Selection and Design of Control Groups in Randomized Clinical Trials of Neuromodulation for Chronic Pain: A Systematic Review and Meta-Research Study

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The question

A stimulator is only as convincing as the control it is compared with.

How do neuromodulation RCTs choose, blind, and report their control groups?

Methods

Design
systematic review and meta-research study

Eligible
RCT reports of spinal cord, dorsal root ganglion, or peripheral nerve stimulation for chronic pain

Extracted
comparator, design, blinding, washout, registration, industry support, follow-up, control-group outcomes

Analysis
descriptive, at the trial-report level

Results

88 trial reports	7,101 participants	60 median n	1995–2026 published

Modality



Design



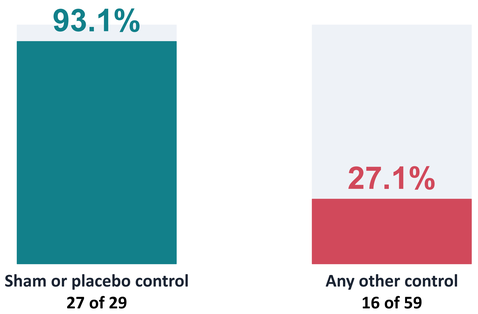
What trials compared against



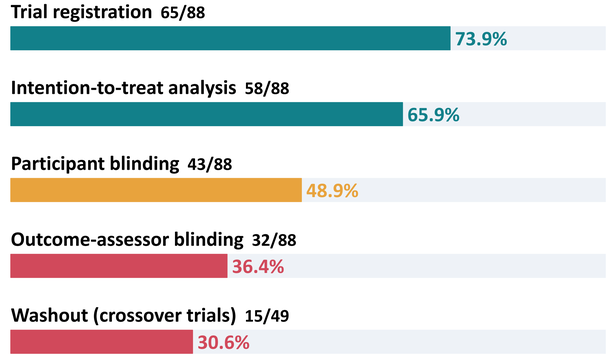
Each square = 1 trial report (n = 88)

Blinding follows the sham

Participants reported as blinded



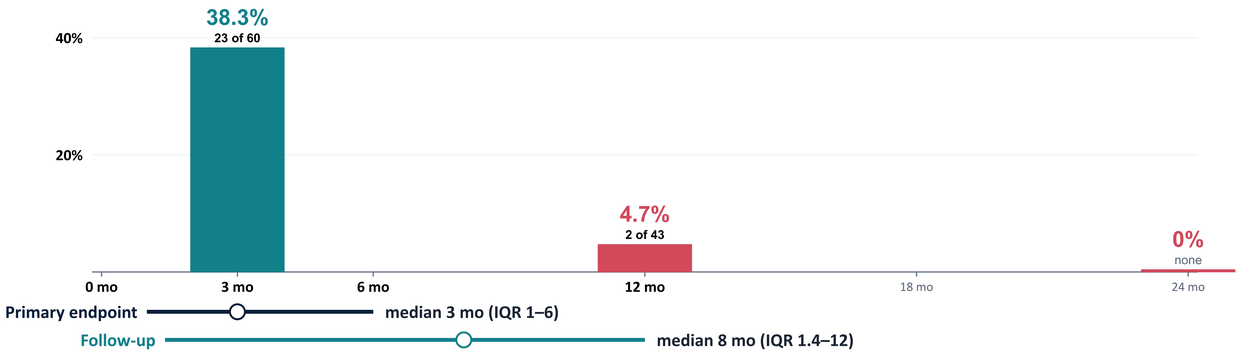
Safeguards reported



Also: industry support reported in 58.0%; regulatory use in 18.2%.

The vanishing control group

Trials reporting extractable control-group pain outcomes, among those with enough follow-up



Functional and opioid outcomes were reported even less consistently.

Conclusions

1. **No standard control.** Trials used five different control types, most often an active device or sham. They answer different questions, so results can't be compared directly.
2. **Anti-bias safeguards are inconsistently reported.** Assessor blinding, washout periods and intention-to-treat analysis were often missing, even though assessor blinding doesn't require a sham.
3. **Control groups disappear over time.** Almost no trial reported control-group outcomes beyond 3 months, so durability relative to control is unknown.

Abbreviations: DRG, dorsal root ganglion stimulation; ITT, intention-to-treat; IQR, interquartile range; mgmt, management; PNS, peripheral nerve stimulation; RCT, randomized clinical trial; SCS, spinal cord stimulation.

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