28th Annual Gabor Racz Advanced Interventional Pain Conference and Workshop
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To Trial or Not to Trial: Challenging the dogma in SCS implementation

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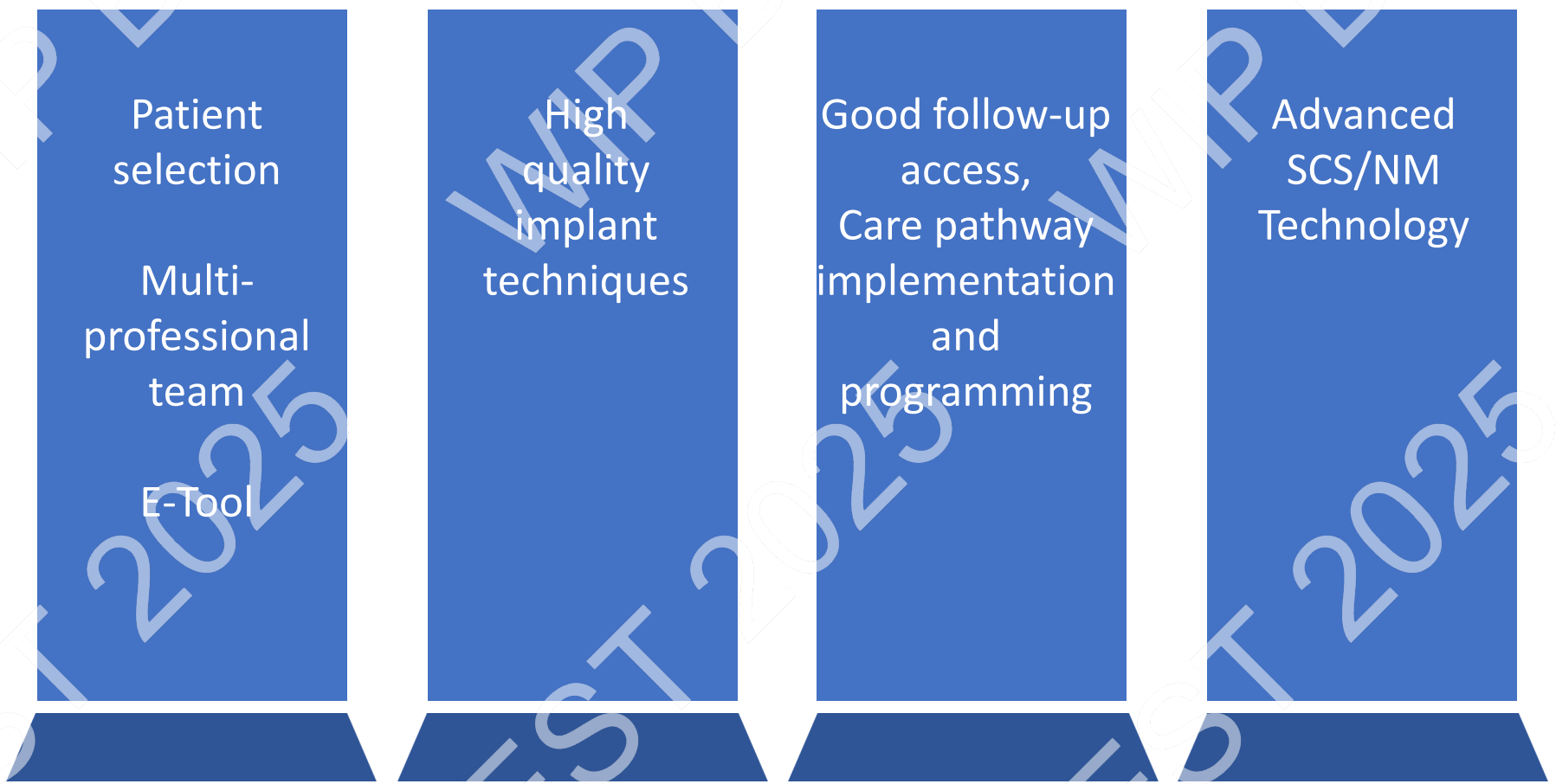
Potential Conflicts of Interest

- Scientific Advisory Board: Boston Scientific, Galvani Bioelectronics, Mainstay Medical, Saluda Medical
- Scientific Research: MSE/BTUH R&D – NIHR, Boston Scientific, Mainstay Medical, Saluda Medical
- Speaker's Bureau: Boston Scientific, Mainstay Medical, Saluda Medical
- Stock Holder: None
- Stock Options: None
- Product Royalties: None
- Employed by
  - National Health Service, UK.

Pillars for successful SCS outcomes



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The 4 Pillars of SCS outcome success

- Patient selection
  - Clinical appropriateness
  - Biomedical
  - Psychosocial
  - Trial procedure
- High quality implant techniques
- Good follow-up arrangements and programming
- Advanced SCS Technology

Where did the notion of a trial period arise?

- Early SCS used open techniques, unipolar or wide spaced electrode arrays
- Rudimentary knowledge base of appropriate SCS selection
- Development of percutaneous through the needle techniques
  - Initially for trial period prior to surgical lead
  - Became definitive leads for both trial and long-term
- Cost containment
  - “Try before you Buy”
- Most randomized controlled trials have a trial period
  - Reporting differences

Questioning the economic value of Trial period

Neuromodulation: Technology at the Neural Interface

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(onlinelibrary.wiley.com) DOI: 10.1111/ner.12898

Trial Versus No Trial of Spinal Cord Stimulation for Chronic Neuropathic Pain: Cost Analysis in United Kingdom National Health Service

Rui V. Duarte, MSc, PhD *; Simon Thomson, MBBS†

Objectives: The aim of the current project was to evaluate the spinal cord stimulation (SCS) screening trial success rate threshold to obtain the same cost impact across two identical sets of patients following either a prolonged screening trial prior to implantation strategy or a full implant without a screening trial.

Materials and Methods: A cost impact analysis was carried out from a health care perspective and considered trial to implant rates reported in the literature. Items of resource use were costed using national averages obtained from the National Health Service (NHS) reference cost data base. Cost components were added up to derive total patient level costs for the NHS. Only the costs associated with the screening trial procedures and devices were considered.

Results: The most conservative of our estimates suggest that a failure rate of less than 15% is cost saving to the NHS. A failure rate as high as 45% can also be cost saving if the less expensive nonrechargeable SCS devices are used. All the thresholds observed represent a considerably higher screening failure rate than that reported in the latest randomized controlled trials (RCTs) of SCS. A trial to implant ratio of 91.6% could represent savings between £16,715 (upper bound 95% CI of rechargeable implantable pulse generator [IPG] cost) and £246,661 (lower bound 95% CI of nonrechargeable IPG cost) per each 100 patients by adopting an implantation only strategy.

Conclusions: Considerable savings could be obtained by adopting an implantation strategy without a screening trial. It is plausible that accounting for other factors, such as complications that can occur with a screening trial, additional savings could be achieved by choosing a straight to implant treatment strategy. Nevertheless, additional evidence is warranted to support this claim.

Keywords: Cost comparison, screening trial, spinal cord stimulation

Conflict of Interest: Rui V. Duarte and Simon Thomson have received honoraria for consulting for Boston Scientific.

INTRODUCTION

The prevalence of chronic pain in Europe is estimated to range between 13 and 51% (1,2), which is considerably higher than that of other chronic conditions such as diabetes mellitus (type 1 or type 2), which has a much lower prevalence of 7% among men and 4.9% among women (3). Chronic pain with neuropathic characteristics has an estimated prevalence between 6.9 and 10% (4).

Spinal cord stimulation (SCS) is a recognized option for the management of chronic pain of neuropathic etiology. The effectiveness of SCS has been demonstrated for the management of neuropathic pain conditions such as failed back surgery syndrome (FBSS) (5), complex regional pain syndrome (CRPS) (6), and painful diabetic neuropathy (7).

Early clinical trials for SCS involved the use of trials of stimulation before permanent implantation of device. The aim was to help better identify patients who would benefit from the complete procedure—allowing physicians to assess the ability of the device to cover the patient's area of pain and the associated level of paraesthesia. Current guidance from the National Institute of Health and Care Excellence (NICE) on SCS for chronic pain of neuropathic or ischaemic origin is based on these trials (8). However, it stipulates that only patients who have undergone a successful trial of stimulation be allowed to have the device.

As the therapy and the devices have evolved, the percentage of patients receiving a definitive implant after the trial appears to have increased. Trial to implant rates observed in randomized controlled trials (RCTs) range from 67% in 2000 (6), to 83% in

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For more information on author guidelines, an explanation of our peer review process, and conflict of interest informed consent policies, please go to www.wiley.com/WileyCDA/Section/id-301854.html

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- Permanent to Trial ratio
- Above which it increases acquisition overall costs
- Base case (Upper/lower 95% bounds)
- Non-rechargeable
- 67% (55% to 75.7%)
- Rechargeable
- 80% (74% to 85%)

Is this the right role of a Trial period of SCS?

- A trial is NOT a substitute for poor patient selection
- Sensitivity good but…specificity poor
- Does it aid selection or simply confirmatory?
- Requirement of most health funding organisations

- A trial period can be On table or prolonged

- Unacceptable risk of infection with prolonged trial > 10 days
- Unacceptable risk of neurological harm with multiple epidural access?

Definition of SCS Trial:

Insertion of SCS leads and application of stimulation in a clinically appropriate patient, to assess :

a) **appropriate coverage** of painful regions where the mode of stimulation elicits a sensation
b) **tolerability** of any induced sensations
c) presence and **magnitude of clinical benefit**, before deciding on the performance of definitive SCS therapy

For **SCS systems independent of induced sensation 'magnitude of clinical benefit' alone** can be considered.

Shanthanna H, Eldabe S, Provenzano DA, Bouche B, Buchser E, Chadwick R, Doshi TL, Duarte R, Hunt C, Huygen F, Knight J, Kohan L, North R, Rosenow J, Winfree CJ, Narouze S. Evidence-based consensus guidelines on patient selection and trial stimulation for spinal cord stimulation therapy for chronic non-cancer pain. Reg Anesth Pain Med 2023.

Potential benefits of SCS Trial

- Health Funder requirement
- Diagnostic Test Value
- Identify Responders (sensitivity)
- Exclude non-responders (specificity)
- Exclude patients that technically are unable to achieve pain area coverage
- Inform choice of implantable pulse generator
- Patient acceptance confirmation

SCS Trial Regulation across Europe

Belgium	France	Netherlands	Germany	UK
Min 3 weeks 2 weeks at home	10 days	Min 1 week	6 - 12 days seem appropriate	No Explicit duration
50% pain relief Pronounced reduction of medication	Pain reduction ≥50%		≥50% pain reduction	Assessment of different Outcomes, tolerability, pain relief etc..
Significant improvement of the daily living activities and quality of life scores	Preferably in an ambulatory care setting where the patient returns home		Improvement of mood or QoL desire expressed by the patient to reduce medication	This assessment must take into account the disabilities or communication difficulties.

Diagnostic accuracy - definitions

Sensitivity ↓ Specificity ↓

follow up outcome	Pain relief ≥50%	Pain relief <50%	Totals
SCS Trial positive	TP	FP	TP+FP
SCS Trial negative	FN	TN	FN+TN
Totals	TP+FN	FP+TN	all

Sensitivity: proportion of individuals who achieve >50% pain relief with SCS who are correctly identified by a positive Trial = TP/(TP+FN)

Specificity: proportion of individuals who achieve <50% pain relief with SCS who are correctly identified by a negative Trial = TN/(TN+FP)

Research Paper

PAIN

OPEN

Does a screening trial for spinal cord stimulation in patients with chronic pain of neuropathic origin have clinical utility and cost-effectiveness (TRIAL-STIM)? A randomised controlled trial

Sam Eldabe[a,*], Rui V. Duarte[b], Ashish Gulve[a], Simon Thomson[c], Ganesan Baranidharan[d], Rachel Houten[b], Susan Jowett[e], Harbinder Sandhu[f], Raymond Chadwick[g], Morag Brookes[a], Anu Kansal[a], Jenny Earle[h], Jill Bell[h], Jennifer Robinson[a], Sarah Walker[i], Shelley Rhodes[i], Rod S. Taylor[i,j]

PAIN 161 (2020) 2820–2829
http://dx.doi.org/10.1097/j.pain.0000000000001977

Research Paper

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Neuromodulation: Technology at the Neural Interface

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To Trial or Not to Trial Before Spinal Cord Stimulation for Chronic Neuropathic Pain: The Patients' View From the TRIAL-STIM Randomized Controlled Trial

Raymond Chadwick, ClinPsyD[1]; Rebekah McNaughton, PhD[2]; Sam Eldabe, MD[1]; Ganesan Baranidharan, MD[3]; Jill Bell, BEd[4]; Morag Brookes, MSc[1]; Rui V. Duarte, PhD[5]; Jenny Earle, BA[4]; Ashish Gulve, MD[1]; Rachel Houten, MSc[5]; Susan Jowett, PhD[6]; Anu Kansal, MD[1]; Shelley Rhodes, PhD[7]; Jennifer Robinson, RGN[1]; Sara Griffiths, BSc[1]; Rod S. Taylor, PhD[7,8]; Simon Thomson, MBBS[9]; Harbinder Sandhu, PhD[10]

Neuromodulation 2021;24:459-470

OPEN

Does a Screening Trial for Spinal Cord Stimulation in Patients With Chronic Pain of Neuropathic Origin Have Clinical Utility (TRIAL-STIM)? 36-Month Results From a Randomized Controlled Trial

Neurosurgery 2022

SCS Trials- A valid diagnostic test ?

Observed data			
	Pain relief ≥50%	Pain relief <50%	Totals
Trial screen positive	15	24	39
Trial screen negative	0	2	2
Totals	15	26	41
Sensitivity (%)	**100 (95% CI: 78 to 100)**		
Specificity (%)	**8 (95% CI: 1 to 25)**		

Trials have a limited diagnostic utility

Eldabe S, Duarte RV, Gulve A, Thomson S, Baranidharan G, Houten R, Jowett S, Sandhu H, Chadwick R, Brookes M, Kansal A, Earle J, Bell J, Robinson J, Walker S, Rhodes S, Taylor RS. Does a screening trial for spinal cord stimulation in patients with chronic pain of neuropathic origin have clinical utility and cost-effectiveness (TRIAL-STIM)? A randomised controlled trial. Pain 2020;161(12):2820-2829.

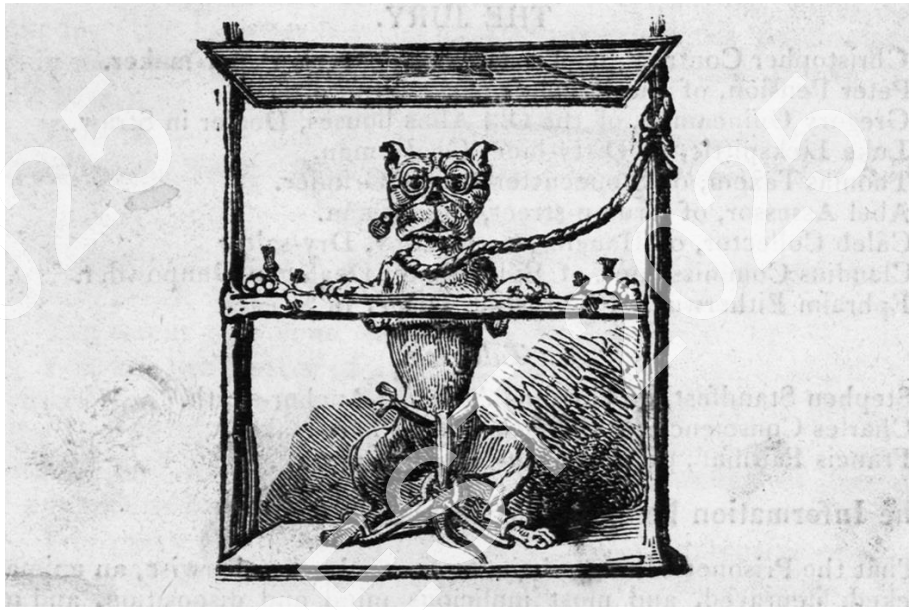
The False Negative dilemma: Long term harms

Successful Long-Term Outcomes of Spinal Cord Stimulation Despite Limited Pain Relief During Temporary Trialing

John C. Oakley, MD* • Elliot S. Krames, MD† • John Stamatos, MD‡ • Allison M. Foster, PhD§

Screening Trials exclude True Responders to Spinal Cord Stimulation

- 12 Patients received Screening Trial
- Mean pain relief 21%
- None reported >50% pain relief
- All Implanted with permanent SCS systems
- Long term pain relief 44-83%



Oakley, J. C., et al. (2008). "Successful long-term outcomes of spinal cord stimulation despite limited pain relief during temporary trialing." Neuromodulation **11**(1): 66-73.

Predictive value of screening trials?

- In many countries, SCS screening trials remain the most important driver of SCS patient selection, with a positive trial often being a prerequisite for the implantation of a permanent SCS device[1]

- The TRIAL-STIM study showed that screening trials have a substantially higher sensitivity (100%) than specificity (8%)[2]
  - All patients who reported ≥50% pain relief at 6-month follow up had a positive trial **but**
  - 92% of patients <50% pain relief at 6-month follow up also had positive trial

False positive rate
(positive screening trial with failure at follow-up after permanent implant)

False negative rate
(negative screening trial with success at follow-up after permanent implant)

- **Predictive models could be considered in future trials to delineate SCS-screening trial utility[1,3,4]**

1. Ounajim A et al. J Clin Med 2021;10:4764; 2. Eldabe S et al. Pain 2020;161:2820-29; 3. Thomson S et al. Neuromodulation 2023;26:164-71; 4. Thomson S et al. Eur J Pain 2022;26:1873-81

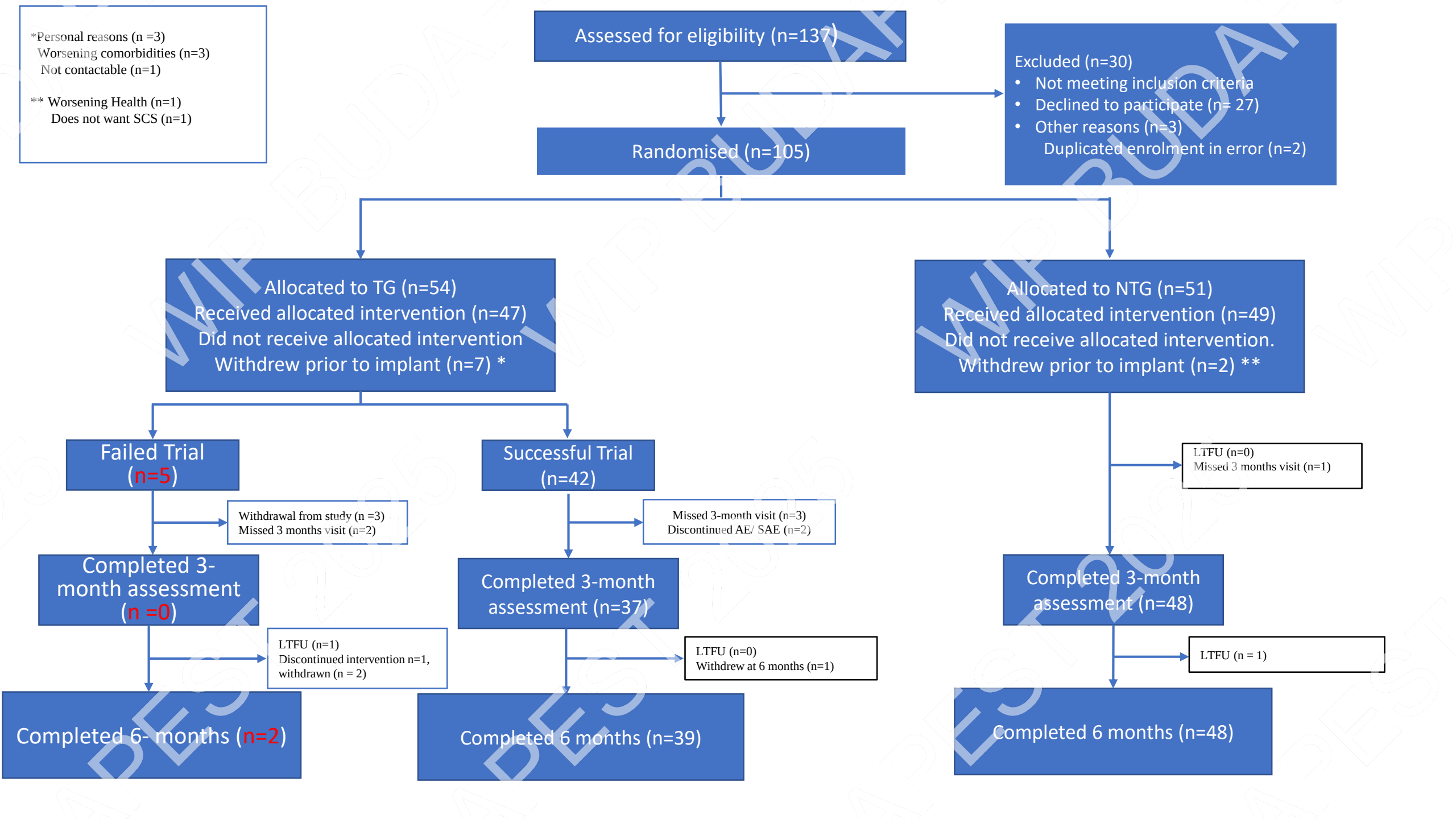
RESEARCH—HUMAN—CLINICAL TRIALS

OPEN

Does a Screening Trial for Spinal Cord Stimulation in Patients With Chronic Pain of Neuropathic Origin Have Clinical Utility (TRIAL-STIM)? 36-Month Results From a Randomized Controlled Trial

Sam Eldabe, MD*
Sarah Nevitt, PhD‡
Sara Griffiths, MSc*
Ashish Gulve, MD*

] Eldabe S, Nevitt S, Griffiths S, Gulve A, Thomson S, Baranidharan G, Houten R, Brookes M, Kansal A, Earle J, Bell J, Taylor RS, Duarte RV. Does a Screening Trial for Spinal Cord Stimulation in Patients With Chronic Pain of Neuropathic Origin Have Clinical Utility (TRIAL-STIM)? 36-Month Results From a Randomized Controlled Trial. Neurosurgery 2022:10.1227/neu.0000000000002165.


*Personal reasons (n =3)
Worsening comorbidities (n=3)
Not contactable (n=1)
** Worsening Health (n=1)
Does not want SCS (n=1)
Assessed for eligibility (n=137)
Excluded (n=30)
Not meeting inclusion criteria
Declined to participate (n= 27)
Other reasons (n=3)
Duplicated enrolment in error (n=2)
Randomised (n=105)
Allocated to TG (n=54)
Received allocated intervention (n=47)
Did not receive allocated intervention
Withdrew prior to implant (n=7) *
Allocated to NTG (n=51)
Received allocated intervention (n=49)
Did not receive allocated intervention.
Withdrew prior to implant (n=2) **
Failed Trial (n=5)
Successful Trial (n=42)
LTFU (n=0)
Missed 3 months visit (n=1)
Withdrawal from study (n =3)
Missed 3 months visit (n=2)
Missed 3-month visit (n=3)
Discontinued AE/ SAE (n=2)
Completed 3-month assessment (n =0)
Completed 3-month assessment (n=37)
Completed 3-month assessment (n=48)
LTFU (n=1)
Discontinued intervention n=1, withdrawn (n = 2)
LTFU (n=0)
Withdrew at 6 months (n=1)
LTFU (n = 1)
Completed 6- months (n=2)
Completed 6 months (n=39)
Completed 6 months (n=48)

Measure	Timepoint	TG (N=30)		NTG (N=36)		Unadjusted Mean Difference (95% CI)[1]	Adjusted Mean Difference (95% CI)[1,2]
		Mean[1]	SD[1]	Mean[1]	SD[1]		
NRS	Baseline	7.03	1.10	7.58	1.23	-0.55 (-1.12 to 0.02)	-
	36-month follow-up	4.63	2.48	5.47	2.37	-0.84 (-2.04 to 0.36)	-0.60 (-1.83 to 0.63)
	Change from baseline at 36 months	**-2.40**	2.40	**-2.11**	2.55	-0.29 (-1.54 to 0.96)	-0.23 (-1.47 to 1.00)
EQ-5D	Baseline	0.39	0.20	0.31	0.23	0.08 (-0.02 to 0.19)	-
	36-month follow-up	0.58	0.20	0.55	0.26	0.03 (-0.08 to 0.15)	0.02 (0.10 to -0.13)
	Change from baseline at 36 months	**0.19**	0.22	**0.24**	0.31	-0.05 (-0.19 to 0.08)	-0.06 (-0.20 to 0.08)
EQ-VAS	Baseline	48.32	20.10	54.08	21.77	-5.76 (-16.11 to 4.59)	-
	36-month follow-up	53.87	20.64	59.29	22.79	-5.41 (-16.16 to 5.33)	-4.14 (-14.90 to 6.61)
	Change from baseline at 36 months	5.55	27.84	5.20	22.94	0.35 (-12.15 to 12.84)	-0.15 (-13.12 to 12.80)

There is no patient benefit from SCS Trials

But trials are cheap as chips

	Trial screen (N=54)	No trial screen (N=51)	Between group unadjusted difference	Between group adjusted difference[a]
	Mean (SD)	Mean (SD)	Mean (95% CI)	Mean (95% CI)
Total costs (£)	19,073.38 (683.84)	17,487.90 (337.31)	1,585.26 (98.24 to 3,198.02)	1,341.22 (-34.26 to 2,832,85)

[a] Adjusted for baseline EQ-5D index score, site, sex, age, failed back surgery syndrome

$$ICER_{B-A} = \frac{Cost_B - Cost_A}{Effectiveness_B - Effectiveness_A} = \frac{\Delta C_{B-A}}{\Delta E_{B-A}}$$

Trials are an Expensive Luxury

SCS screening trial vs no trial

£78,895 per additional QALY gained

- Screening Trials are:
  - Poor predictors of long-term outcome.
  - Sensitivity is artificially high (false negatives)
  - Specificity very low =many false positives
  - Direct comparison with no trial : No patient benefit from trials
  - No increase in explant rate to 36 months
  - Expensive to conduct routinely
  - Multiwave trials

Change from baseline in NRS at 36 months									
Paraesthesia Stim	11	-3.18	2.99	17	-2.56	2.73	28	**-2.80**	2.80
HF Stim	9	-1.89	2.15	14	-1.50	2.37	23	**-1.87**	2.18
Burst Stim	9	-2.44	1.81	5	-2.30	2.59	14	**-2.04**	2.22

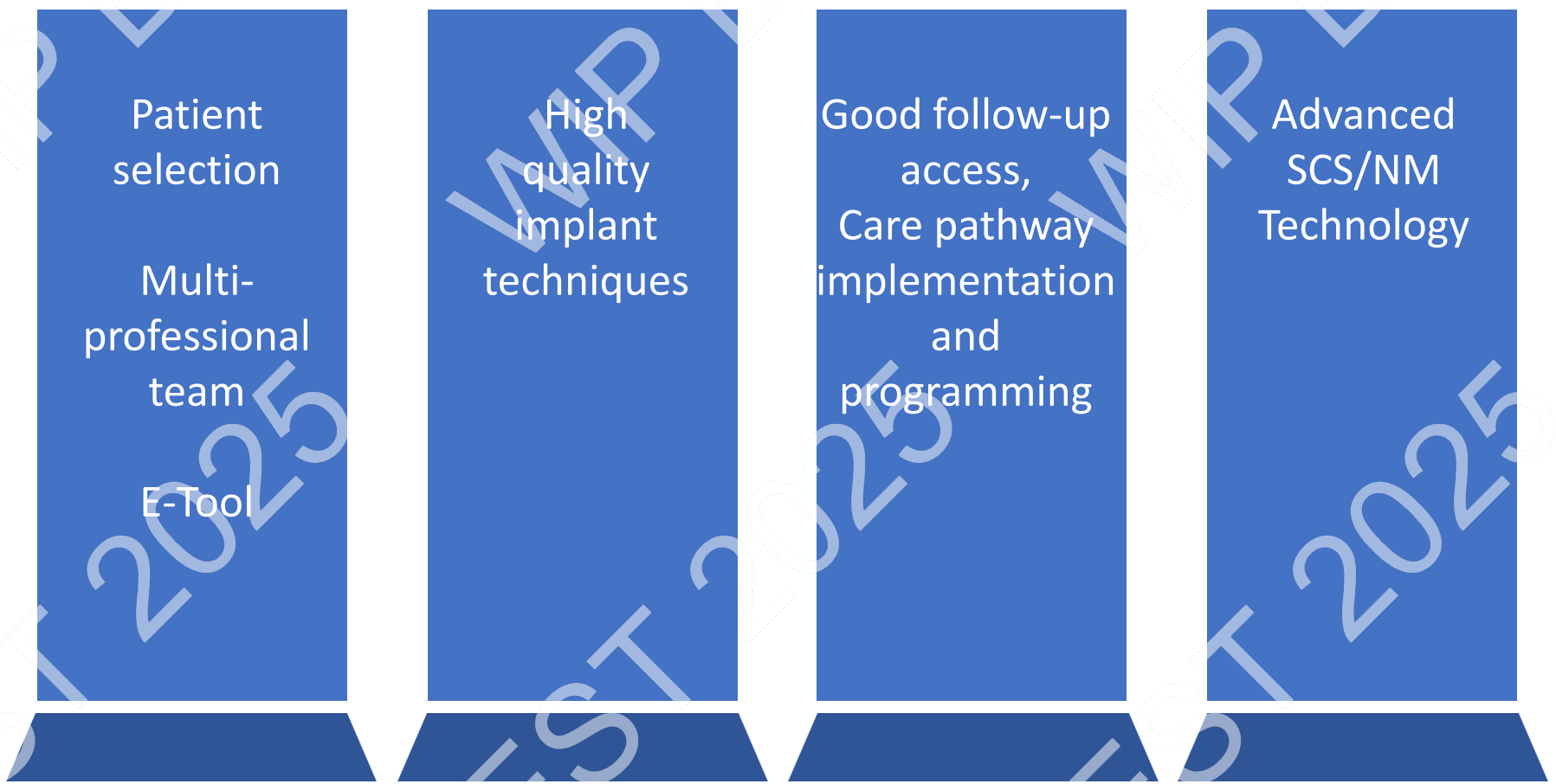
- Weight of the existing evidence (within its limitations) supports the need for trials.

- Trials remain justified in a number of scenarios (rare indications, patient request, physician doubts….)

TRIAL-STIM
Conclusions

- SCS trial screen may have some diagnostic utility
- However, and more importantly, we found no evidence that SCS trials provide better patient outcomes compared to a “no SCS trial” (implantation only)
- Screening trials are not cost-effective from an NHS perspective.
- Participants (whichever group, before and after) overwhelmingly preferred a “no SCS trial” screen (implantation only) strategy.
- Study portrays the UK clinical practice impact of SCS as an intervention

Pillars for successful SCS outcomes



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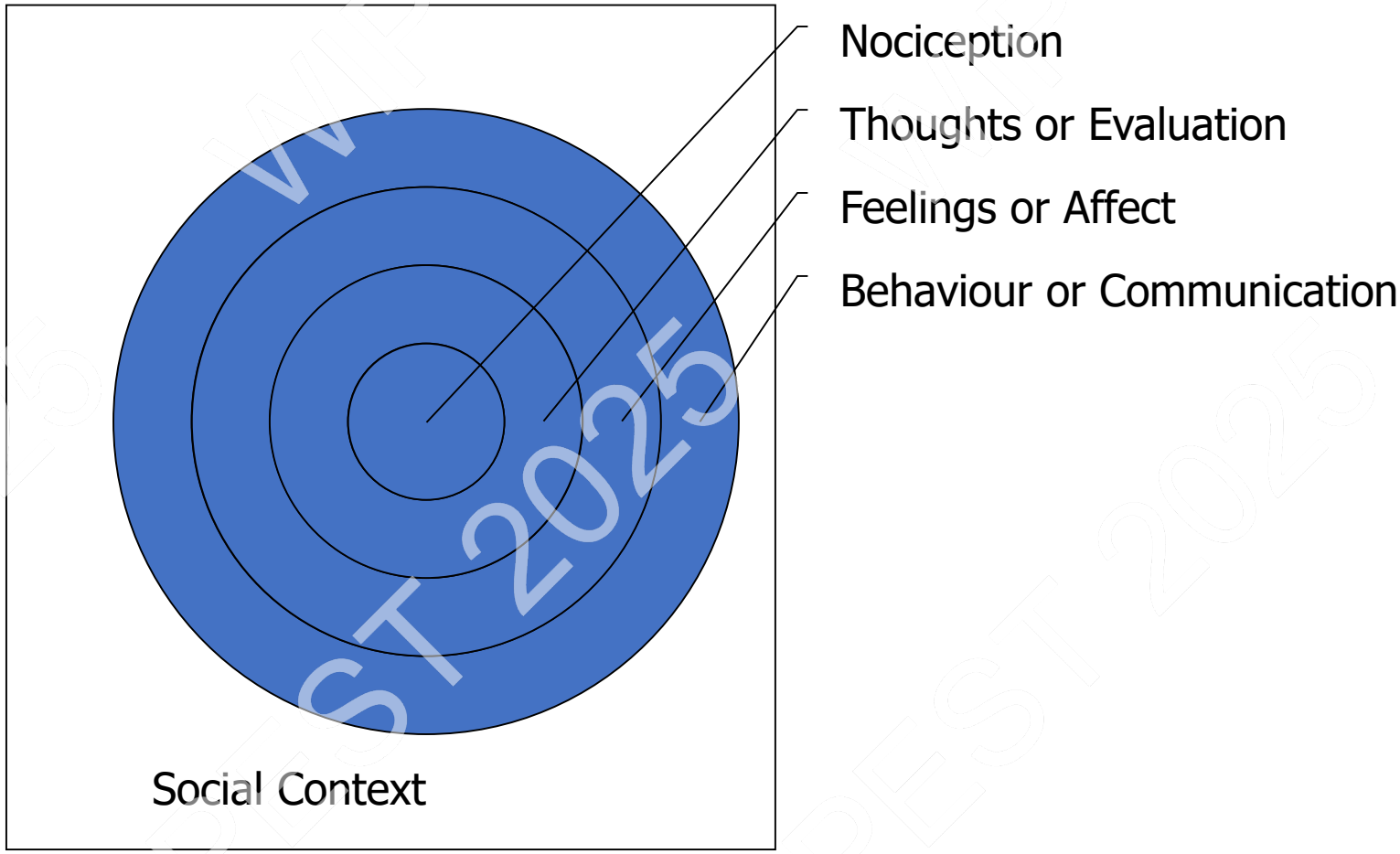
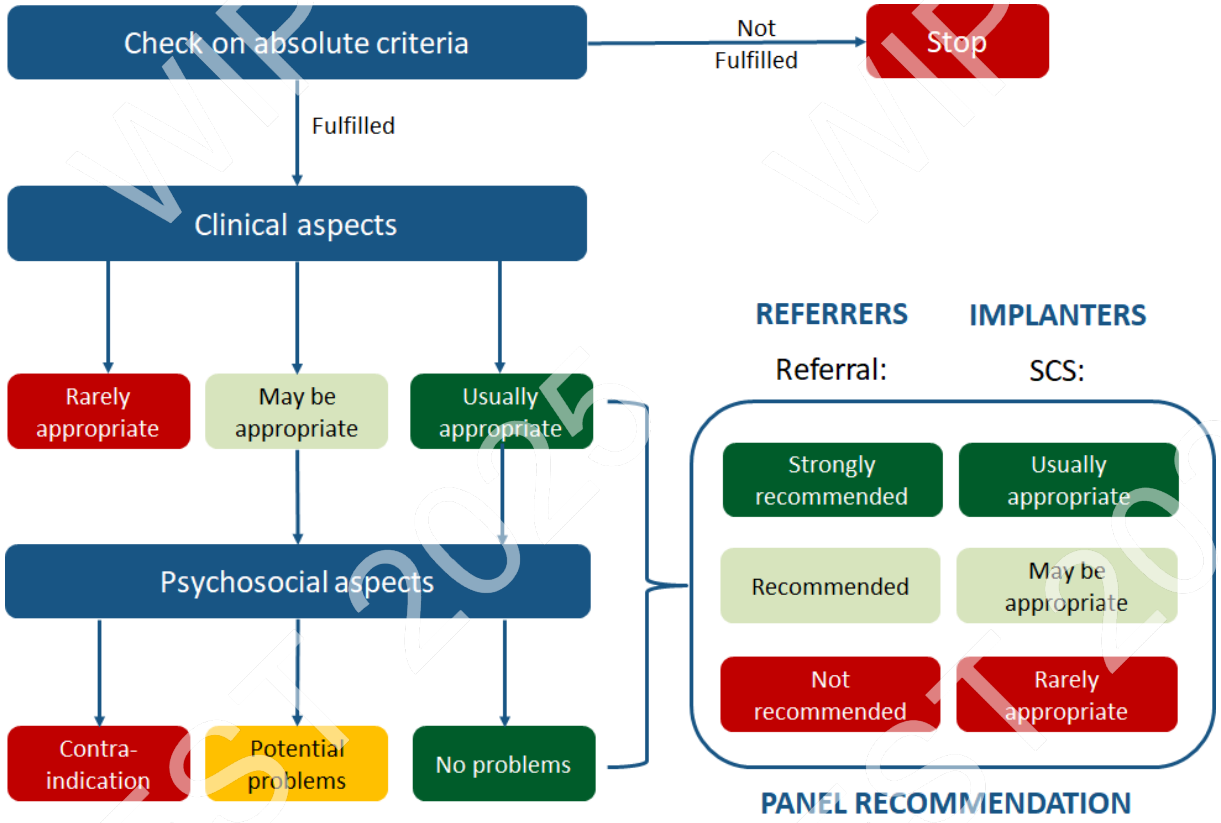
The Biopsychosocial model of Pain



Educational e-health tool (https://scstool.org)



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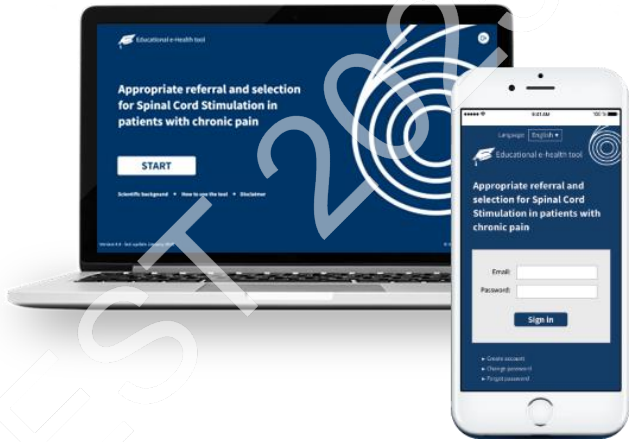
DOI: 10.1002/ejp.1562

ORIGINAL ARTICLE

EJP

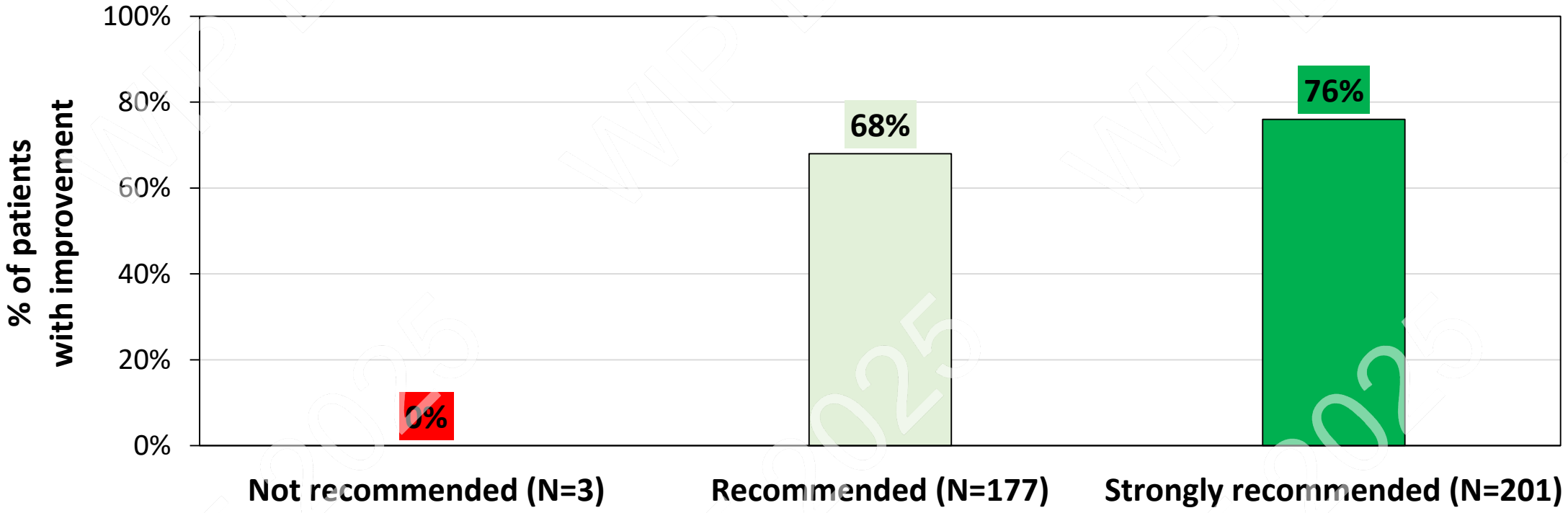
Appropriate referral and selection of patients with chronic pain for spinal cord stimulation: European consensus recommendations and e-health tool

Simon Thomson[1] | Frank Huygen[2] | Simon Prangnell[3] | José De Andrés[4] | Ganesan Baranidharan[5] | Hayat Belaïd[6] | Neil Berry[7] | Bart Billet[8] | Jan Cooil[9] | Giuliano De Carolis[10] | Laura Demartini[11] | Sam Eldabe[12] | Kliment Gatzinsky[13] | Jan W. Kallewaard[14] | Kaare Meier[15] | Mery Paroli[10] | Angela Stark[16] | Matthias Winkelmüller[17] | Herman Stoevelaar[18]



Thomson S et al. Eur J Pain 2020;24:1169-81

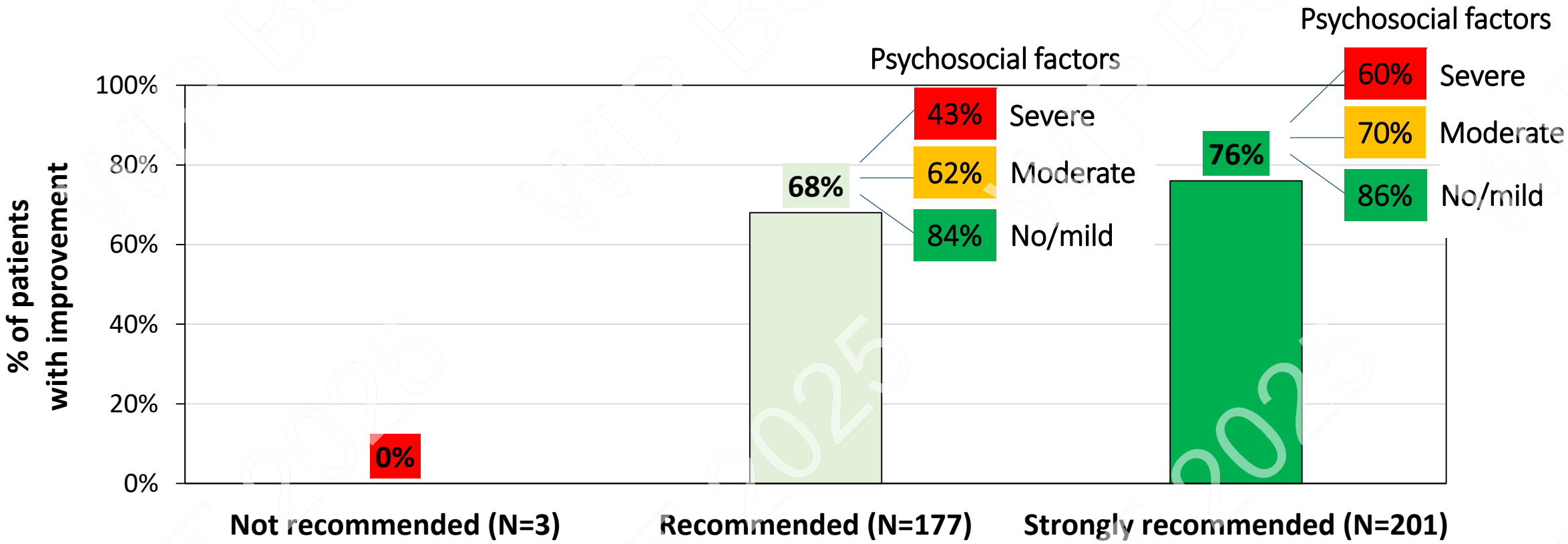
SCS e-health tool: predictive value of clinical factors for 6-month patient outcomes



Psychosocial factors not considered

Thomson S et al. Eur J Pain 2022;26:1873-81

SCS e-health tool: predictive value of an integrated approach for 6-month patient outcomes



A gradual decrease in the % of patients with pain improvement with the severity of psychosocial problems

Thomson S et al. Eur J Pain 2022;26:1873-81

National Neuromodulation Registry

- UK-wide registry for all spinal neuromodulation implants
- Started in 2018
- 29 contributing centres with more coming “online”
- Independently contracted to NEC Software Solutions
- Governed by the Neuromodulation Society of UK and Ireland
- Conscious decision to collect simple data, and is being expanded currently

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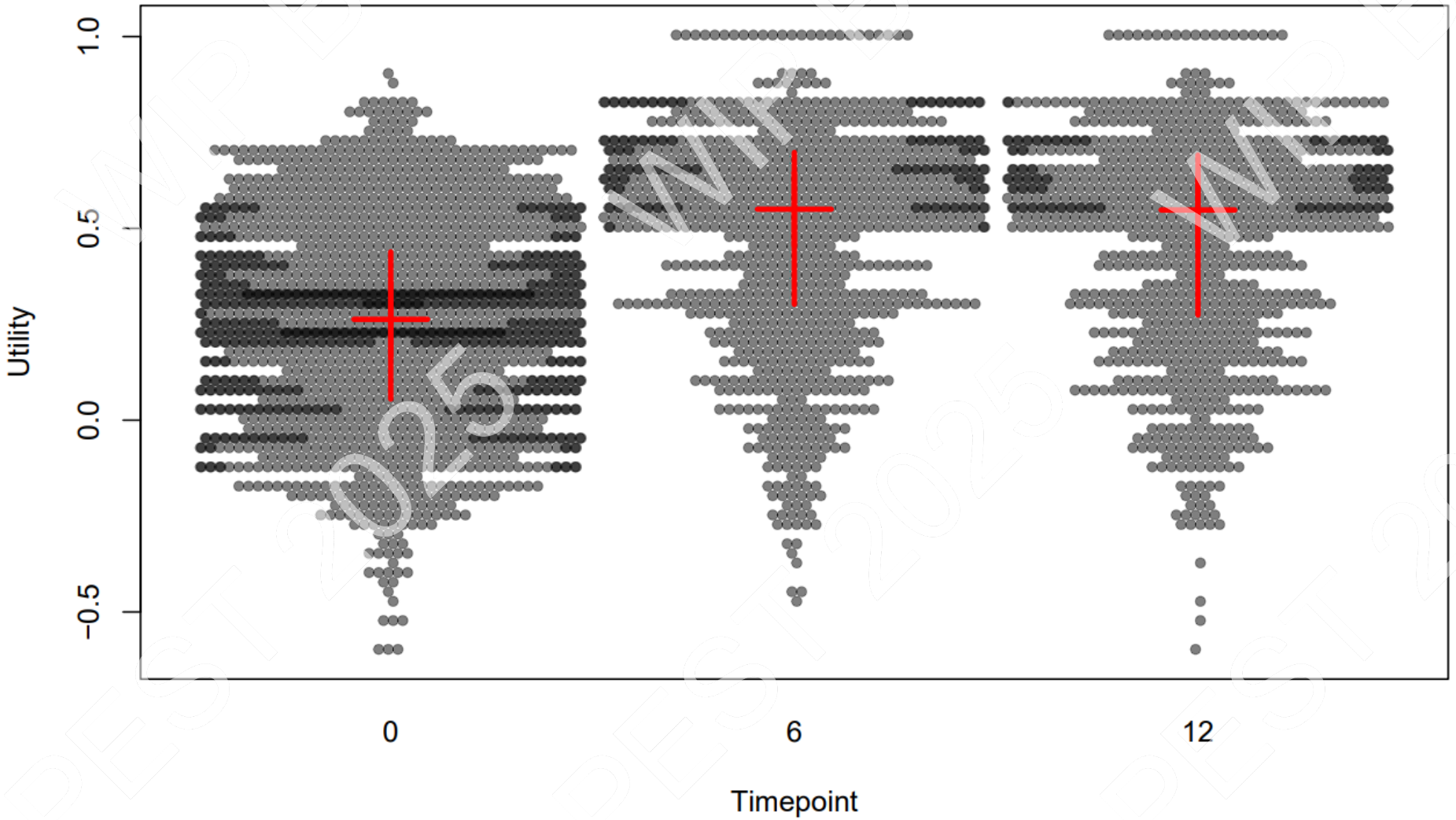
Spinal Cord Stimulation Improves Quality of Life for Patients With Chronic Pain
Data From the UK and Ireland National Neuromodulation Registry



Martin S et al. Neuromodulation 2024 1-13

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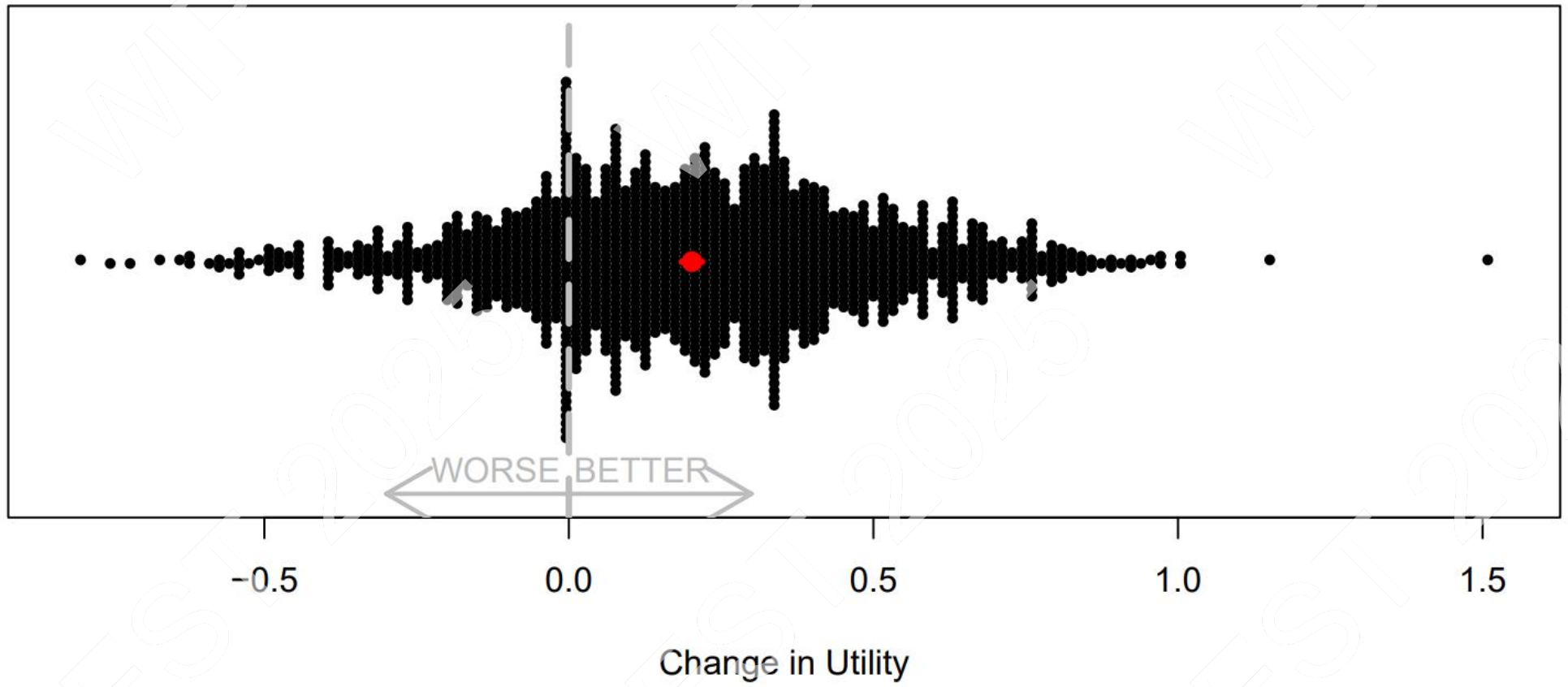
Overall results of SCS

- 1236 with paired preop and postop utility
- using 12 month if available or 6 month if not



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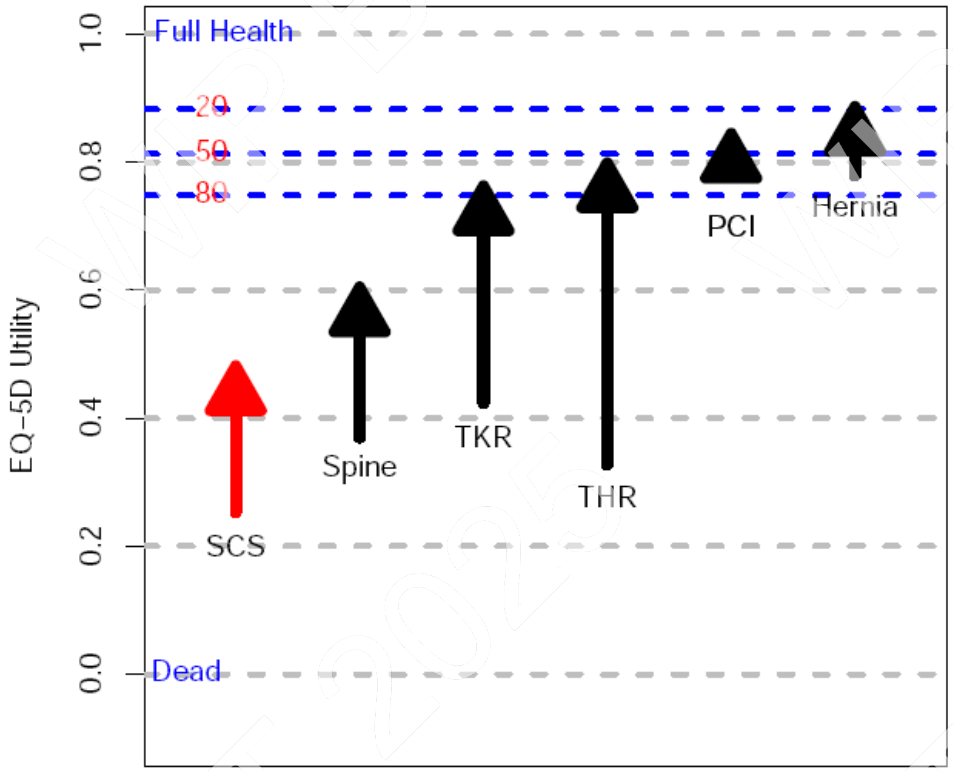
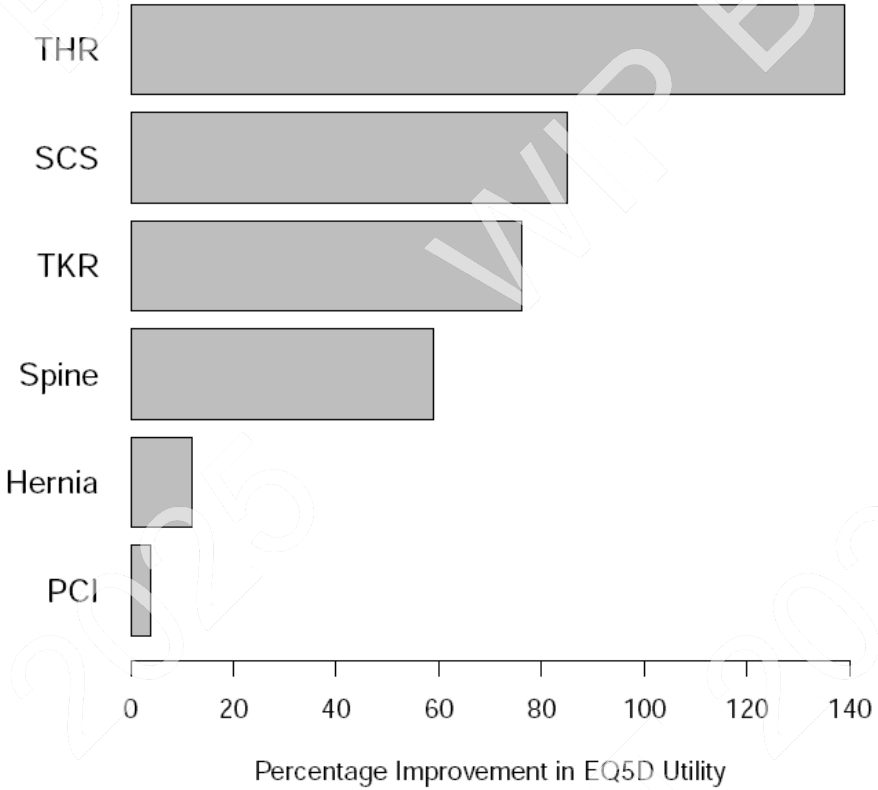
Comparison with other interventions





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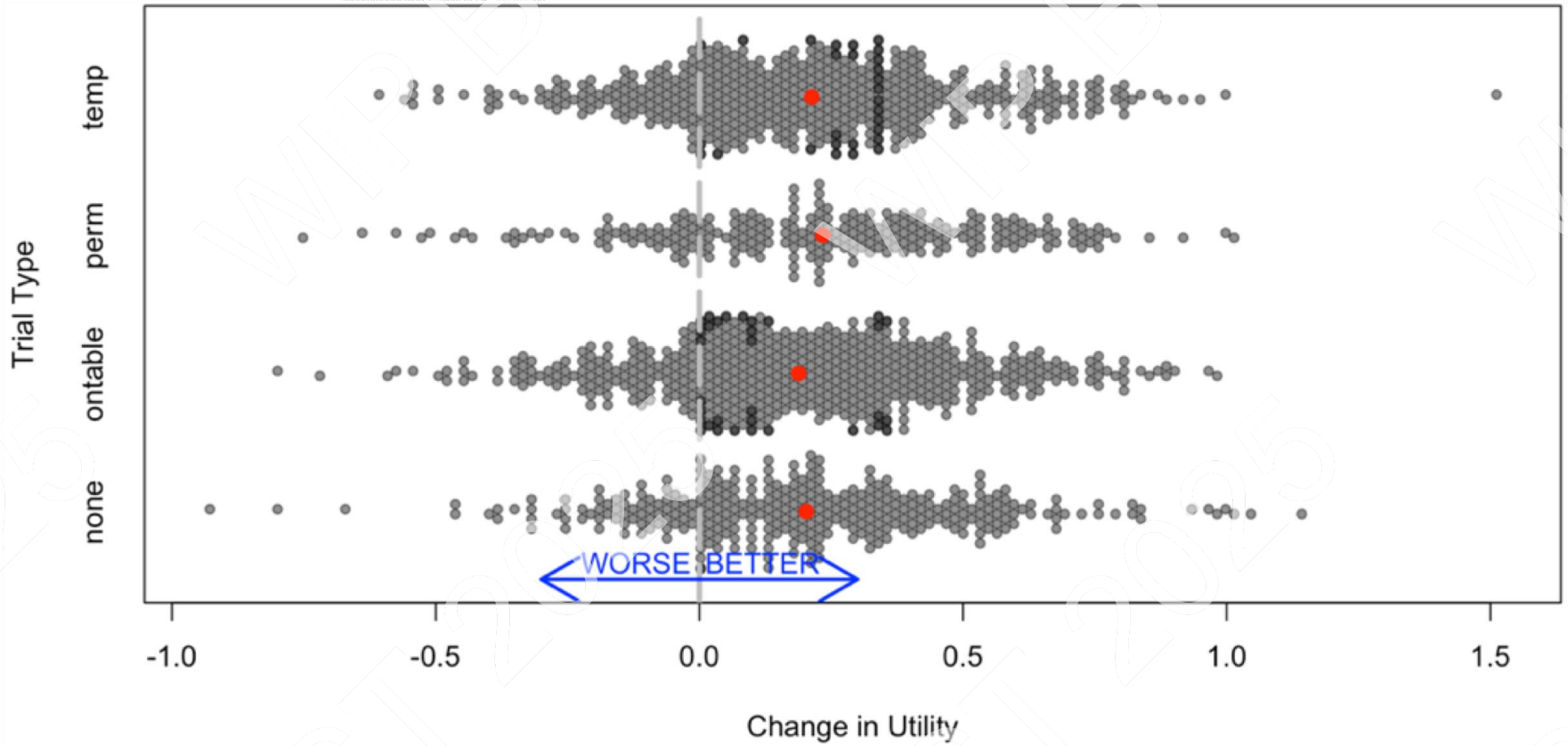
The UK and Ireland National Neuromodulation Registry

Trial or No Trial for Spinal Cord Stimulation in the Real World

Seán C. Martin[1,2,3], Ganesan Baranidharan[1,4], Sam Eldabe[1,5], Roger Strachan[1,6], Ashish Gulve[1,5], Vivek Mehta[1,8], Sarah Love-Jones[1,8], Stana Bojanić[1,3], James J FitzGerald[1,2,3] , Simon Thomson[1,9]



Extracted from NNR

SCS Patients registered from February 2018 to July 2023

Exclude those without baseline, trial typ or paired follow-up (12/12) – n= 1565

EQ5D-5L Utility index mean change

No Trial 0.203 (n= 323)

Trial 0.207 (n=1242)

P=0.85 Welch's two-sample t-test

Results

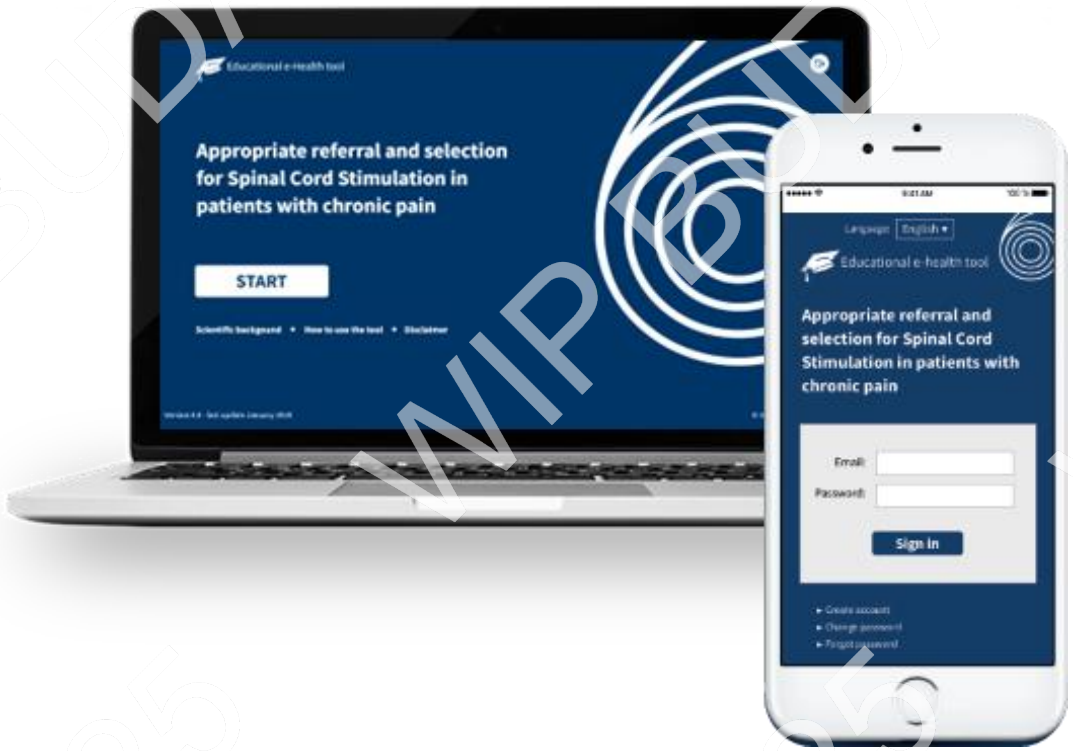
Of the 1565 included patients, 323 (20.6%) had no trial and 1242 (79.4%) had a trial before full implant. Of those that had a trial, 231 (18.6%) had a permanent trial, 485 (39.0%) had a temporary trial, 526 (42.4%) had an on-table trial.

For patients that did not have a trial, the utility index improvement of 0.194 (n=849) vs. 0.219 (n=716); p=0.08, Welch's two sample t-test.

Conclusion

With current patient selection practices in the UK, a trial of any type prior to permanent implant does not offer additional value in terms of health-related quality of life improvement after spinal cord stimulation for chronic pain.

The E-Tool for SCS



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