

A Prospective, Open-Label, Pilot Study to Assess the Effect of Spinal Cord Stimulation on Quality of Sleep and Activity Levels in patients with Chronic Low Back pain with or without Leg Pain

ACTRN12614000902695

Status RECRUITING
Sponsor Dr. Bruce Mitchell
Enrollment 10 participants

Plain Language Summary

This study tests whether a smart spinal cord stimulation device that automatically adjusts its settings based on body position (the Medtronic RestoreSENSOR) improves sleep quality and daily activity levels in people with chronic low back pain or back-and-leg pain.

You may be eligible if:

- You are 18 years or older
- You have been diagnosed with chronic low back pain (with or without leg pain) for at least 6 months
- You have successfully completed a spinal cord stimulator trial and are scheduled for a permanent implant using the Medtronic RestoreSENSOR device
- You are able to walk
- You are privately insured

You may NOT be eligible if:

- You have cancer or a malignant disease
- You have a history of schizophrenia, delusion, psychosis, or dissociative disorder
- You had pain-related surgery within the last 12 weeks or are planning surgery during the study
- You have a previously diagnosed sleep disorder like sleep apnea
- You are not a native or fluent English speaker
- You are not privately insured

Talk to your doctor about whether this trial might be right for you.

Key Eligibility Criteria

Inclusion (13)

- years of age or older
- Have undergone a positive Spinal Cord Stimulator (SCS) trial and scheduled for an SCS implant with the Medtronic Restore-SENSOR implantable pulse generator (IPG)
- Subject is ambulatory
- Diagnosed with low back pain or low back pain plus leg pain for at least 6 months
- Undergoing treatment for low back pain or low back pain plus leg pain
- ... and 8 more (see full listing online)

Exclusion (6)

- Have plans to enrol in another clinical study during their participation in this study, or are currently enrolled in a clinical study that could interfere in participation in the trial or affect the scientific soundness of this study
- Cancer or any other malignant disease

<https://presentonpastdiagnosisofschizophreniaanddissociativeorder/ACTRN12614000902695>

- A pain-related surgery in the previous 12 weeks of enrolment, the intent to undergo surgery during the period of the study
 - Non-English speaking or an inability to complete questionnaires accurately.
- ... and 1 more (see full listing online)

Locations (1 total)

VIC, Australia