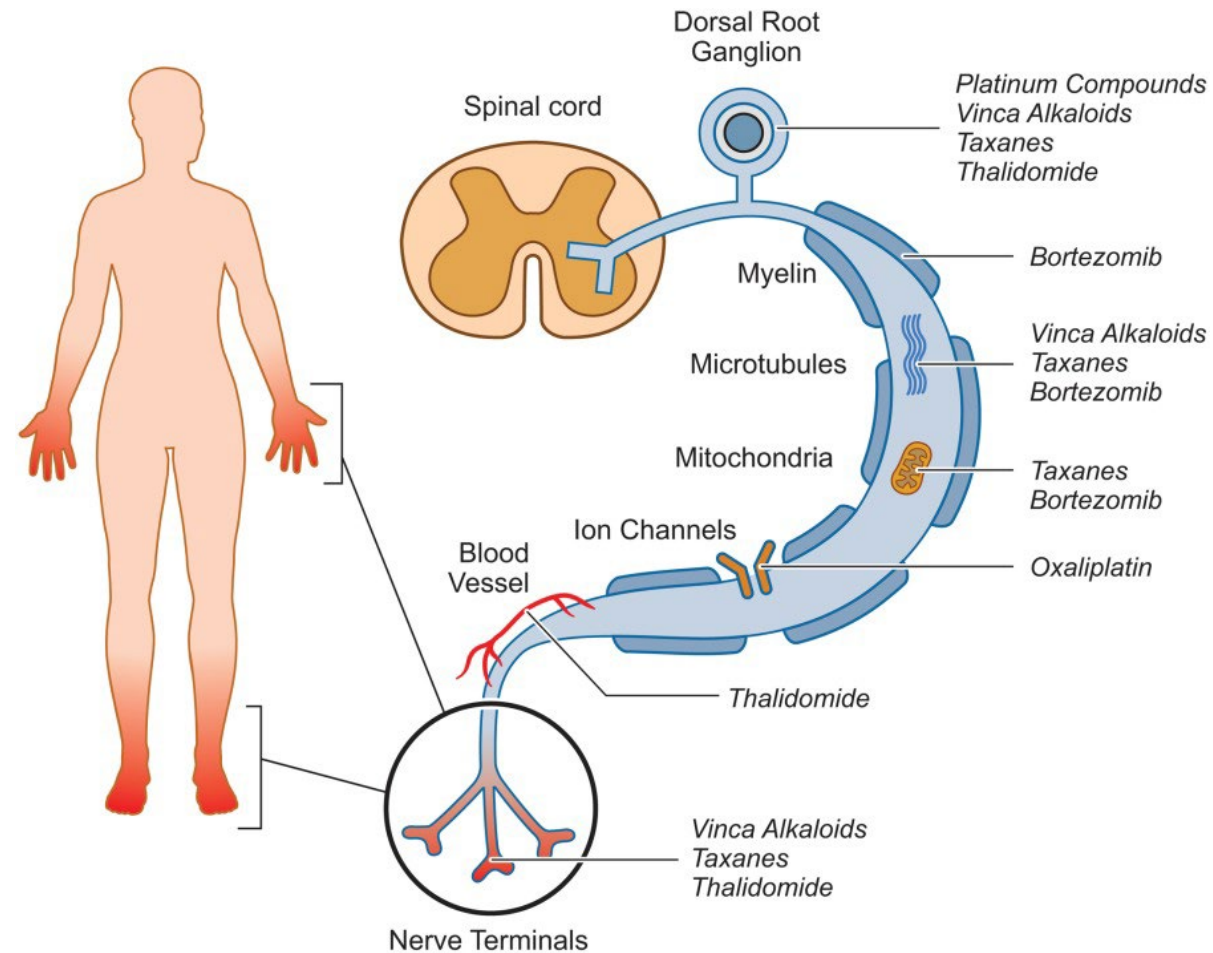


- Chemotherapy dose reductions



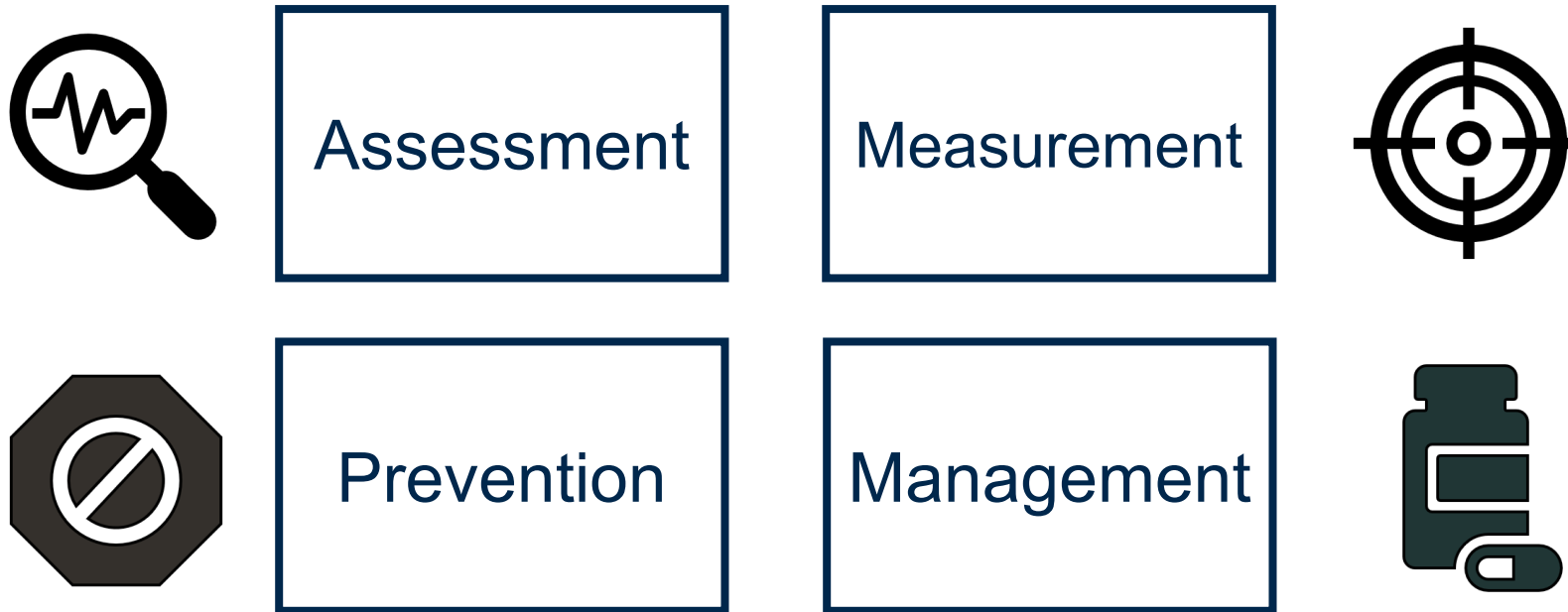
- Persists after treatment

# Why Does Neuropathy Occur?





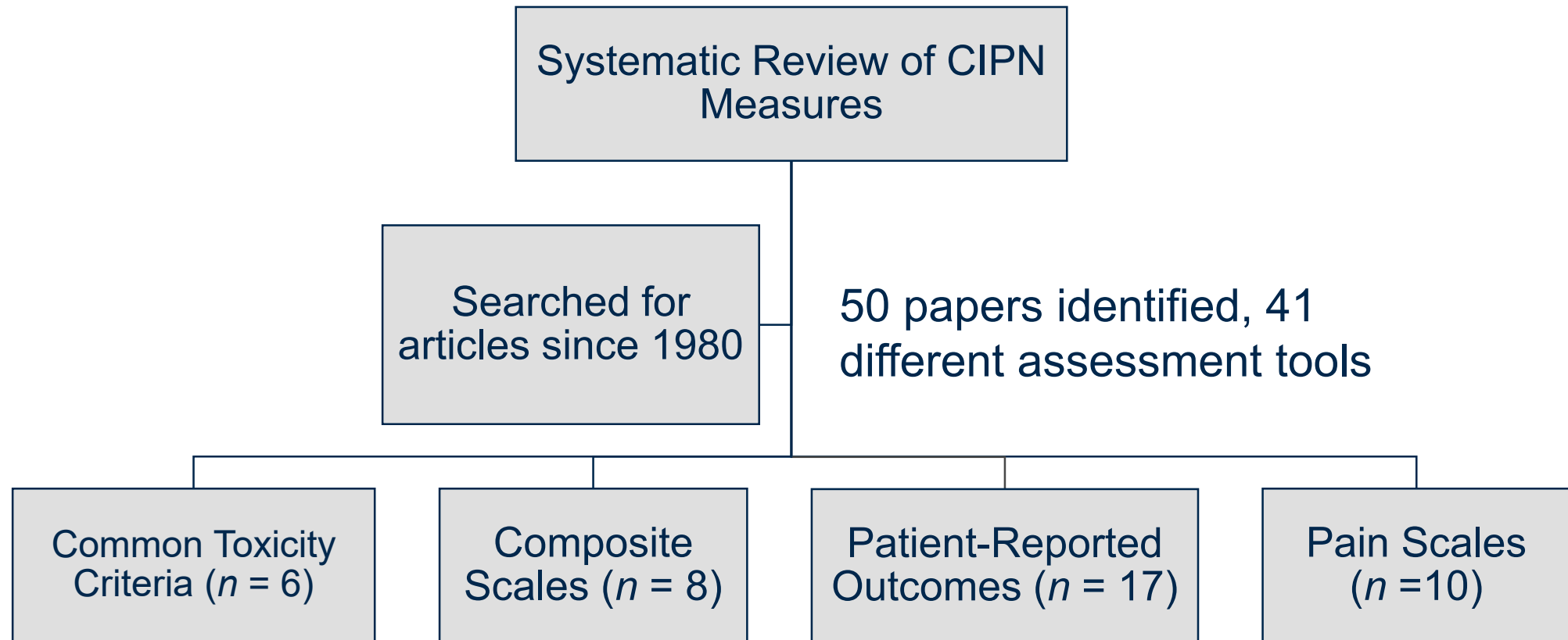
# CIPN is a Multifaceted Problem



# CIPN is Infrequently Discussed in Practice

- *N* = 159 audio recorded patient-clinician (e.g., MD, NP/PA outpatient visits)
  - ~94% of visits occurred during neurotoxic chemotherapy
- CIPN discussed in 70/159 (44%) of encounters
- CIPN documented in 73/159 (46%) of encounters
- 11/44 (25%) clinicians asked about numbness/tingling in hands and feet
  - Any neuropathy?
  - Any numbness or tingling?
  - Any hand problems?

# There are No Gold Standard CIPN Measures



No consensus on best outcome measure



# What Can We Use to Measure Neuropathy?



## Non-Painful CIPN

- Total Neuropathy Score – Clinical Version
- QLQ-CIPN20
- FACT/GOG-NTX
- PRO-CTCAE Numbness and Tingling Items



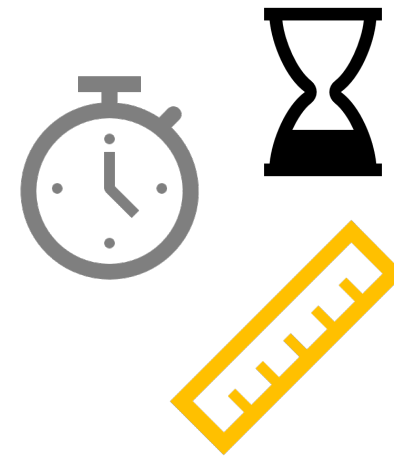
## Painful CIPN

- Brief Pain Inventory
- Numeric Rating Scale
- Neuropathic Symptom Inventory



## Functional Limitations

- Five times sit-to-stand
- Timed Up and Go
- PRO-CTCAE Numbness and Tingling Interference Item
- Chemotherapy-Induced Peripheral Neuropathy Assessment Tool



# There are Few Effective CIPN Treatments

## Prevention

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- No recommended preventative treatments

## Pharmacological Treatments

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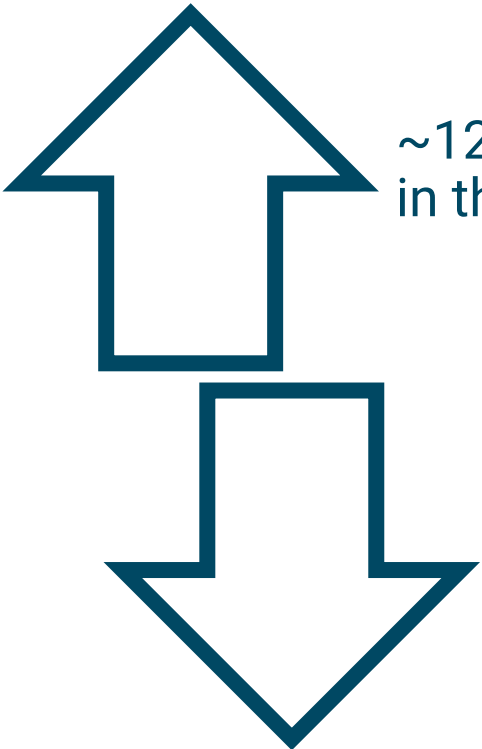
- Duloxetine 60 mg/day is the first line recommendation for CIPN pain
- No recommendations for more common sensory symptoms

## Non – Pharmacological Treatments

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- No recommended non-pharmacological treatments

# Non-Pharmacological Interventions: High Interest, Low Efficacy



~12 systematic reviews in the past 5 years

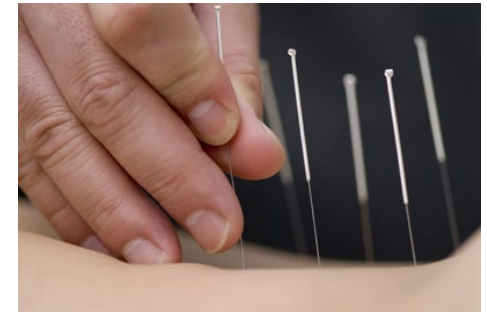
No high level evidence for any one intervention

Recommendation	Level of Evidence: Prevention	Level of Evidence: Treatment
Exercise, endurance, and strength training	B	C
Balance and Sensorimotor Training	B	B
Neurofeedback	N/A	C
Massage	D	D
Cryo/Compression	D	N/A
TENS	D	D

# Acupuncture

## What is it?

- Component of traditional Chinese medicine in which very thin needles are inserted into defined acupoints



## What the data teach us?

- 7 prevention or treatment trials within the past 5 years
- Acupuncture with more than ten sessions may be promising



## What will the data teach us in the future?

- Phase III, 250-patient, randomized controlled trial comparing eight-week electroacupuncture treatment to sham acupuncture among cancer survivors with persistent CIPN

# Cryotherapy and Compression Therapy

## What is it?

- Cryo: Regional hypothermia provided by frozen gloves/socks to decrease microvascular flow in hands/feet
- Compression: Wearing stocking/sleeves for 24 h to decrease microvascular flow in the hands/feet

## What the data teach us?

- Less than half of studies ( $N = 8$ ) reported improvements in CIPN symptoms following cryo or compression therapy

## What will the data teach us in the future?

- Randomized controlled trial of frozen vs. compression vs. loose (placebo) gloves & socks to reduce pain among patients receiving 12 weeks of taxane-based chemo ( $N = 100$ )





# Exercise

## What is it?

- Endurance, strength, balance and/or sensorimotor training



## What the data teach us?

- Results of meta-analysis ( $N = 9$  RCTs, 663 patients) demonstrate benefit for sensorimotor training (twice a week)
- Variability in intervention design/dose, outcomes, and small sample sizes



## What will the data teach us in the future?

- Phase II, multi-site, randomized controlled trial to determine the efficacy of exercise in comparison to usual care among adults receiving or who have completed neurotoxic chemotherapy ( $N = 120$ )

# Yoga

## What is it?

- Yoga is a meditative movement therapy that improves body conditioning, flexibility, and balance through mind-body awareness

## What the data teach us?

- Two recent pilot randomized-controlled trials ( $N = 41$ ,  $N = 44$ )
- Yoga led to improvements sensory CIPN, functional reach, anxiety, fatigue in comparison to usual care among cancer survivors

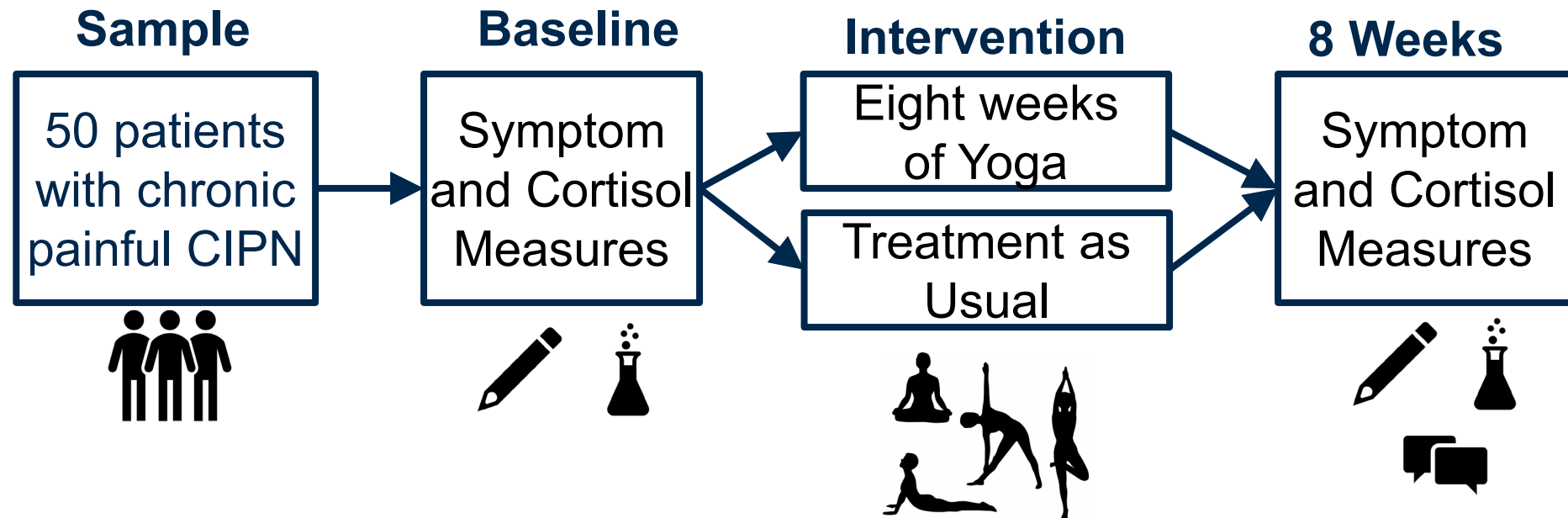
## What will the data teach us in the future?

- Phase III, 268-patient, randomized controlled trial to determine the efficacy of an eight-week yoga treatment on CIPN symptoms among cancer survivors with persistent CIPN



# Yoga for Chronic Painful Neuropathy

- Explanatory-sequential mixed methods
  - Randomized controlled trial (2:1 randomization)
  - Semi-structured interviews



# Purpose

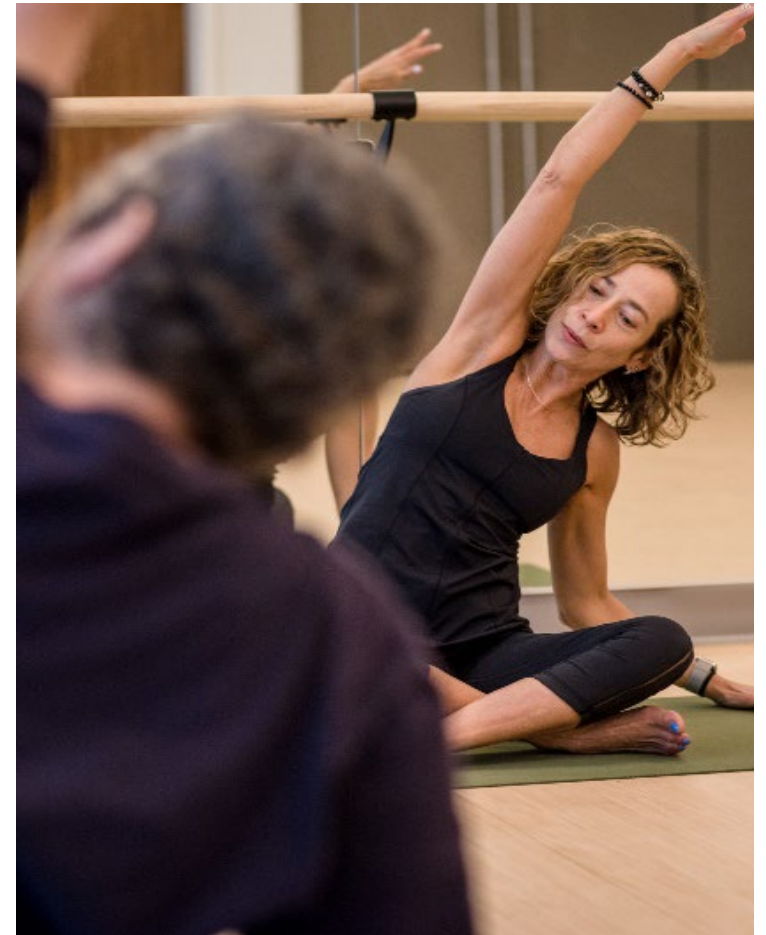
**Aim 1a:** Determine the feasibility of yoga implementation by calculating participant recruitment, retention, and adherence rates in both groups of a randomized eight-week yoga trial.

**Aim 1b:** Explore yoga group participants' perspectives of acceptability and satisfaction with the intervention

**Aim 2:** Evaluate the impact of an eight-week yoga intervention on CIPN severity, physical function, and other symptoms.

# Yoga Intervention Format

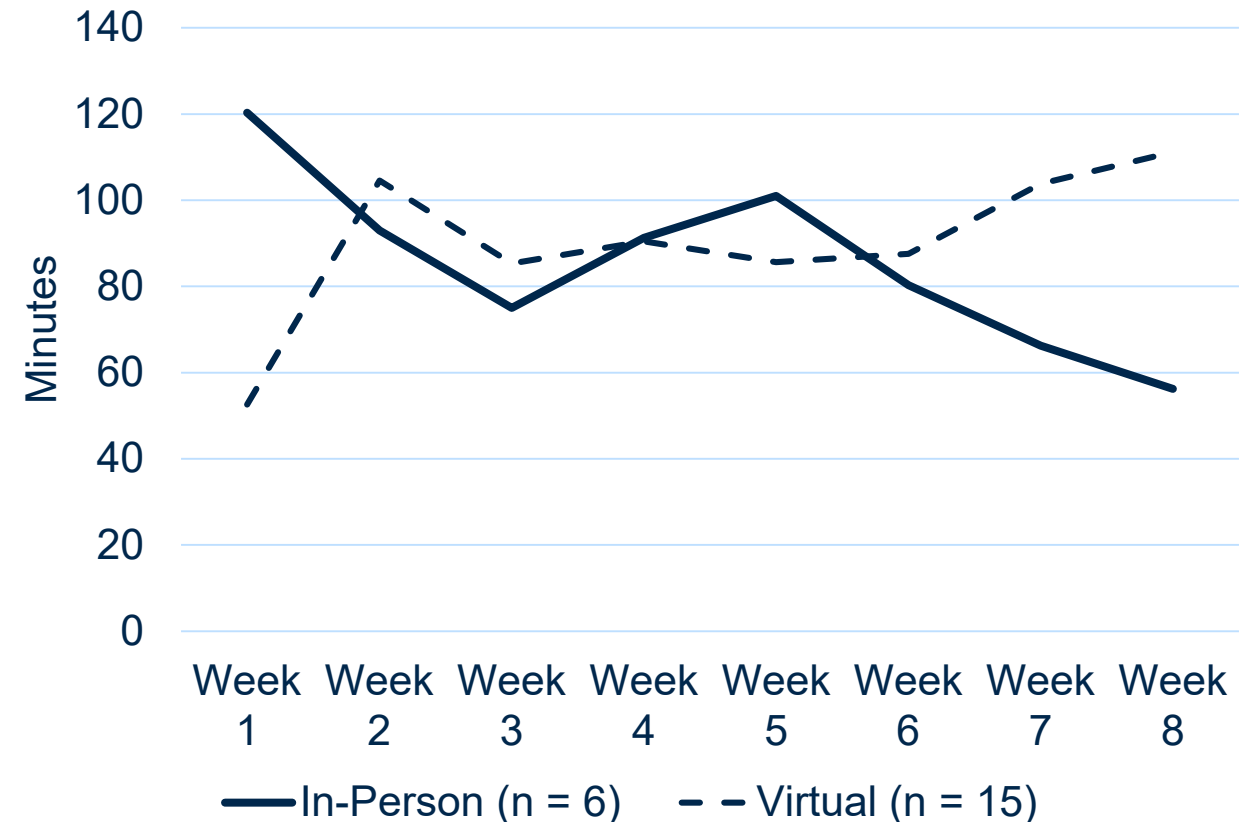
- Eight weeks
- 1 on 1 meeting with yoga instructor
- 45 minutes in person at Zakim Center
  - Chair Flow or Flow
  - Regularly offered
- 45 minutes at home using video
  - Yoga blocks and balls
- All classes & videos incorporate hand and foot massages or stretches



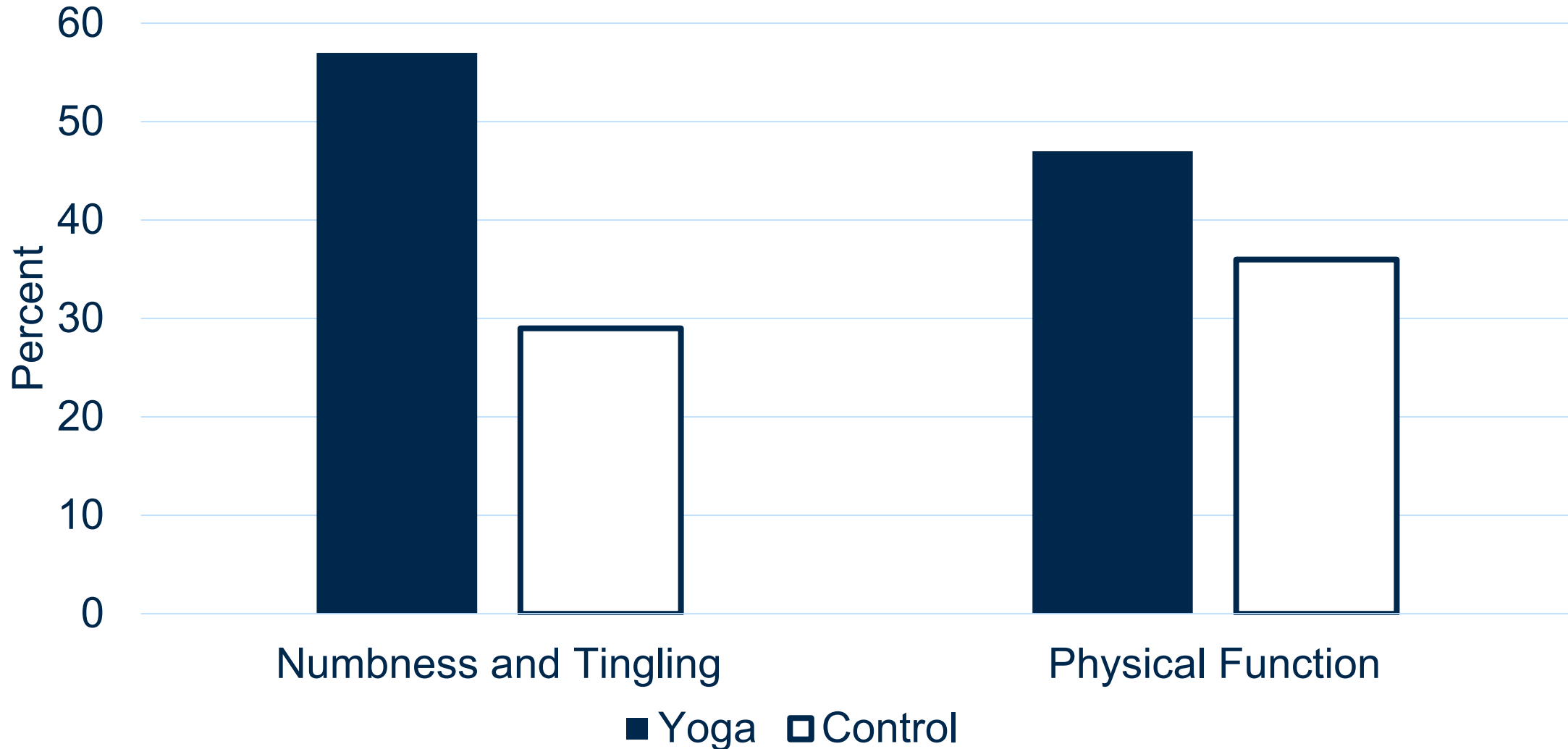
# Feasibility

- Accrual to virtual yoga was considerably higher (4.6/month) than accrual to in-person (2.5/ month)
- 35/44 (79.5%) of participants completed the study measures
- 87.5% of virtual participants completed  $\geq 12$  yoga sessions, while 33% of in-person participants completed  $\geq 12$
- Results from interviews revealed that participants highly rated the flexibility and structure of virtual yoga

**Average Minutes of Yoga Practice Each Week by Intervention Format (N = 21)**



## Percent of Yoga and Control Group Participants Experiencing Clinically Significant Improvements



**Why are strategies needed to increase communication and the uptake of recommended CIPN management strategies?**



# Electronic Symptom Reporting Software Positively Impacts CIPN Outcomes

## Pilot Testing a Web-Based System for the Assessment and Management of Chemotherapy-Induced Peripheral Neuropathy

Robert Knoerl, BSN, RN, William N. Dudley, PhD, Gloria Smith, MS, RN, ACNP, Celia Bridges, BA, BSN, RN, Grace Kanzawa-Lee, BSN, RN, Ellen M. Lavoie Smith, PhD, ANP-BC, AOCN

## Electronic versus paper-pencil methods for assessing chemotherapy-induced peripheral neuropathy

Robert Knoerl<sup>1</sup> & Evan Gray<sup>2</sup> & Carrie Stricker<sup>3</sup> & Sandra A. Mitchell<sup>4</sup> & Kelsey Kippe<sup>5</sup> & Gloria Smith<sup>6</sup> & William N. Dudley<sup>2</sup> & Ellen M. Lavoie Smith<sup>1</sup>

## Use of an electronic care planning system to improve adherence to recommended assessment and management practices

Robert Knoerl, PhD, RN, Celia Bridges, BA, BSN, RN, Gloria L. Smith, DNP, RN, ACNP, James J. Yang, PhD, Grace Kanzawa-Lee, BSN, RN, and Ellen M.L. Smith, PhD, APRN, AOCN®, FAAN

### RESEARCH ARTICLE

Exploring the efficacy of an electronic symptom assessment and self-care intervention to preserve physical function in individuals receiving neurotoxic chemotherapy

Robert Knoerl<sup>1</sup>, Edie Weller<sup>2</sup>, Barbara Halpenny<sup>3</sup> and Donna Berry<sup>4</sup>

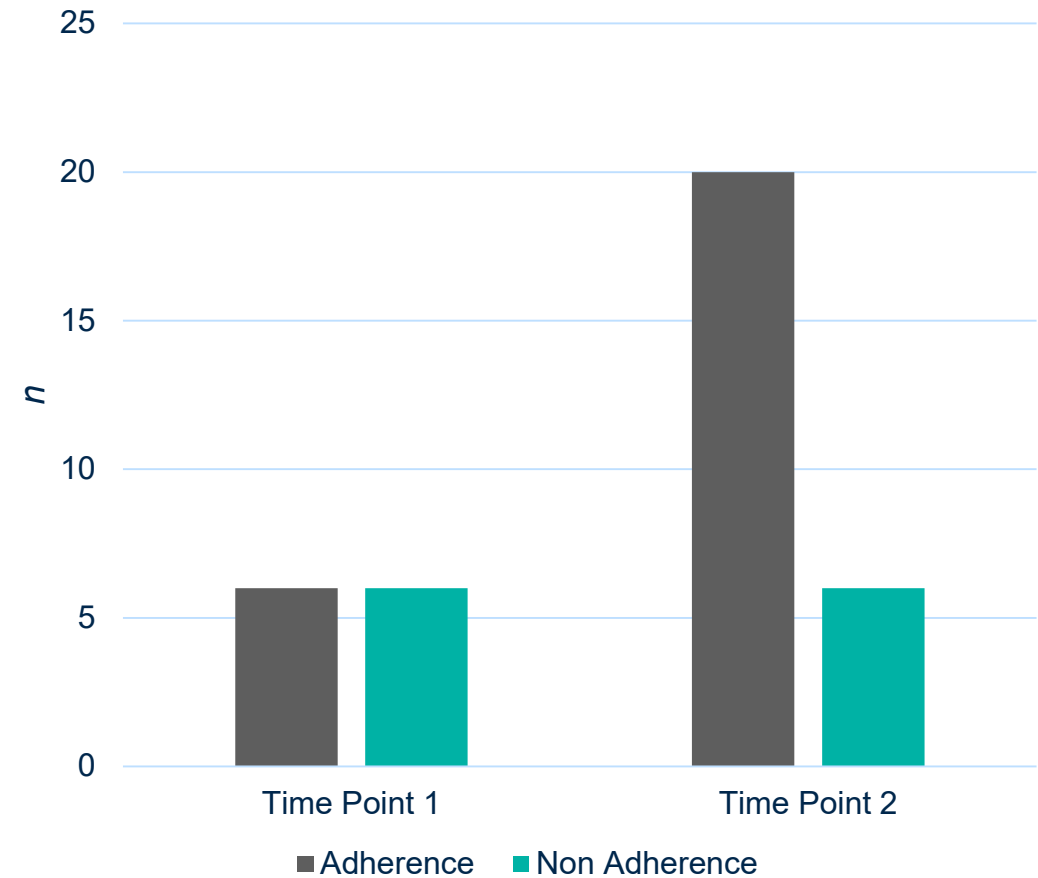
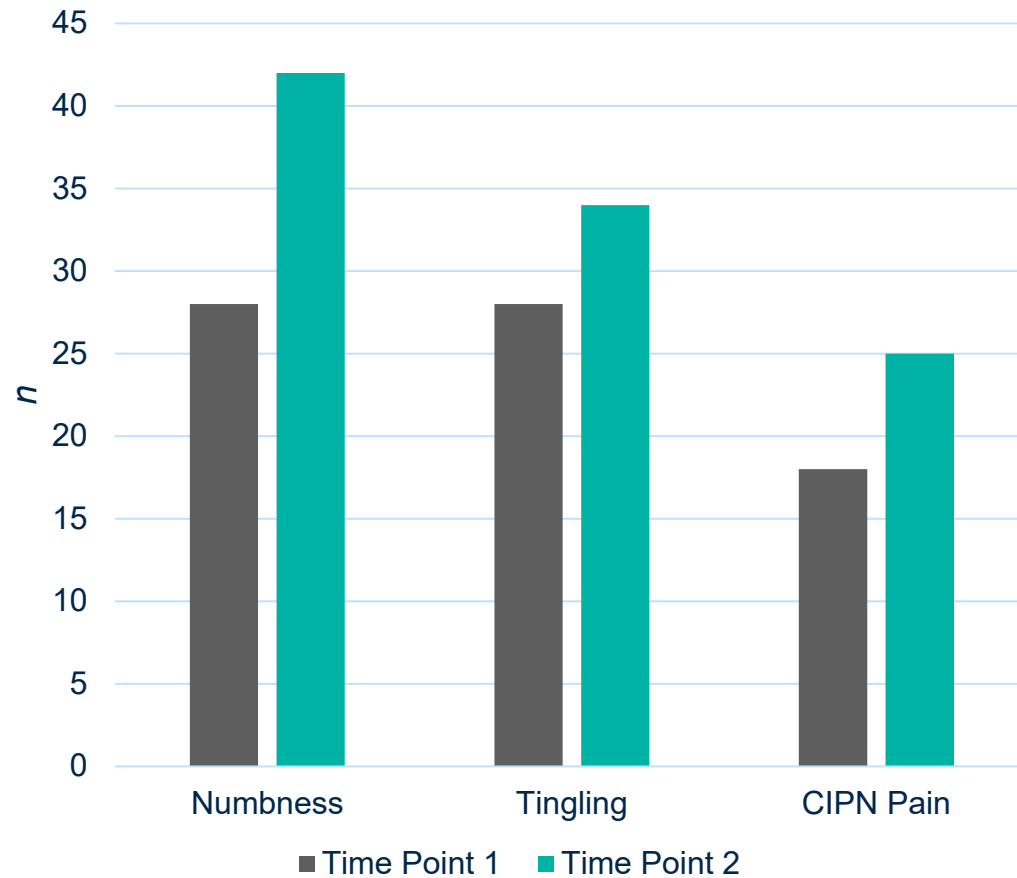
Characterizing patient-clinician chemotherapy-induced peripheral neuropathy assessment and management communication approaches

Robert Knoerl<sup>1,a,\*</sup>, Ellen M.L. Smith<sup>b</sup>, Amy Han<sup>c</sup>, Allison Doe<sup>d</sup>, Katelyn Scott<sup>e</sup>, Donna L. Berry<sup>f</sup>

## Examining the Impact of a Web-Based Intervention to Promote Patient Activation in Chemotherapy-Induced Peripheral Neuropathy Assessment and Management

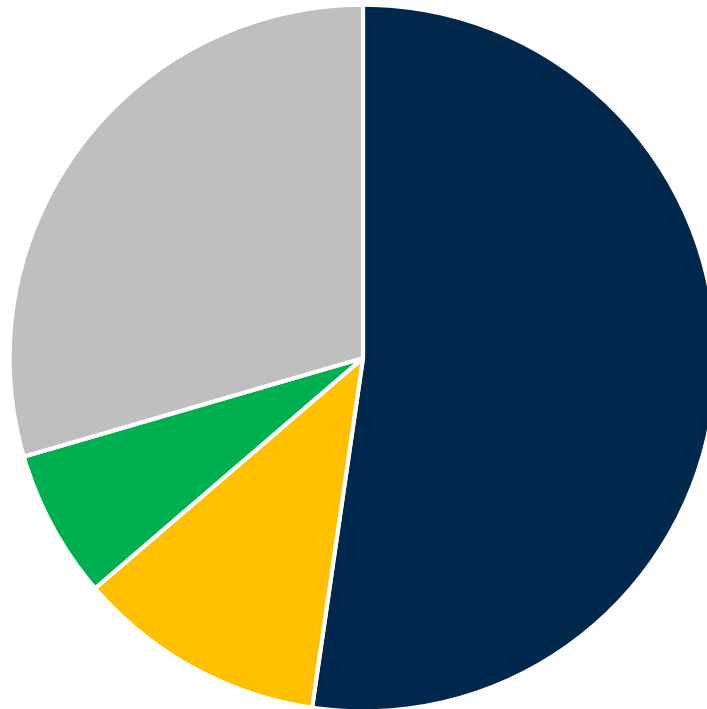
Robert Knoerl<sup>1</sup> & Deborah Lee<sup>2</sup> & James Yang<sup>1</sup> & Celia Bridges<sup>1</sup> & Grace Kanzawa-Lee<sup>1</sup> & G. Lita Smith<sup>3</sup> & Ellen M. Lavoie Smith<sup>1</sup>

# Provider Documentation of CIPN Assessment and Management Action



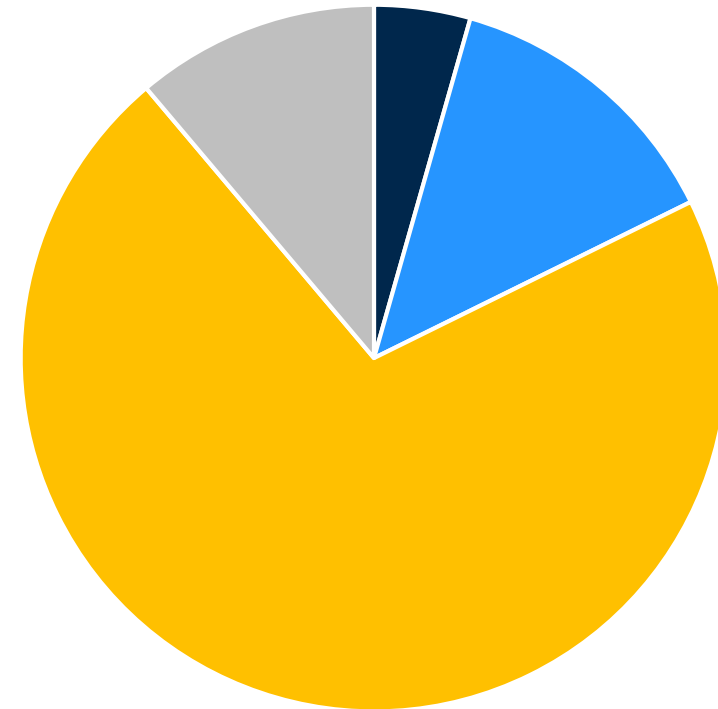
# First Line Prevention and Management (N = 44)

First-Line Prevention



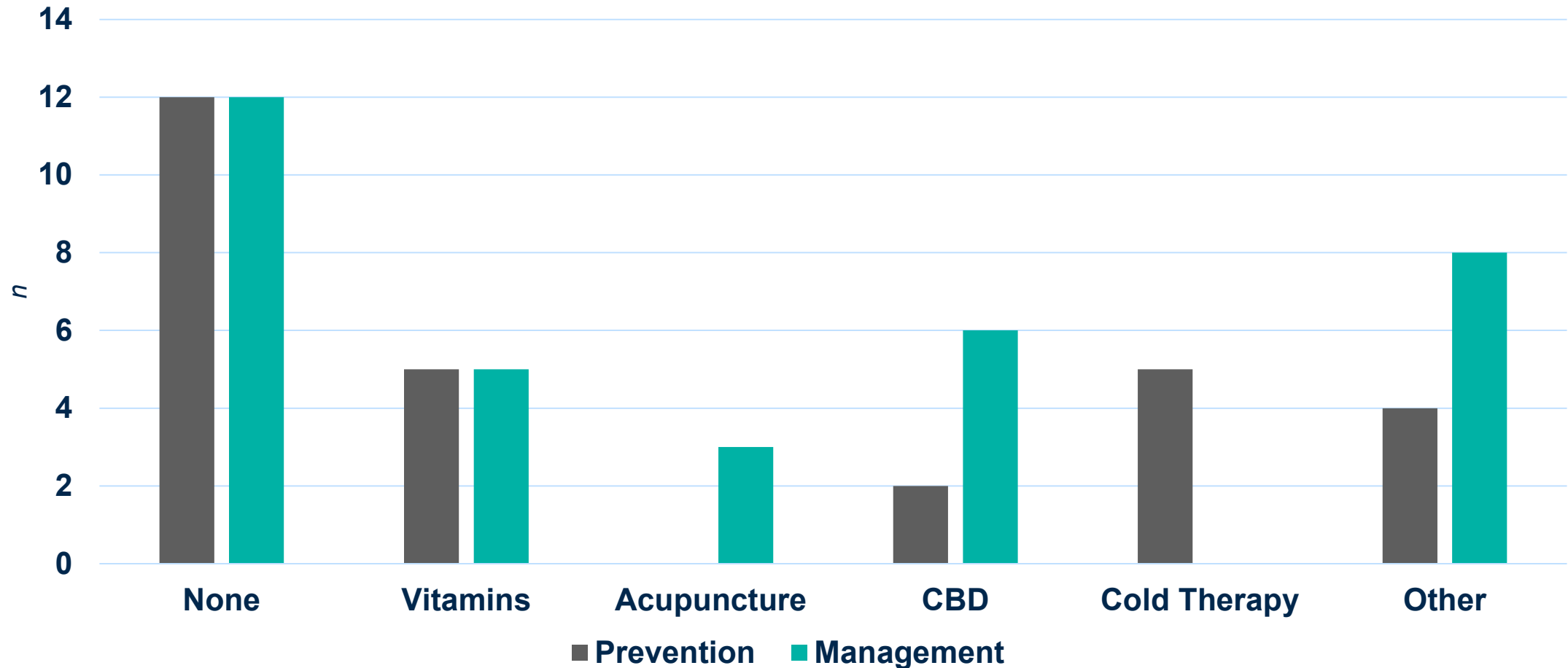
■ None ■ Gabapentin ■ Physical Exercise ■ Other

First-Line Management



■ None ■ Duloxetine ■ Gabapentin ■ Other

# What strategies do you observe your patients using to prevent or manage CIPN?



# Exemplar

# Implementing a Clinician Decision Support Tool to Facilitate CIPN Assessment and Management

**Principal Investigator: Robert Knoerl, PhD, RN**

- Co-Investigators: Donna Berry, Jennifer Ligibel, Elahe Salehi, Nadine McCleary, Kaitlen Reyes
  - Funding: Mittelman Integrative Oncology Family Fund

# Specific Aims



Explore the impact of a CIPN clinician decision support tool on clinicians' documentation of CIPN assessment and adherence to management guidelines



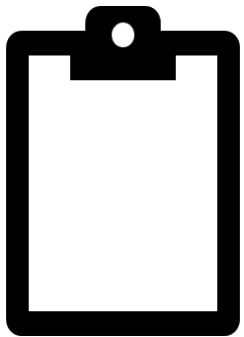
Explore Clinicians' Perspectives of CIPN Assessment and Management

# Design and Sample

- Design: Two-phase, longitudinal
- Sample
  - 162 patients receiving neurotoxic chemotherapy (e.g., paclitaxel, oxaliplatin, bortezomib)
  - 53 clinicians (i.e., MD, NP, PA) providing care
- Patient Eligibility
  - Adults who completed  $\geq 1$  infusion of neurotoxic chemotherapy
  - Scheduled to attend  $\geq 3$  clinic visits associated with chemotherapy
  - Did not have neuropathy due to other causes



# Measures



- PRO-CTCAE™ Numbness and Tingling Severity and Interference
  - 0 – 4, higher scores represent worse severity and interference
- 0 – 10 Numerical Rating Scale of Worst CIPN Pain Intensity
- Algorithm follow up questions
  - Duration, location, and characteristics of symptoms



- Medical Record Chart Abstraction

# Procedures

## Phase I

**N = 81 patients, 45 clinicians**



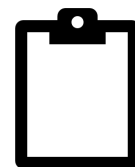
DFCI MM Oncology
DFCI Breast Oncology
DFCI GI Oncology



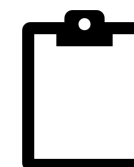
**Baseline**



**Visit 2**



**Visit 3**



**Post Study**



## Phase II

**N = 81 patients, 45+8 clinicians**



DFCI MM Oncology
DFCI Breast Oncology
DFCI GI Oncology



**Baseline**



**Visit 2**



**Visit 3**

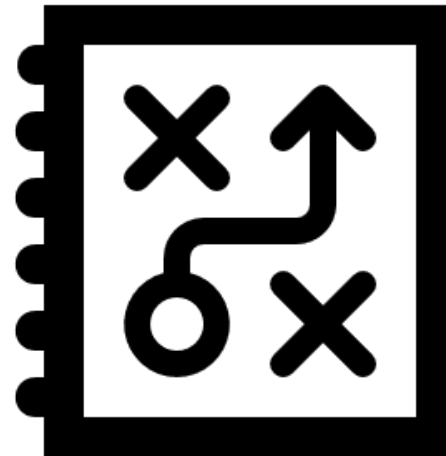
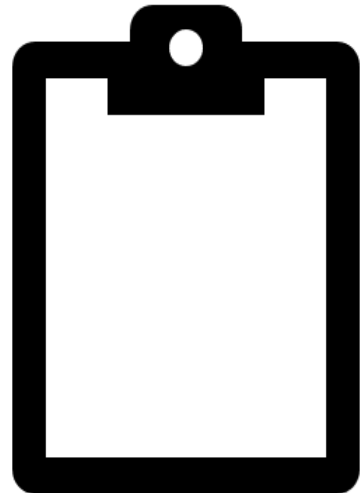


**Post Study**



# CIPN Assessment and Management Algorithm

- Inspired by the Algorithm for Nursing Assessment and Management



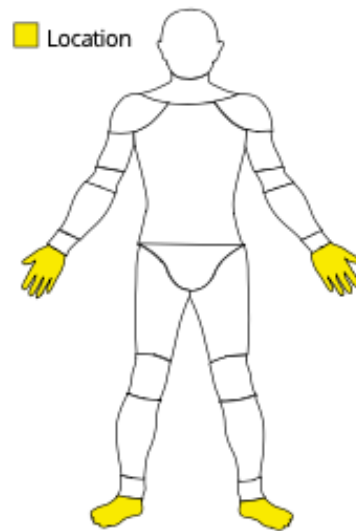
### Non-Painful CIPN

PRO-CTCAE Severity Score 2 / 4 ( Moderate )

Frequency 5 days / week

Characteristics Numbness  
Tingling

Location



Fingers  
Toes

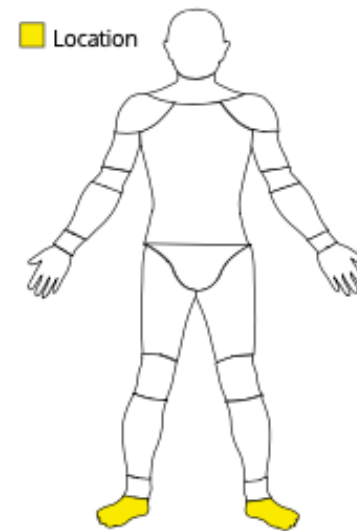
### Painful CIPN

Worst CIPN Pain 4 / 10

Frequency 3 days / week

Characteristics Burning  
Electric shock  
Intermittent

Location



Toes

### Motor CIPN

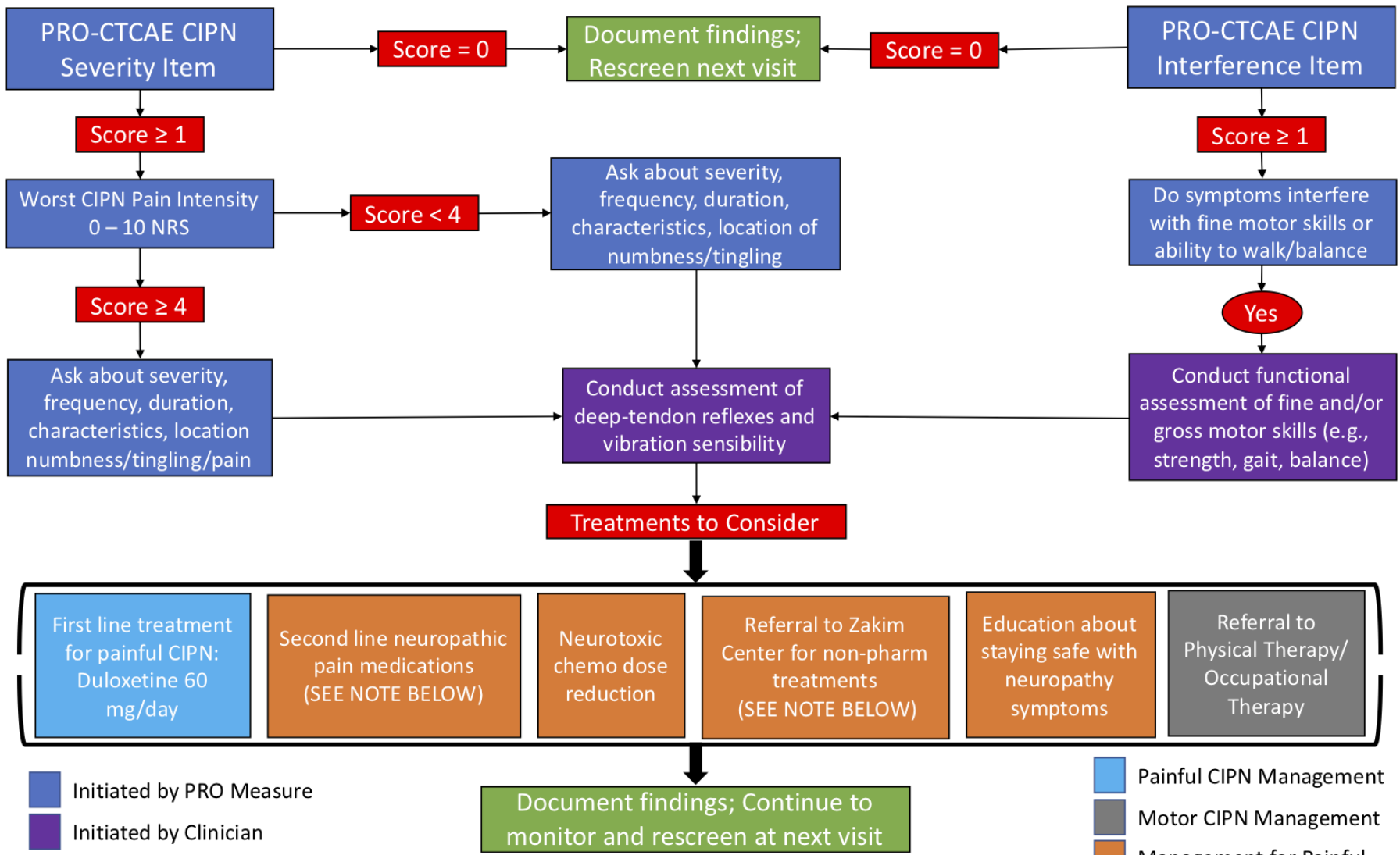
PRO-CTCAE Interference Score 2 / 4 ( Somewhat )

Functional Limitations Zipping up a coat  
Using a fork, spoon, or knife  
Walking  
Climbing stairs

Location

See activities  
listed above

### CIPN Assessment and Management Algorithm

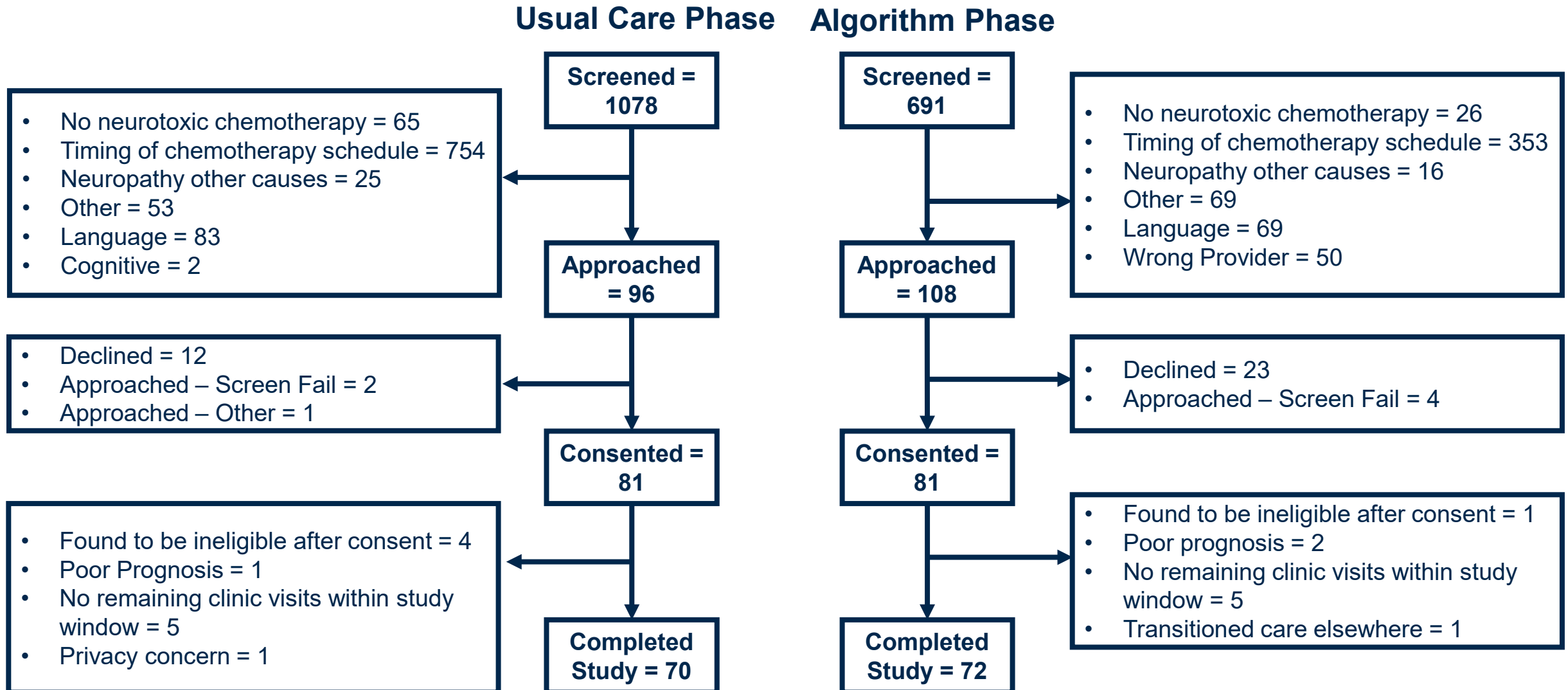


NOTE: There is no strong evidence to support second line neuropathic pain medications (i.e., gabapentin, pregabalin, tricyclic antidepressants, topical gel containing baclofen, amitriptyline, and ketamine) and non pharmacological treatments for CIPN, but these treatments may be reasonable to prescribe based on potential benefit/harm, cost, patient preference.

# Analyses

- Appropriate clinician-related CIPN management for mild or moderate CIPN was scored yes/no at T3
  - Reviewed by team of investigators/clinicians
  - Mild CIPN (PRO-CTCAE Numbness and Tingling Severity= 1): Presence of CIPN documented or “continue to monitor”
  - Moderate CIPN (PRO-CTCAE Numbness and Tingling Severity  $\geq 2/4$ ): Pharmacological management, dose reduction, referral
- Changes in CIPN documentation between phases at T3 were compared using Pearson’s chi-squared test for equality of proportions

# Participant Flow



# Demographics

## Patients (*N* = 142)

Mean Age: 57

Female (66%)

White (90%)

Breast or  
Gastrointestinal  
Cancers (88%)

Platinum or  
Taxane chemo  
(86%)

Received  $\geq 2/3$   
of Planned  
Treatment (56%)

## Clinicians (*N* = 53)

Doctor (55%)

Nurse  
Practitioner  
(39%)

Physician  
Assistant (6%)

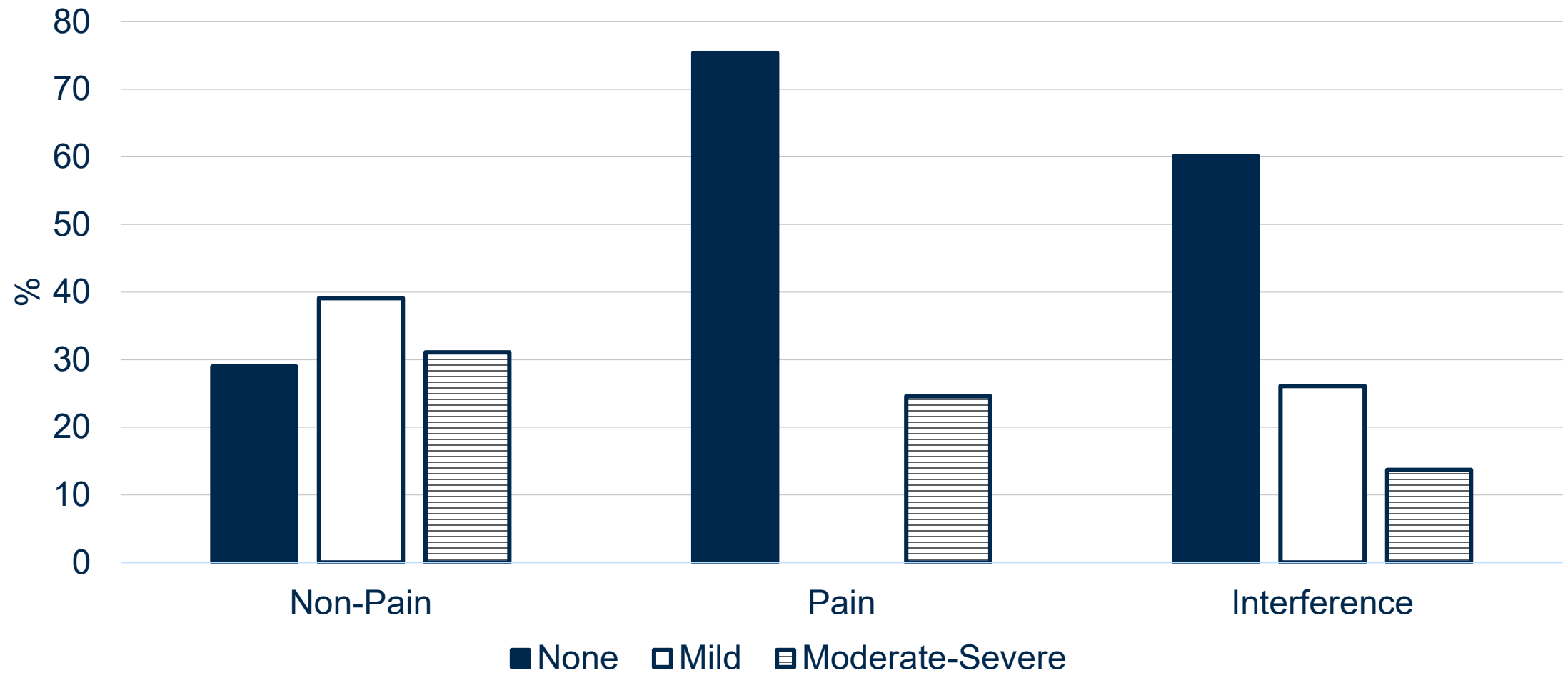
Breast (45%)

Gastrointestinal  
(34%)

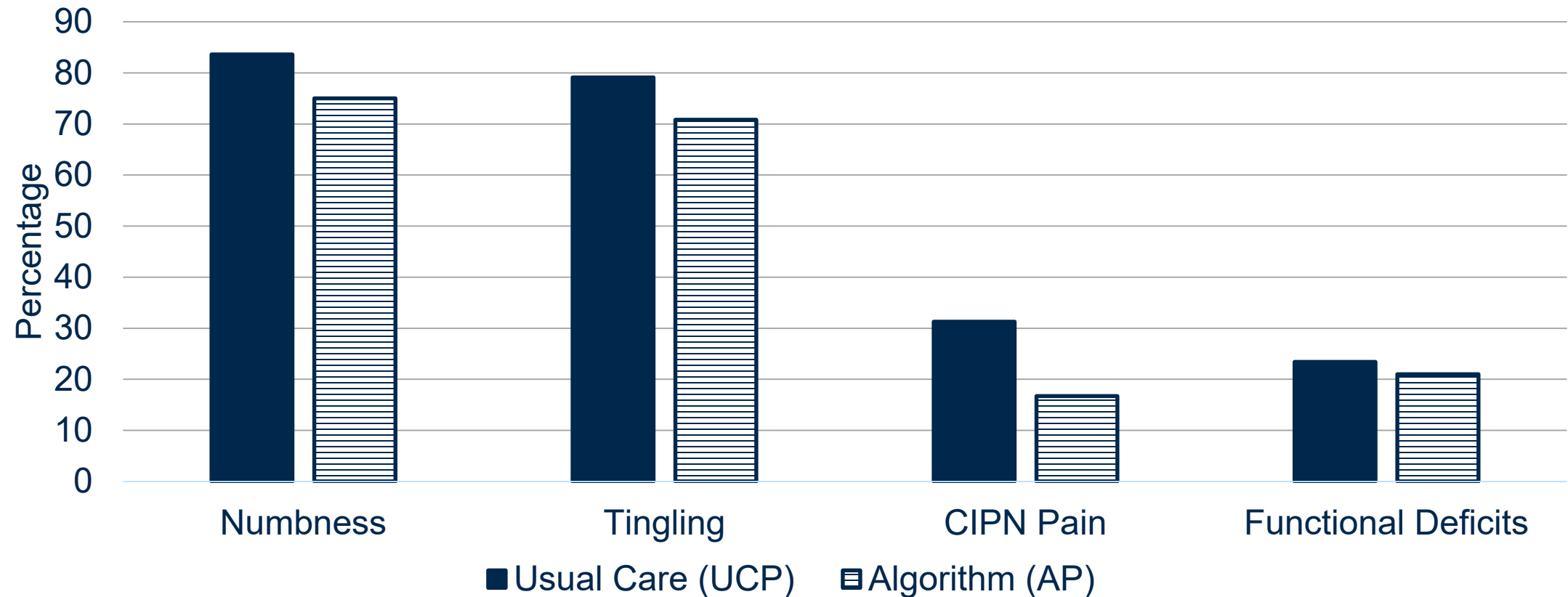
Multiple  
Myeloma (21%)



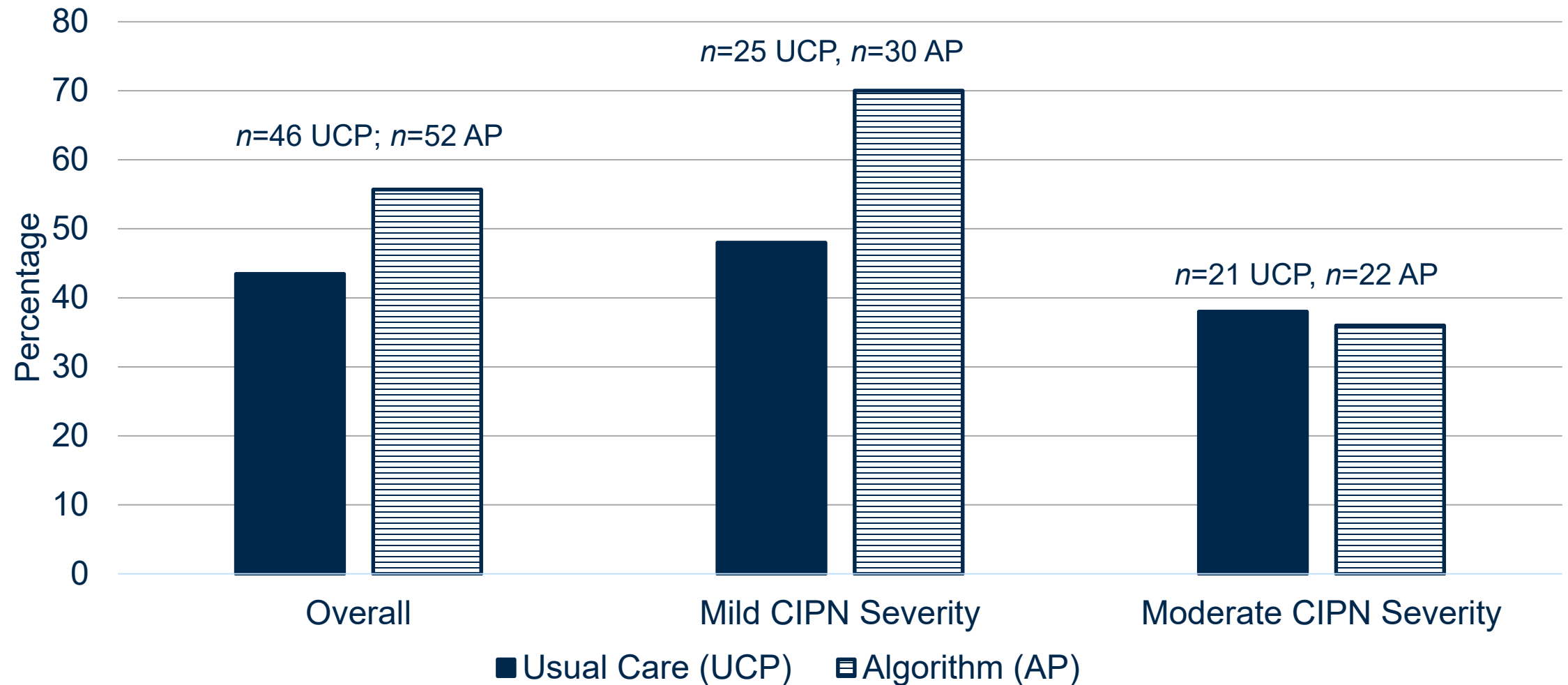
# Self-Reported Frequency of CIPN at T3



## Frequency (%) of Clinicians' CIPN Assessment Documentation at the Final Study Visit Between the Usual Care ( $n = 70$ ) and Algorithm Phases ( $n = 72$ )

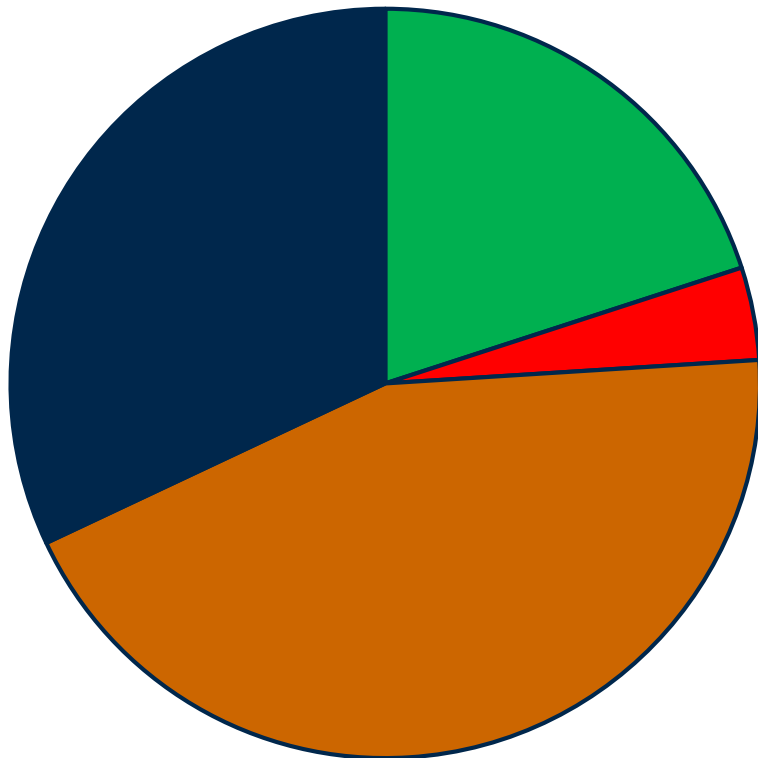


# Frequency (%) of Clinicians' Appropriate CIPN Management at the Final Study Visit in the UCP and AP



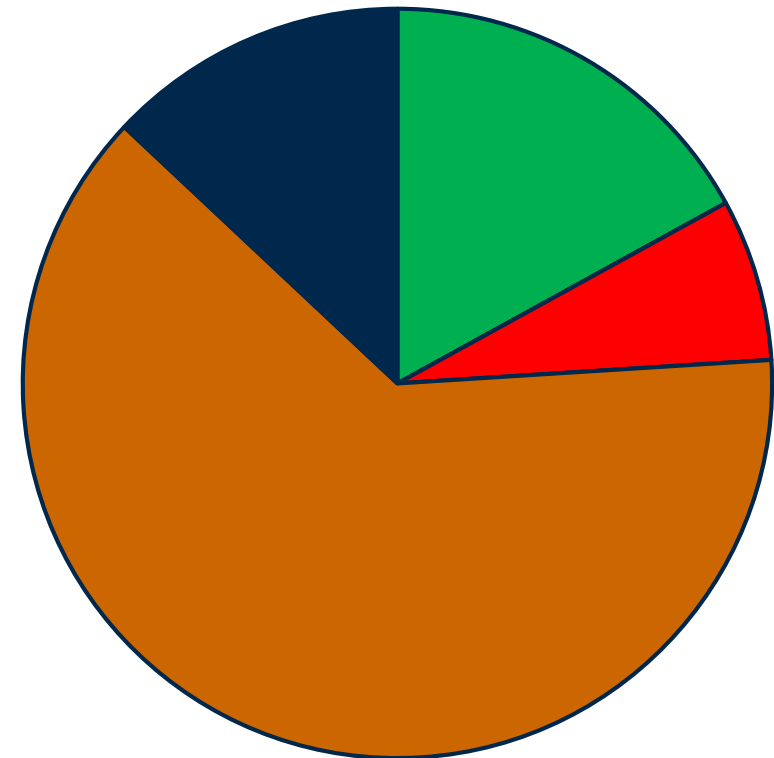
# Management of Mild CIPN

Usual Care (n = 25)



■ Continue to Monitor ■ Dose Reduction  
■ Documentation only ■ No documentation

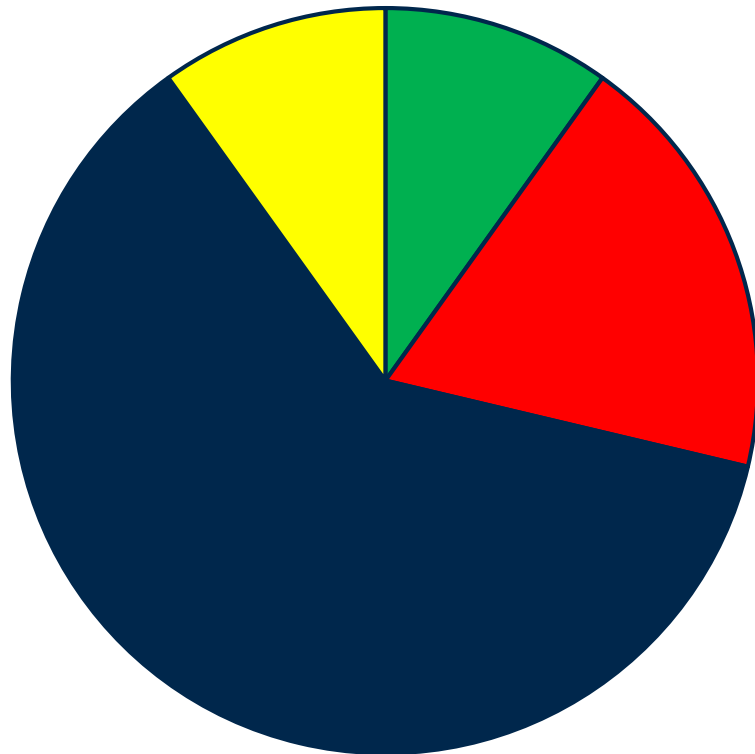
Algorithm (n = 30)



■ Continue to Monitor ■ Dose Reduction  
■ Documentation only ■ No documentation

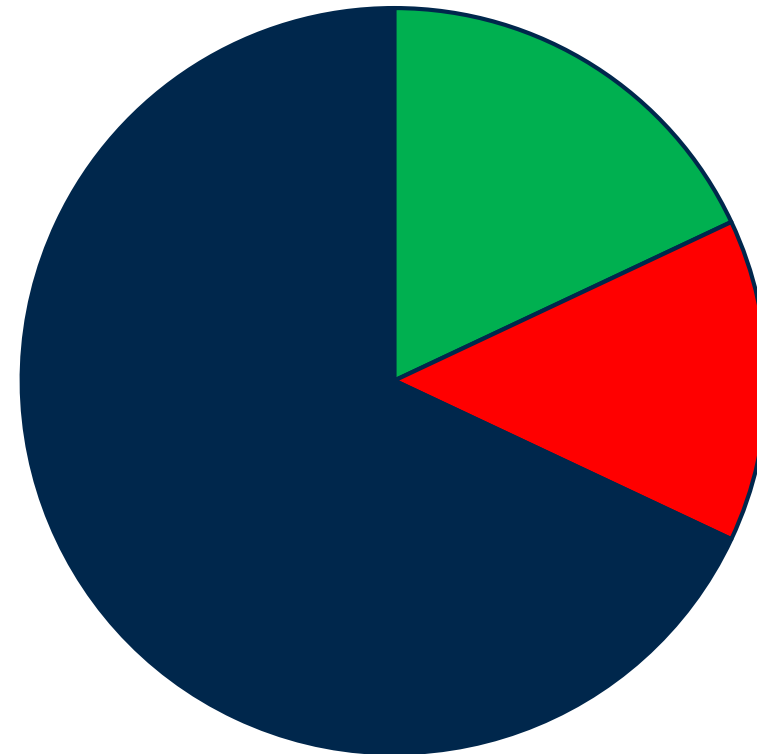
# Management of Moderate-Severe CIPN

Usual Care (n = 21)



■ Continue to Monitor ■ Dose Reduction  
■ No management ■ Medicine

Algorithm (n = 22)



■ Continue to Monitor ■ Dose Reduction  
■ No management

# Key points

- Availability of the algorithm improved clinicians' management of mild CIPN by 22%, mainly via improved identification and monitoring
- No impact on assessment documentation or initiation of management for moderate-severe CIPN
- First-line treatment (duloxetine) was never prescribed, despite ~25% of sample experiencing painful CIPN

# **Clinicians' Perspectives on CIPN Assessment and Management**

# Clinician Interviews

## Clinicians, Michigan (N = 9)

Doctor (56.8%)

Advanced  
Practice  
Provider (9.1%)

Registered  
Nurse (34.1%)

Female  
(67.2%%)

Median Age =  
43

Platinums  
(90.9%)



## Clinicians, DFCI (N = 15)

Doctor (73%)

Nurse  
Practitioner  
(20%)

Physician  
Assistant (7%)

Breast (47%)

Gastrointestinal  
(40%)

Multiple  
Myeloma (13%)



# CIPN Assessment Practice Patterns and Barriers

- Use of subjective instead of objective CIPN assessment
  - Minimal use of objective (e.g., reflex) or standardized measures
  - Lack of time, equipment, confidence
  - Asked about ability to complete functional tasks (e.g., button a shirt)
- Barriers
  - Patients underreport CIPN severity
  - Timing of development is unpredictable
  - Education about CIPN lost in shuffle
  - Lack of time
  - CIPN terminology may mean different symptoms to different clinicians
  - Unclear how to interpret patient-reported outcomes scores

# CIPN Management Practice Patterns and Barriers

- Endorsement of non-recommended management strategies
  - Most endorsed gabapentin over duloxetine (e.g., familiarity)
  - Referral to integrative medicine center was popular
  - Some endorsed use of supplements
  - Cryotherapy for prevention, but uncomfortable for patient and unsure about efficacy
- Factors considered when reducing neurotoxic chemotherapy
  - No standardized approach
  - Frequent decision point: when patients report functional deficits
- Barriers to duloxetine prescription
  - Insurance authorizations required (fail gabapentin first)
  - Patients may be unwilling to begin another medication (side effects)
  - Stigma with antidepressant

# Utilization of the CIPN Decision Support Tool

- Algorithm
  - All paths led to same treatment options
  - Repetitive of usual care or not consistent with clinic practice patterns
- Summary
  - Helpful overview of CIPN and to start a conversation with patient
  - Unclear how PROs linked with algorithm or discordant with patient report
- Recommendations for future
  - Prioritize/streamline non-pharmacological referrals
  - Desired more information about CIPN prevention and management in general

# Limitations

- Frequency of CIPN documentation may
  - have been influenced by external factors to the study (e.g., clinician-staff interaction, lack of true control group)
  - not have been representative of actual clinical practice
    - did not audio record patient-clinician interactions
    - based on clinician documentation and patient self-report only
  - have been influenced by the number of notes written by particular clinicians within each phase
  - have been influenced by the number of times each clinician received the algorithm (e.g., intervention dose)

# Future Work



- Are there enough evidence-based treatments for CIPN at this time?



- Identify gold standard screening measure



- Little is known regarding how to use CIPN PRO scores to guide clinicians' decision making for individual patients (e.g., dose reduction)

**Long Term:** Work towards the improved identification of CIPN in practice

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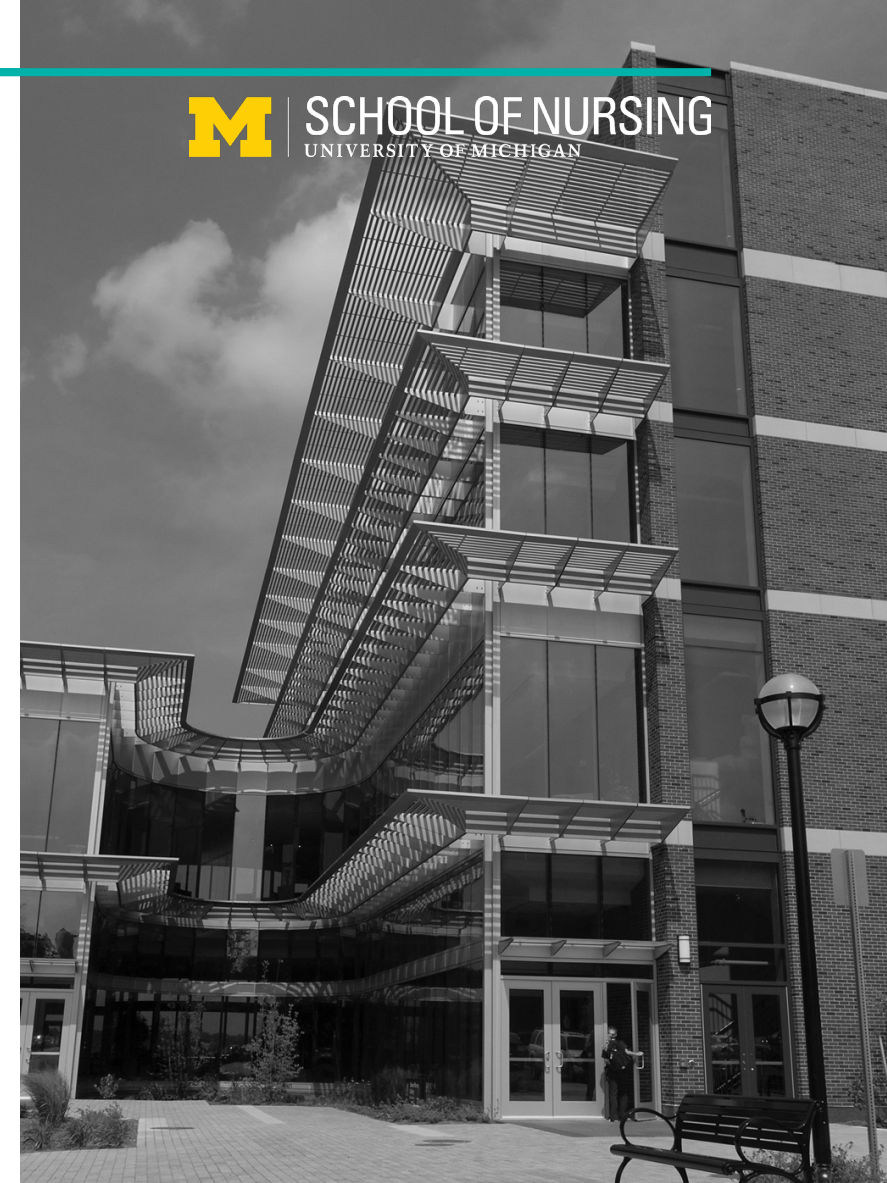
# Questions

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UNIVERSITY OF MICHIGAN



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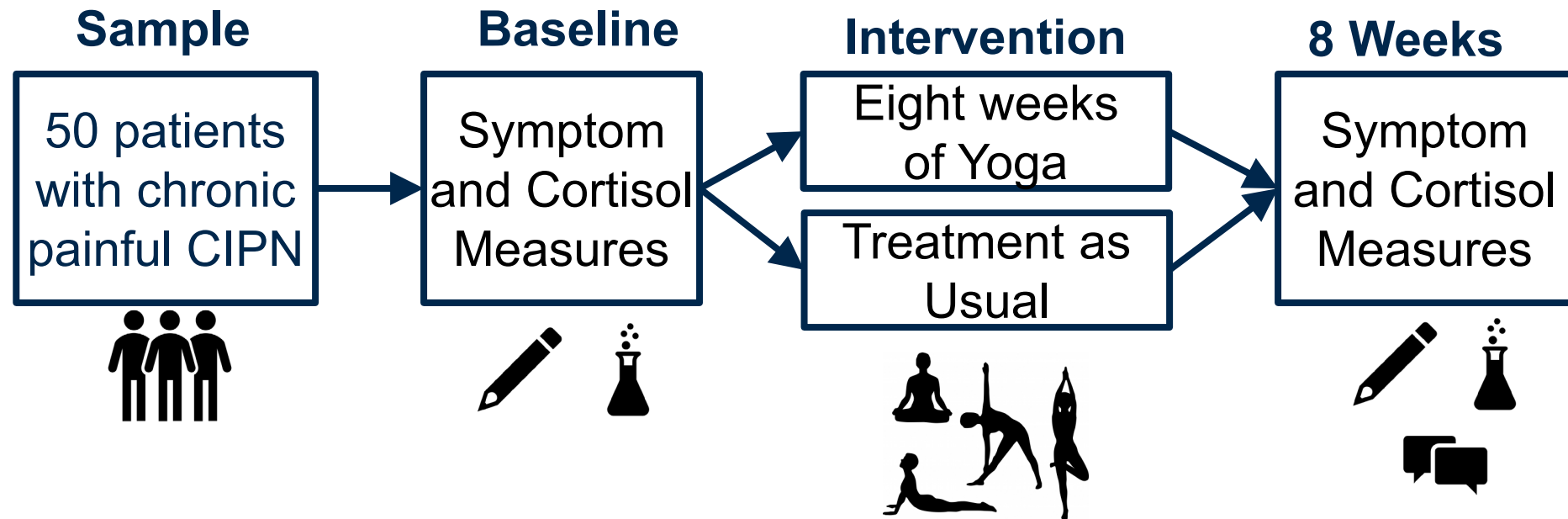
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# Yoga for Chronic Painful Neuropathy

- Explanatory-sequential mixed methods
  - Randomized controlled trial (2:1 randomization)
  - Semi-structured interviews



# Purpose

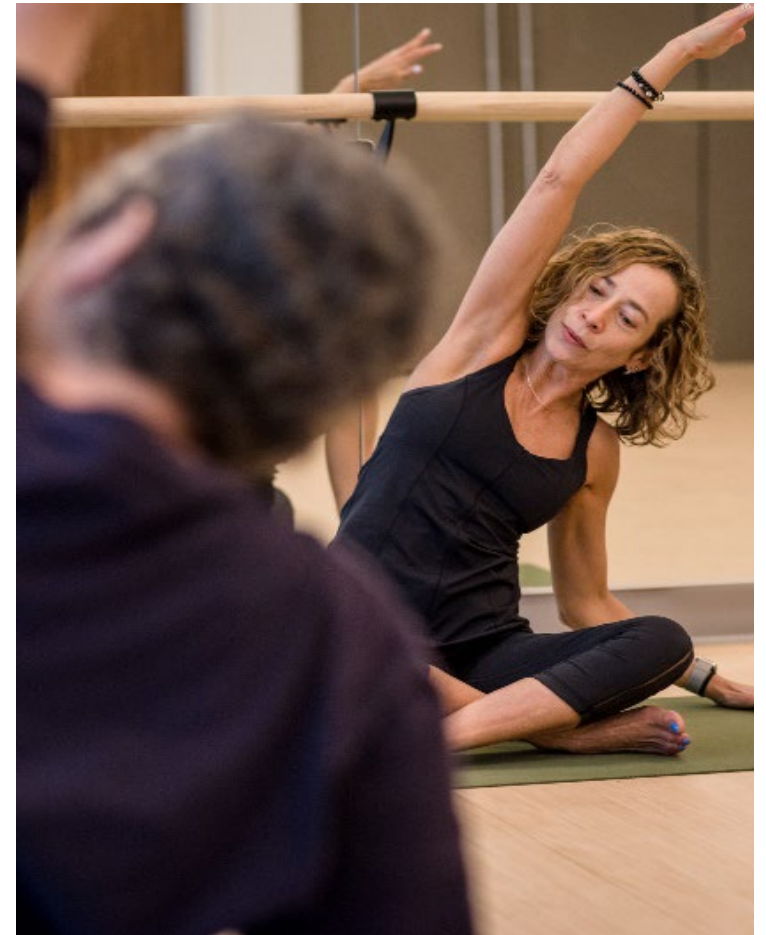
**Aim 1a:** Determine the feasibility of yoga implementation by calculating participant recruitment, retention, and adherence rates in both groups of a randomized eight-week yoga trial.

**Aim 1b:** Explore yoga group participants' perspectives of acceptability and satisfaction with the intervention

**Aim 2:** Evaluate the impact of an eight-week yoga intervention on CIPN severity, physical function, and other symptoms.

# Yoga Intervention Format

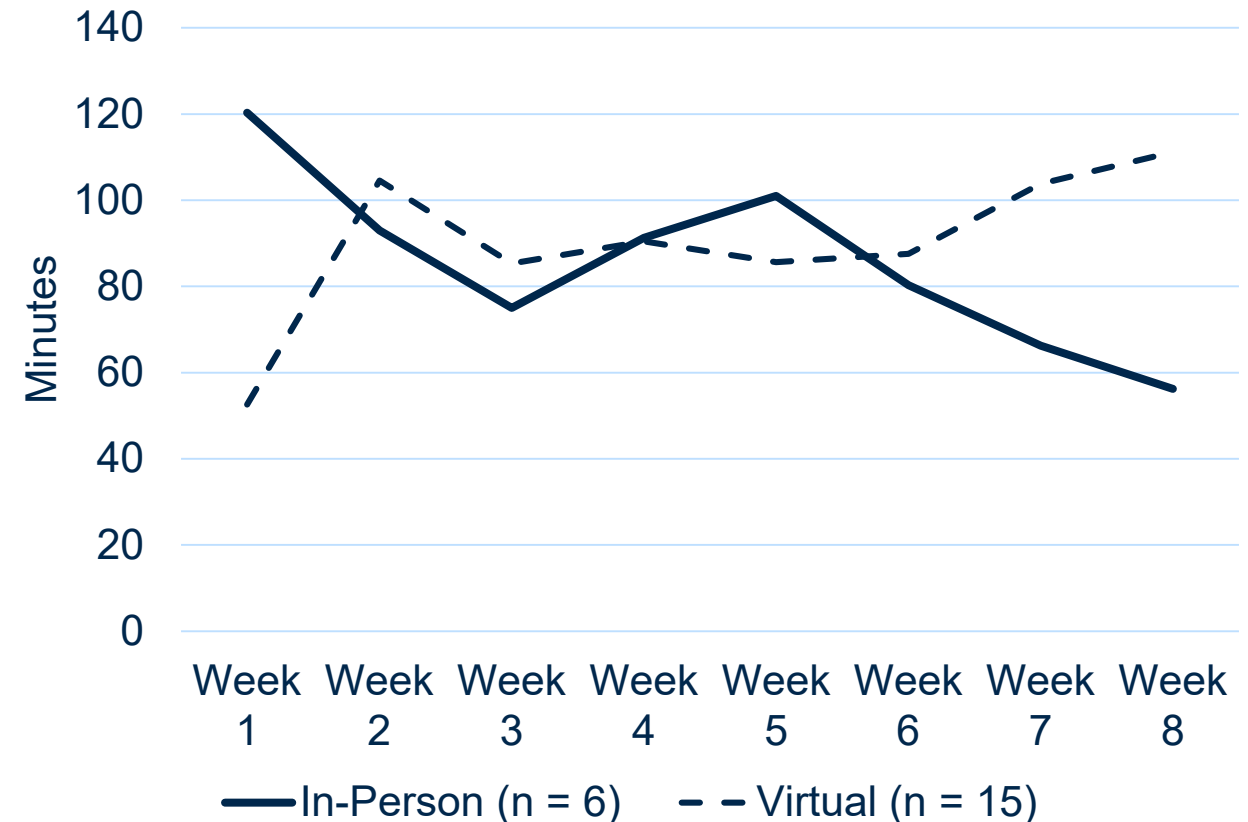
- Eight weeks
- 1 on 1 meeting with yoga instructor
- 45 minutes in person at Zakim Center
  - Chair Flow or Flow
  - Regularly offered
- 45 minutes at home using video
  - Yoga blocks and balls
- All classes & videos incorporate hand and foot massages or stretches



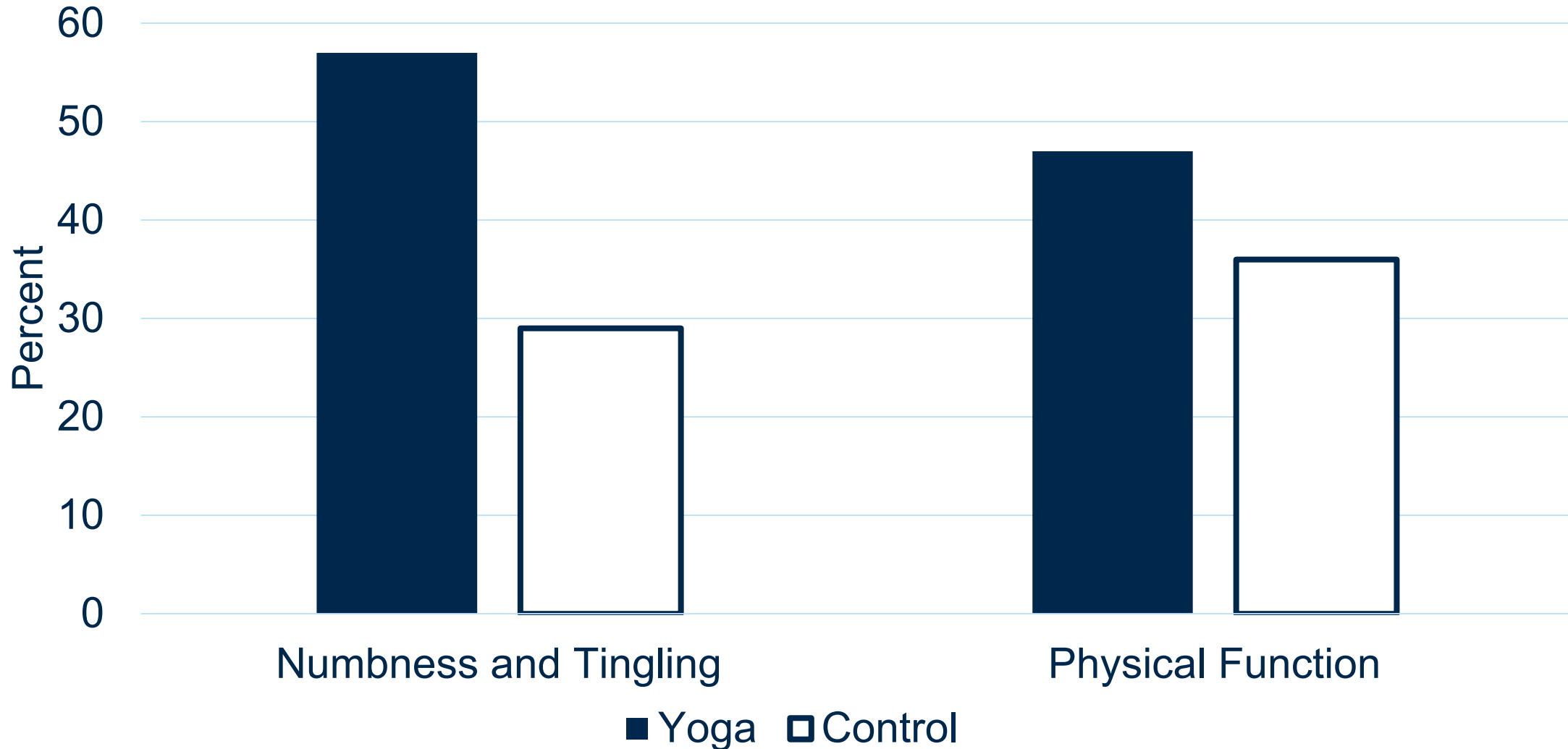
# Feasibility

- Accrual to virtual yoga was considerably higher (4.6/month) than accrual to in-person (2.5/ month)
- 35/44 (79.5%) of participants completed the study measures
- 87.5% of virtual participants completed  $\geq 12$  yoga sessions, while 33% of in-person participants completed  $\geq 12$
- Results from interviews revealed that participants highly rated the flexibility and structure of virtual yoga

**Average Minutes of Yoga Practice Each Week by Intervention Format (N = 21)**



## Percent of Yoga and Control Group Participants Experiencing Clinically Significant Improvements





# Future Work

## Next Steps:

- ✓ Determine the efficacy of yoga for chronic painful CIPN in an adequately powered randomized controlled trial
- 📶 Consider virtual delivery of yoga based on higher feasibility metrics

**Long Term:** Work towards the identification of an efficacious non pharmacological treatment to decrease CIPN-related functional deficits

## Frequency (*n*) of Clinician Documentation of Moderate Severity CIPN Symptoms at the Third Visit

