

24th Annual
Pain Medicine Meeting
November 13-15, 2025 | Austin, TX

50
ANNIVERSARY

ASRA

PAIN
MEDICINE



Patient Decision-Making in Clinical Trials: A Prospective Preference Assessment Survey on Patient Willingness to Participate in a Blinded Trial Comparing Spinal Cord Stimulation against Placebo Stimulation



Anna Kalleitner RN, Victoria Bains, MN, CNS, Danielle Alvares PhD, Emma Robertson RN, Abigail Muere PhD C, Kathryn Curtis PhD C,
Yanzhi Zeng MBBS Mmed (Anaes), Anuj Bhatia MD PhD FRCPC
Neuromodulation for Pain Program, Department of Anesthesia and Pain Medicine, Toronto Western Hospital, Toronto, Ontario, Canada

INTRODUCTION

- Spinal cord stimulation (SCS) is a well-established treatment for chronic refractory pain.
- PF-SCS (paresthesia-free) offers pain relief without the sensory side effects of traditional SCS.
- Absence of paresthesia enables blinded, placebo-controlled randomized controlled trials (RCT) with crossover designs to rigorously assess analgesic efficacy.
- Participant willingness is essential for trial success.
- A Prospective Preference Assessment Survey (PPAS) was conducted to understand patient perspectives and improve trial design and enrollment.

METHODS

- A prospective preference assessment survey (PPAS) describing a planned RCT was distributed to 41 SCS-eligible patients at Toronto Western Hospital.
- The survey assessed understanding of study design, prior SCS knowledge, expectations, willingness to participate, and perceived benefits/barriers.
- Demographic and pain-related data were also collected.

Variable	Value
Age (years)	60.2±16.3
Sex: Female	51%
Visible minority: Yes No Prefer not to disclose	20% 78% 2%
Pain Duration (years)	10.0±12.1
Average pain NRS Score (0-10)	7.5±1.3
Education Grade School High School Post-Secondary Graduate	5% 27% 41% 27%
Previous involvement in research Yes No Not sure	20% 78% 2%
Site of Pain Only back Leg Back and leg Another Area	27% 34% 24% 15%

Previous Back Surgery: Yes No	49% 51%
Analgesic effectiveness of treatments tried None Occasional Sometimes Mostly Fully	56% 20% 15% 7% 2%
Prior Understanding of paresthesia-based and paresthesia-free SCS: Yes No	15% 85%
Knowledge about SCS: None Some Moderate A lot	25% 41% 34% 0%
Confidence about SCS reducing pain and improving quality of life: Unlikely Uncertain Likely	0% 50% 50%
Risk Perception about SCS: Not dangerous Slightly dangerous Moderately dangerous Extremely dangerous	32% 51% 15% 2%

RESULTS

- Preliminary data indicate most participants comprehended the blinded crossover design concept of the planned RCT.
- Over half voiced concerns about inadequate pain control during placebo phase and burden of neurophysiological testing.
- Among respondents, 47.5% expressed willingness to participate, 32.5% were unwilling, and 20% were unsure.
- Key motivators for participation included gaining insights into own pain, contributing to scientific research, and improving individual SCS outcomes.

CONCLUSION

- Patient willingness to enroll in a PF-SCS versus placebo trial is shaped by:
 - Understanding of the study design
 - Perceived personal benefits
 - Logistical considerations
- Insights from survey informed protocol adjustments aimed at enhancing enrollment.
- Findings are broadly relevant to other neuromodulation trials involving placebo comparisons.

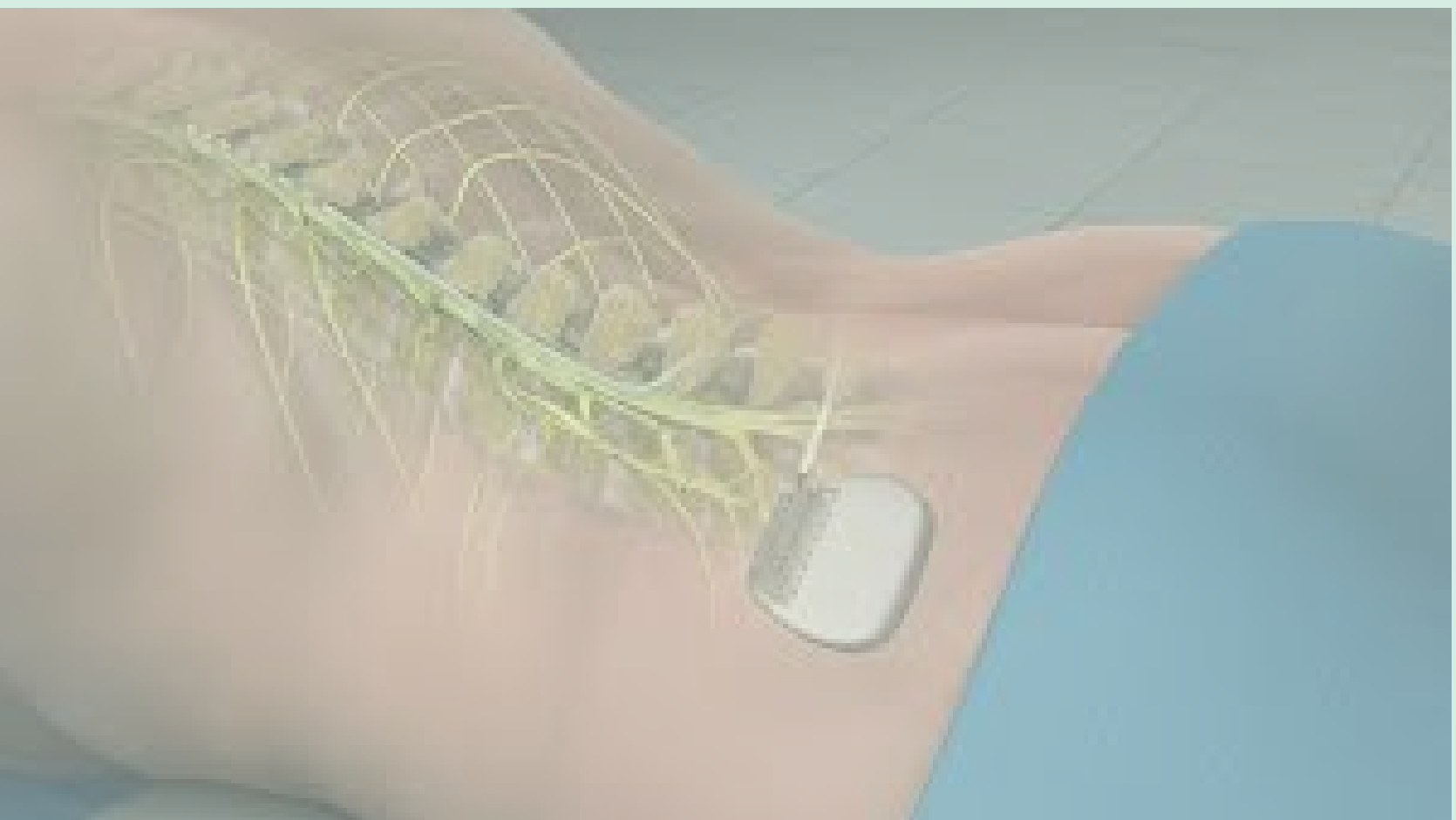


Table 1. Characteristics of participants enrolled and their responses in the Prospective Preference Assessment Survey.

