

Why participate in clinical trials?

Thursday, June 12th, 2025

featuring **Jennifer Gewandter, PhD, MPH**

**Associate Professor
University of Rochester Medical Center**

Lilly A MEDICINE COMPANY



Today's moderator:



Lindsay Colbert
Executive Director
the Foundation for Peripheral Neuropathy



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We're recording!

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FoundationForPN.org/past-webinars



Questions?

Submit questions anytime in the **questions box.**

We will answer as many as we can.



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Check your email for how-to.



Today's expert:



Jennifer Gewandter
PhD, MPH

Associate Professor
University of Rochester Medical Center



Why participate in clinical trials?

A discussion of the contributions you can make
to the future of neuropathy treatment.

The Foundation for Peripheral Neuropathy Seminar Series
June 12, 2025

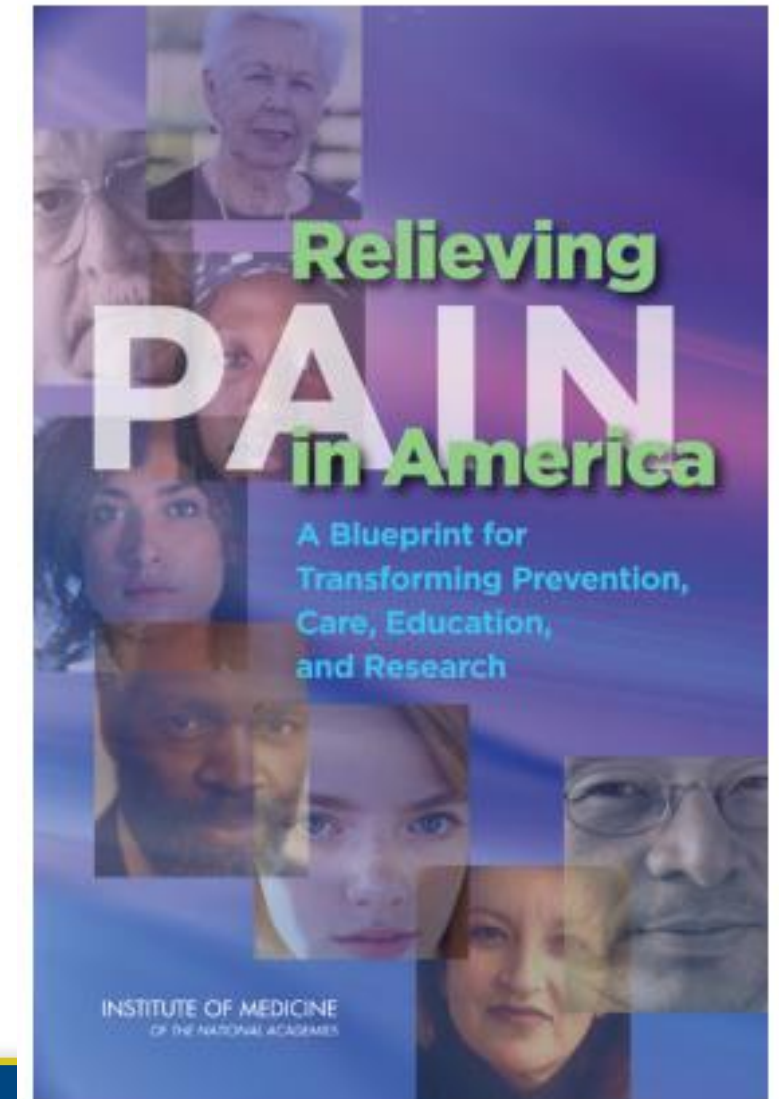
Jennifer Gewandter, PhD, MPH
Associate Professor
University of Rochester Medical Center

Conflict of Interest Disclosure

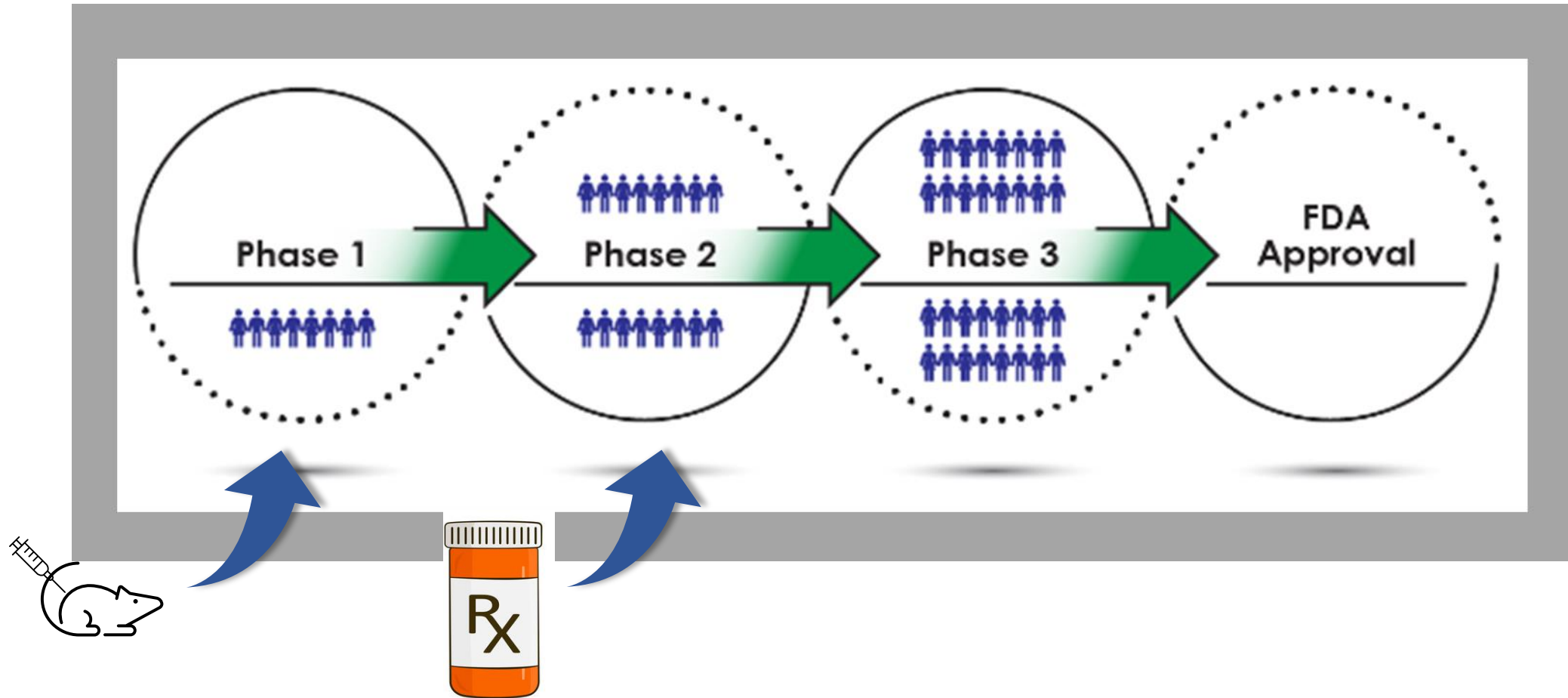
- I serve as a consultant for Eli Lilly and am an investigator in one of their clinical trials.
- Neurometrix (company that developed the TENS technology I will talk about) provided the TENS units for the clinical trial data I will present.

Why I study pain and peripheral neuropathy.

- Chronic pain affects over 100 million American adults.
- Costs up to \$635 billion / year in medical costs and lost productivity.
- Opioid epidemic.
- Most treatments for chronic pain are only modestly effective and do not work for everyone.



Steps for developing novel medical therapies



Roles for people living with neuropathy: Research Partners



Research partners provide input on:

- Study design
 - Outcomes
 - Entry criteria
 - Design of intervention
- Recruitment materials
 - Language
 - Presentation
 - Images
 - Outreach methods

Roles for people living with neuropathy:

Research Participants

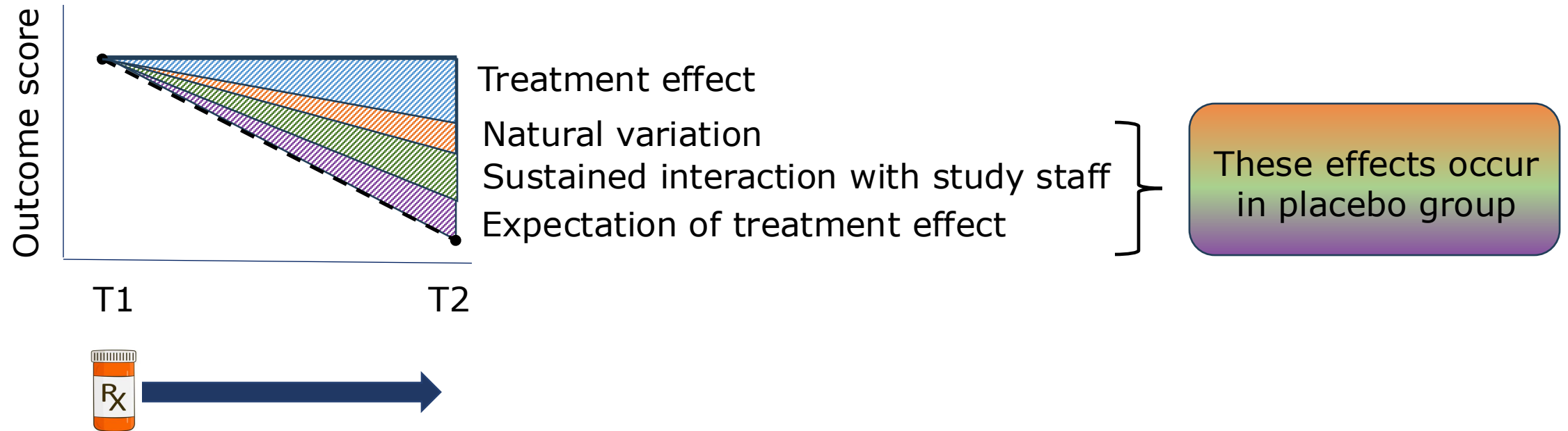


Research participants:

- Generously donate their time.
- Receive an experimental treatment (or control).
- Complete questionnaires.
 - At visits
 - At home
- Undergo testing.
- Provide biological samples (e.g., blood).

What I would want my loved one to know about trials.

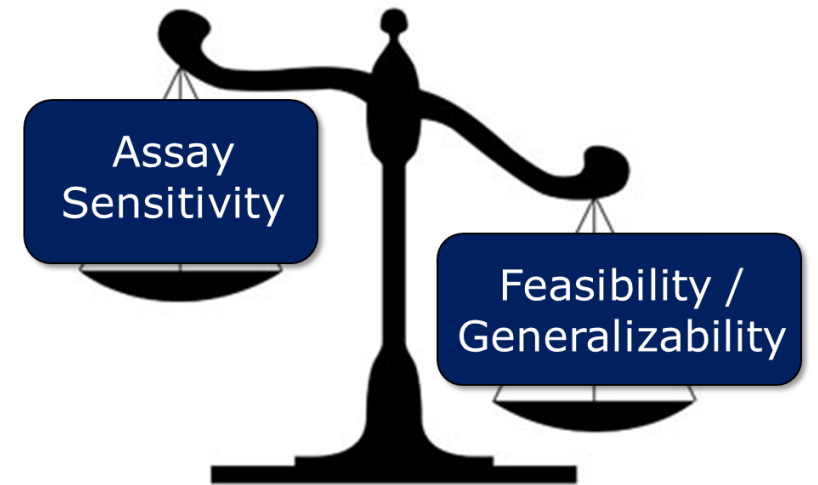
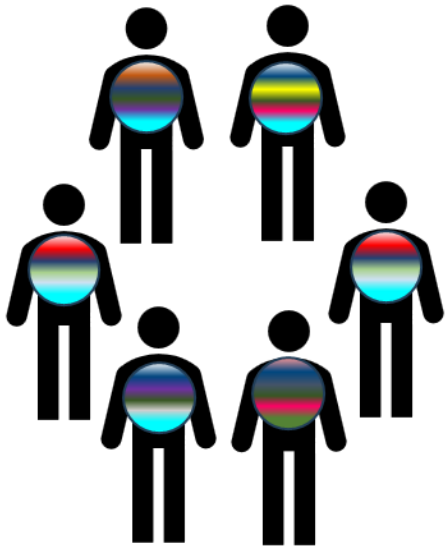
Why do some people have to get a control (placebo) in trials?



What I would want my loved one to know about trials.

Why do phase III trials have to be so large?

Variability among people living with
peripheral neuropathy/ pain



What I would want my loved one to know about trials.

Participation in one clinical trial can have a far-reaching impact.

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Wireless Transcutaneous Electrical Nerve Stimulation (TENS) for Chronic Chemotherapy-Induced Peripheral Neuropathy (CIPN): A Proof-of-Concept Randomized Clinical Trial

Jennifer S. Gewandter,^{*} Eva Culakova,[†] Jenae N. Davis,[‡] Umang Gada,[†] Joseph J. Guido,[†] James D. Bearden,[§] Brain Burnette,[¶] Dhaval Shah,^{||} Gary R. Morrow,[†] Karen Mustian,[†] Kathleen A. Sluka,^{**} and Nimish Mohile^{††}

Main entry criteria

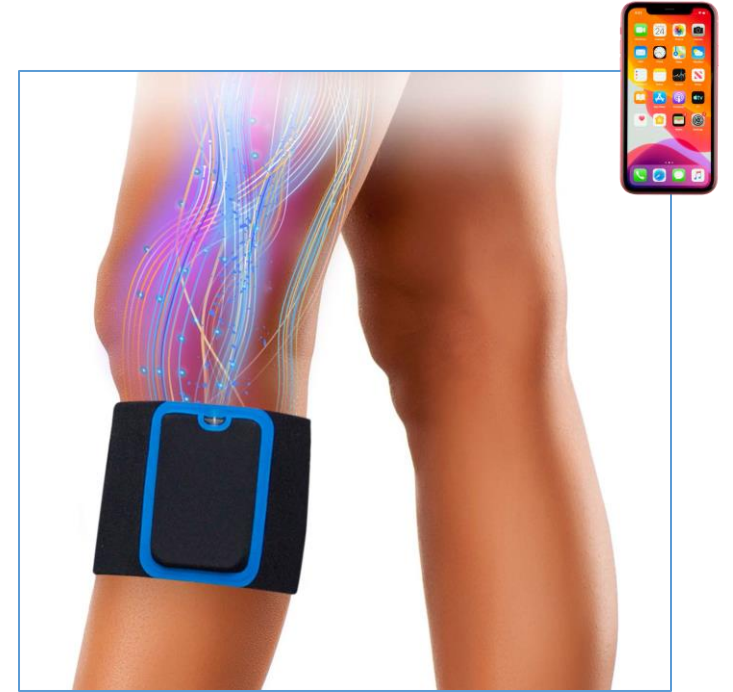
- Completed neurotoxic chemotherapy ≥ 3 months ago
 - Platinums, taxanes, vinca alkaloids, bortezomib
- Diagnosed with CIPN (bilateral stocking/glove distribution)
- At least 2 of the following symptoms rated ≥ 4 out of 10:
 - Sharp/shooting pain
 - Hot/burning pain
 - Numbness
 - Tingling
 - Cramping

TENS Intervention

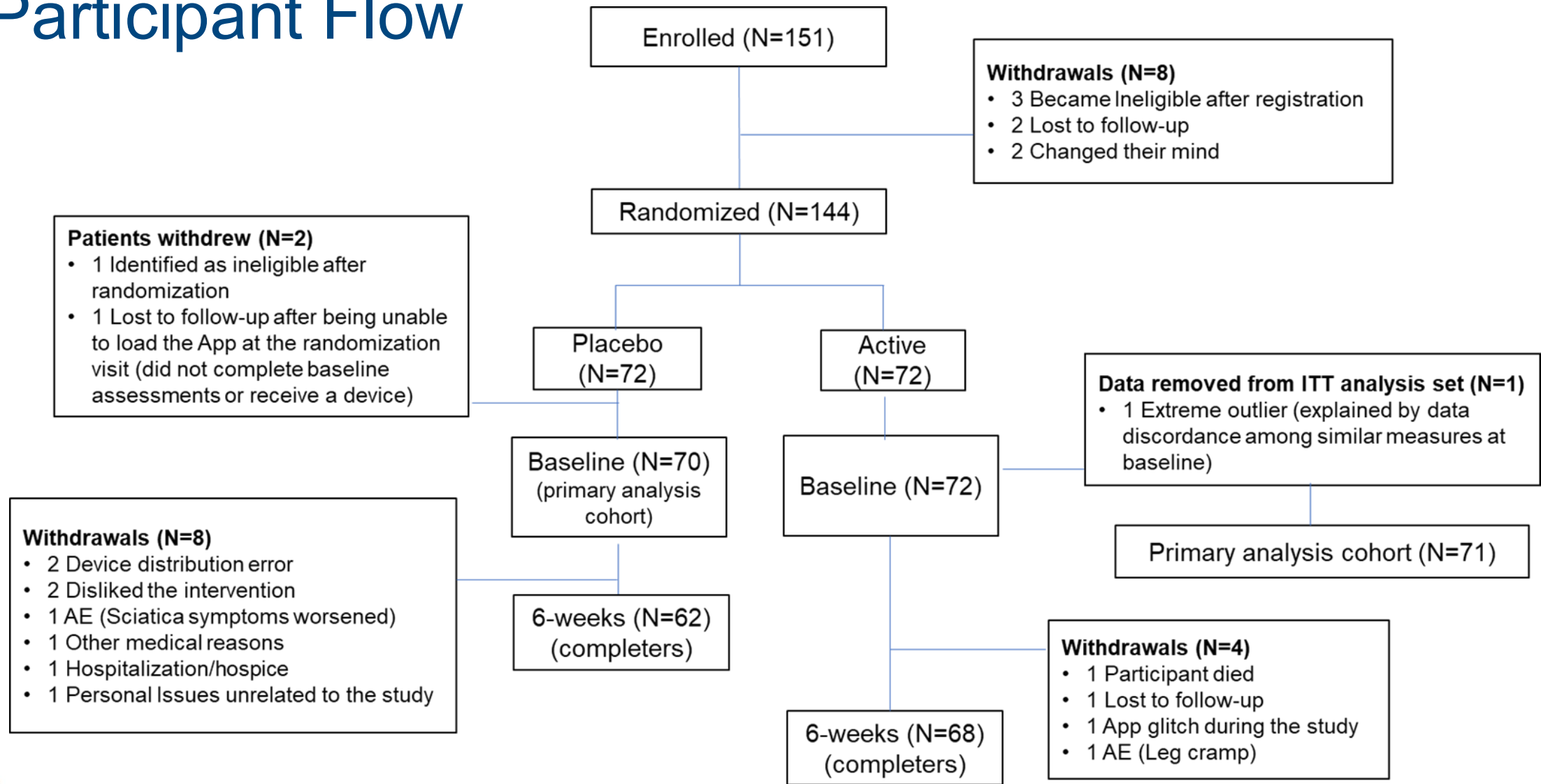
Device worn for 5 hours per day.

- Active device: (1-hour sessions every other hour) → 3 hours stimulation.
- Placebo device: (2.5-minute sessions every ~2 hours) → 7.5 minutes of stimulation.

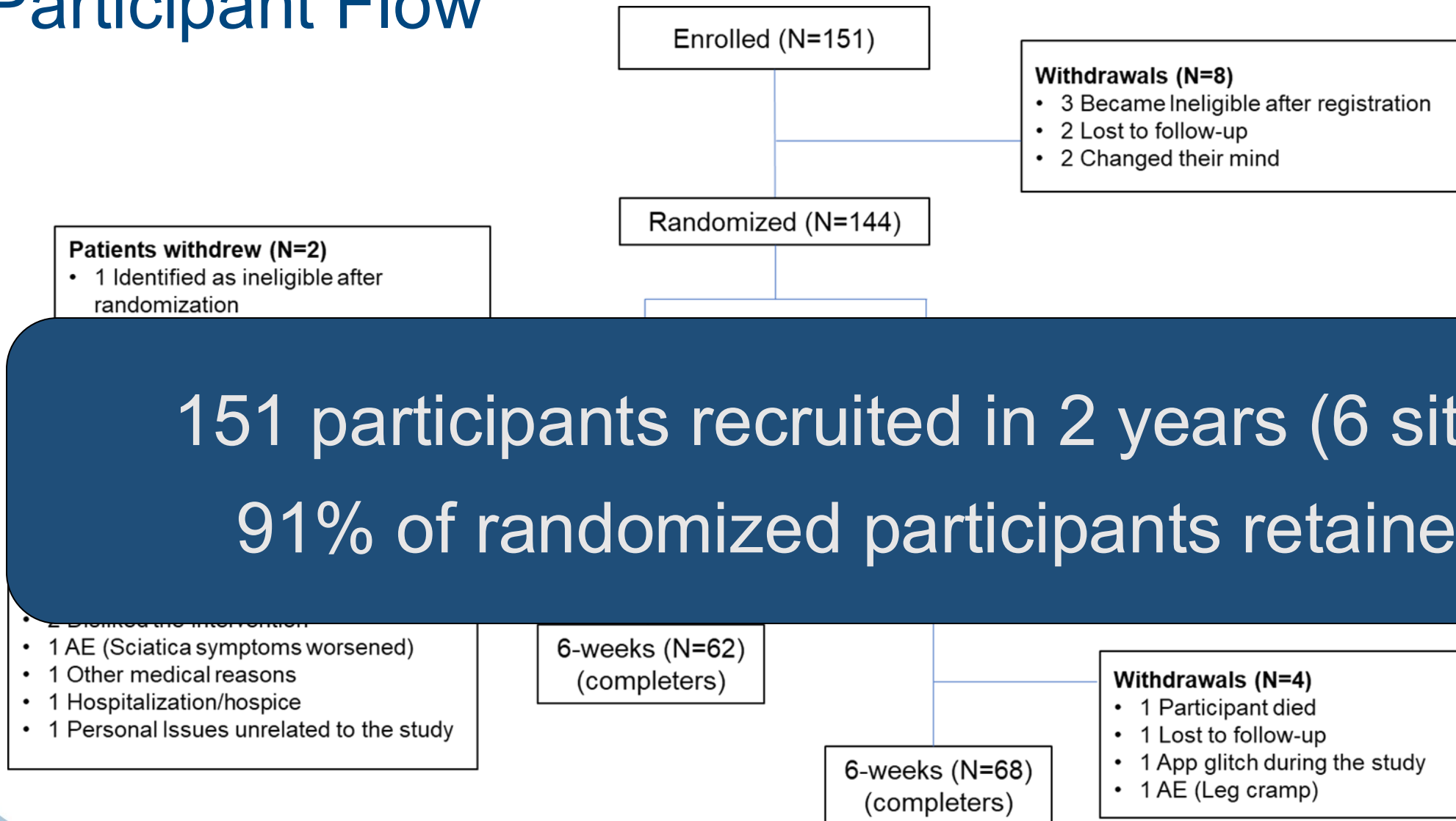
Treatment period: 6 weeks (primary endpoint).



Participant Flow



Participant Flow



Primary and Secondary results

Symptom	% Change from baseline		Marginal mean group difference [placebo-active] (95% CI)	p-value
Primary analysis population (N=142)				
	Placebo	Active		
EORTC-CIPN20	-8.7%	-11.6%	1.05 (-0.56, 2.67)	0.199

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Subgroup analyses including only those with ≥4 at baseline in the particular symptoms				
	Placebo	Active		
Hot/burning pain (N: P=22; A=22)	-28.3%	-49.2%	1.37 (-0.33, 3.08)	0.112
Sharp/shooting pain N: P=24; A=23)	-34.3%	-52.5%	1.21 (-0.36, 2.79)	0.128
Cramping (N: P=18; A=18)	-30.2%	-52.1%	1.35 (-0.32, 3.02)	0.110
Tingling (N: P=50; A=56)	-23.7%	-27.5%	0.24 (-0.60, 1.08)	0.572
Numbness (N: P=50; A=61)	-18.4%	-24.0%	0.27 (-0.51, 1.05)	0.492

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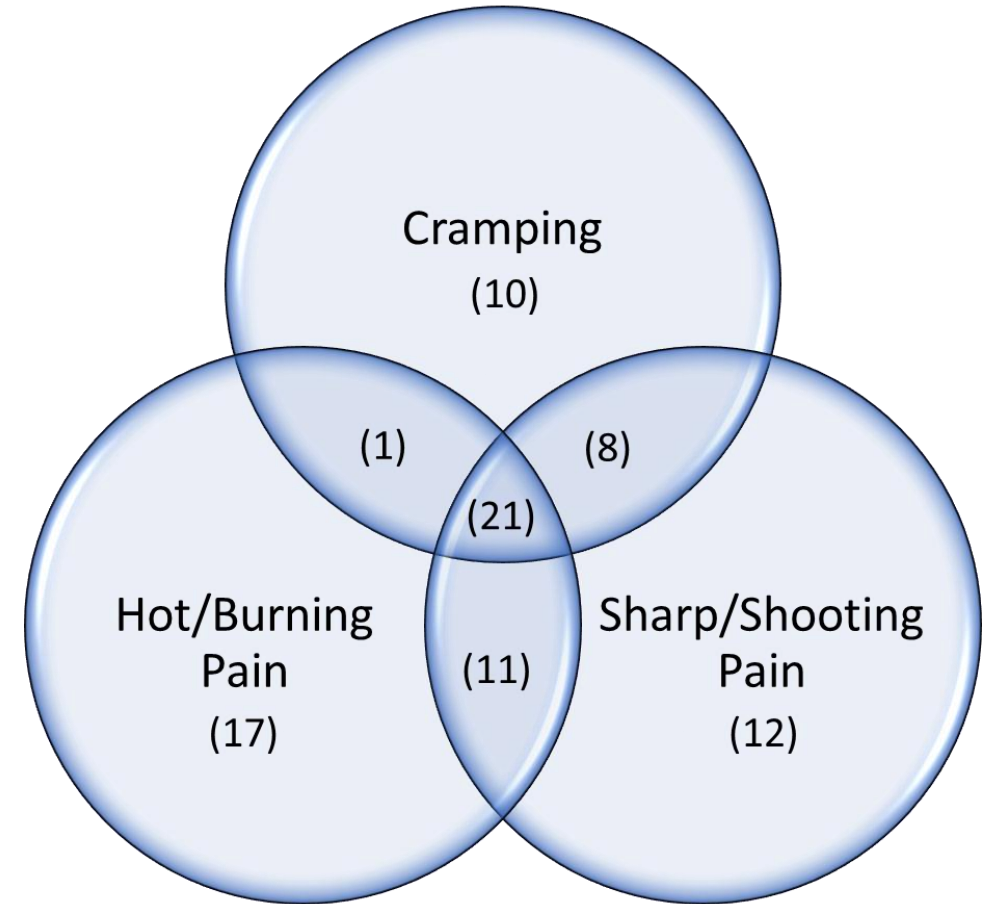
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Primary and Secondary results

Symptom	% Change from baseline	Marginal mean group difference [placebo-active]	p-value	
Chronic pain trials are generally powered to confirm a Δ of 1 NRS point.				
The Δ in the RCT of duloxetine for CIPN was 0.73.				
Subgroup analyses including only those with ≥4 at baseline in the particular symptoms				
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Interindividual variability in pain qualities

Subjects reporting ≥ 4 out of 10 for each symptom or combination at baseline (Total N=80; 56%)



Personalized outcome

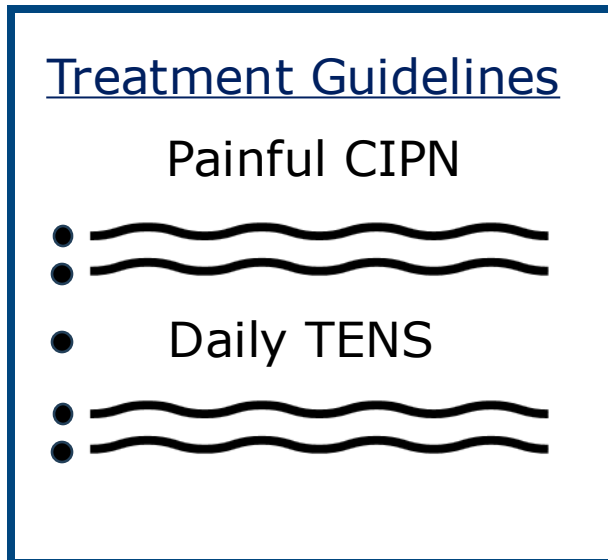


Outcome (n=71)	Mean difference (Placebo-active) (95% CI)	p-value
Mean of symptoms with ≥ 4 severity**	1.24 (0.07, 2.41)	0.038

Impact of this trial...

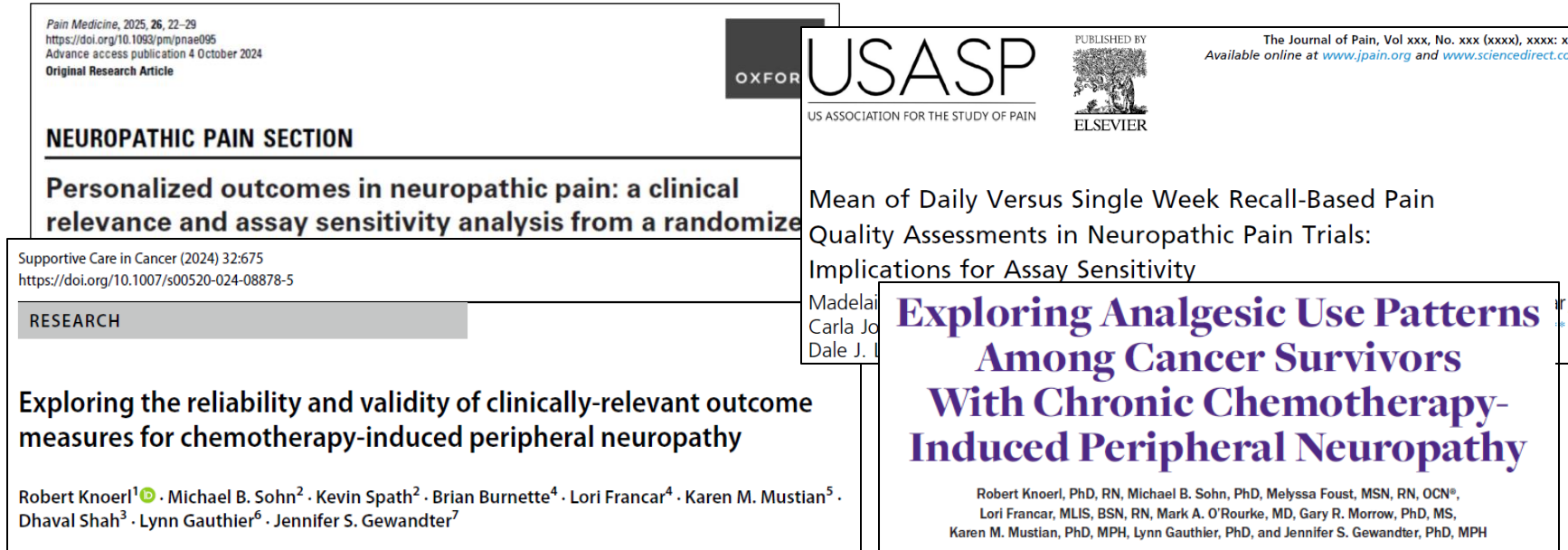
Which would not have been possible without 151 people who volunteered their time.

- Support funding applications for a phase 3, confirmatory trial.



Dissemination

Amplified impact



4 additional peer-reviewed publications.

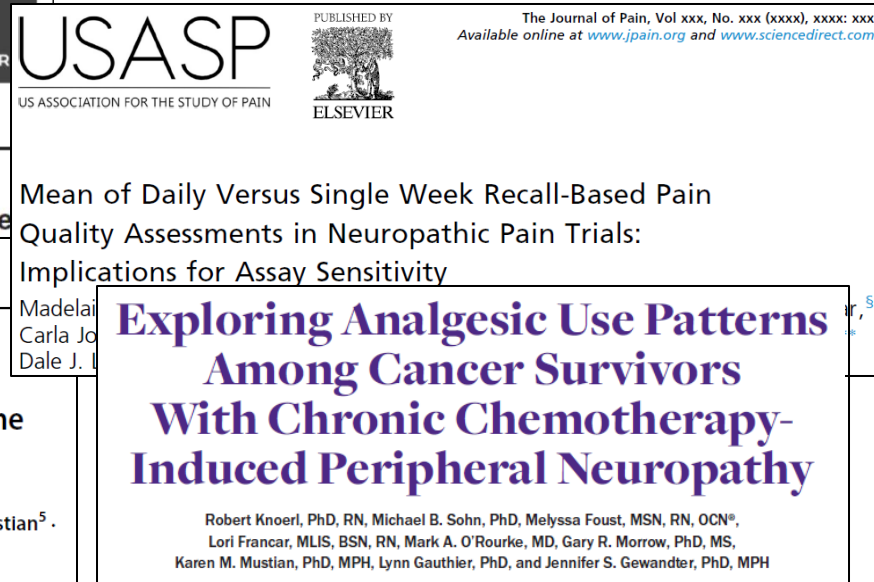
6 poster presentations at national & international meetings.

2 additional papers in progress.

Contribution to science and treatment of CIPN:

- Inform future clinical trial designs (including better understanding currently available outcome measures and developing novel ones)
- Increase understanding of impact of pain associated with neuropathy on important health domains.
- Characterization of analgesic use in patients with CIPN.

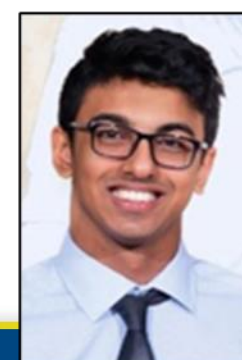
Amplified impact



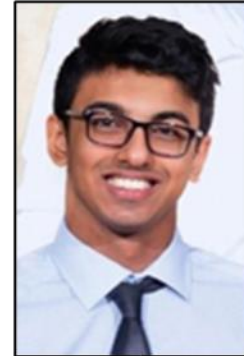
4 additional peer-reviewed publications.

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Amplified impact



All the great things these Brilliant young people will do in the world.

Where to find opportunities

- Foundations or patient advocacy group websites & listservs.
- Clinicaltrials.gov
- Academic medical centers near you.
 - Social media pages.
 - Research volunteer registries.
 - Email researchers directly.
 - Find them on their department websites (Anesthesiology or Neurology most likely for peripheral neuropathy).
- Ask your doctor and look around the office for flyers.
- Look for flyers in your community.

Many thanks

**The participants
who made our
clinical trial
possible.**

Current mentees

Junior Faculty

- Robert Knoerl, PhD
- Umang Gada, MS

Post-doc

- Karim Saab, MD

Residents/Fellows

- Soroush Besharat, MD

Medical Students

- Maddy Rangel
- Jithin George
- Jeremy Huang
- Saanya Lingineni
- Joyce Liu
- Felicia Ko
- Abe Choe

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Coordinators / administrator

- Valerie Chiodo
- Rachel DeGuzman
- Tammy Ortiz

Colleagues

- Roy Freeman, MD
- Robert Edwards, PhD
- Paul Geha, MD
- Dale, Langford, PhD
- Michael McDermott, PhD
- Michael Sohn, PhD
- Kathleen Sluka, PhD
- Ajay Wasan, MD
- Gordon Smith, MD
- Simon Hauroutunian, PhD
- Lynn Gautier, PhD
- Annie Philip, MD
- Mark Williams, MD
- John Markman, MD
- Nimish Mohile, MD

Thanks for joining us!

ANY QUESTIONS?!



HOW WAS IT?

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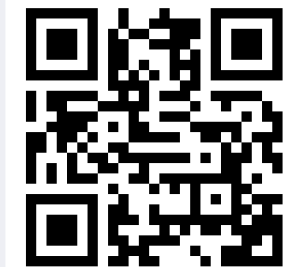
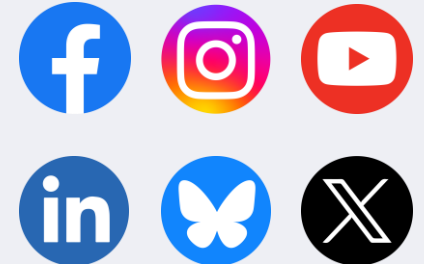


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