



A Systematic Review to Assess Clinical Utility of Composite Outcomes in Studies Assessing Outcomes of Implantable Neuromodulation Therapies for Pain

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Introduction

Treatment outcomes with implantable neuromodulation therapies for treatment of refractory pain are most typically evaluated by unidimensional outcome like numerical rating or visual analogue pain scores.

Composite outcome measures use at least two pain metrics that can describe the multidimensional aspect of pain.

This review synthesized existing literature on the clinical utility of composite outcomes in evaluating efficacy of neuromodulation for refractory pain.

Methods

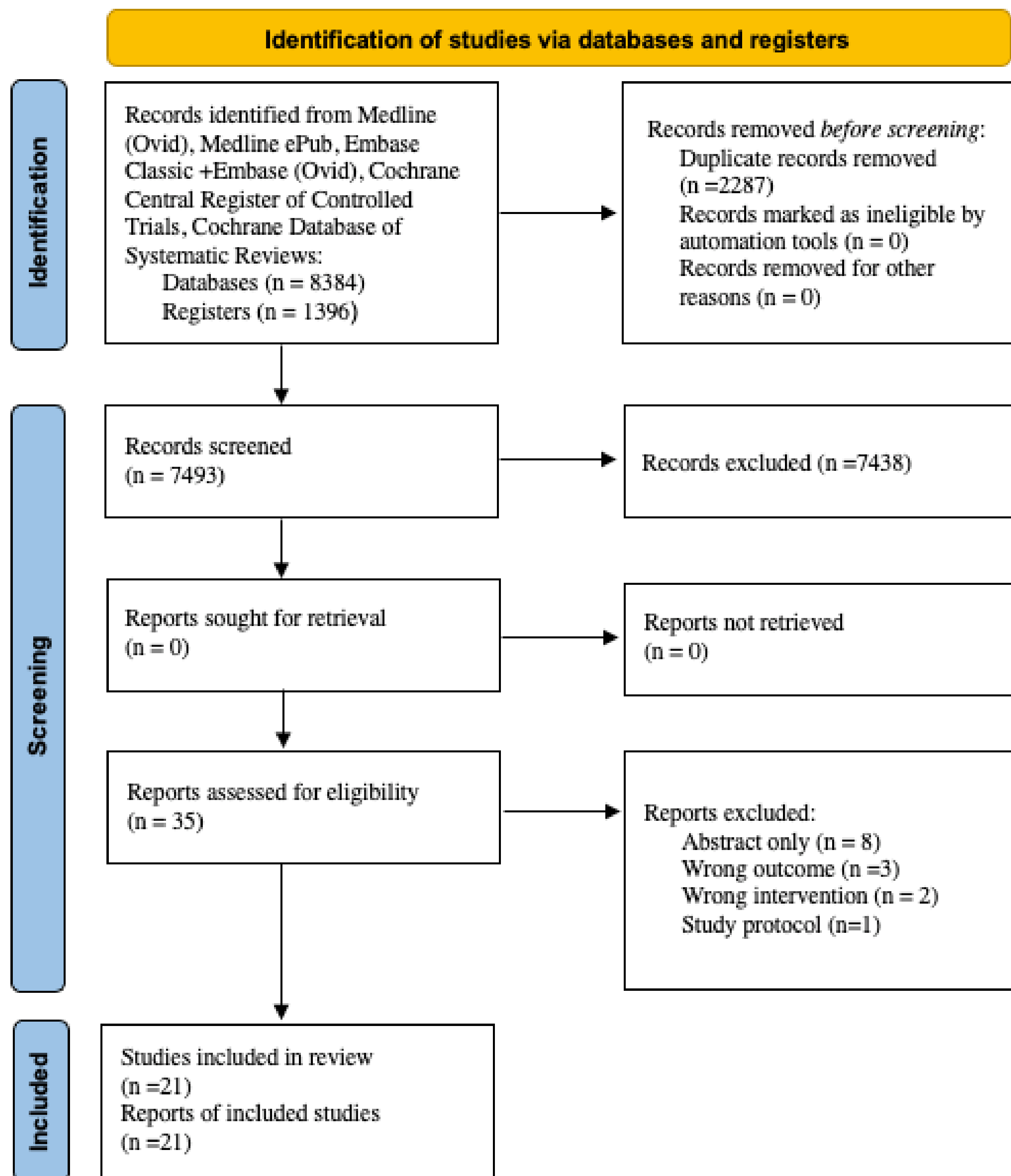


Figure 2: Composite Outcome Models/ Algorithms

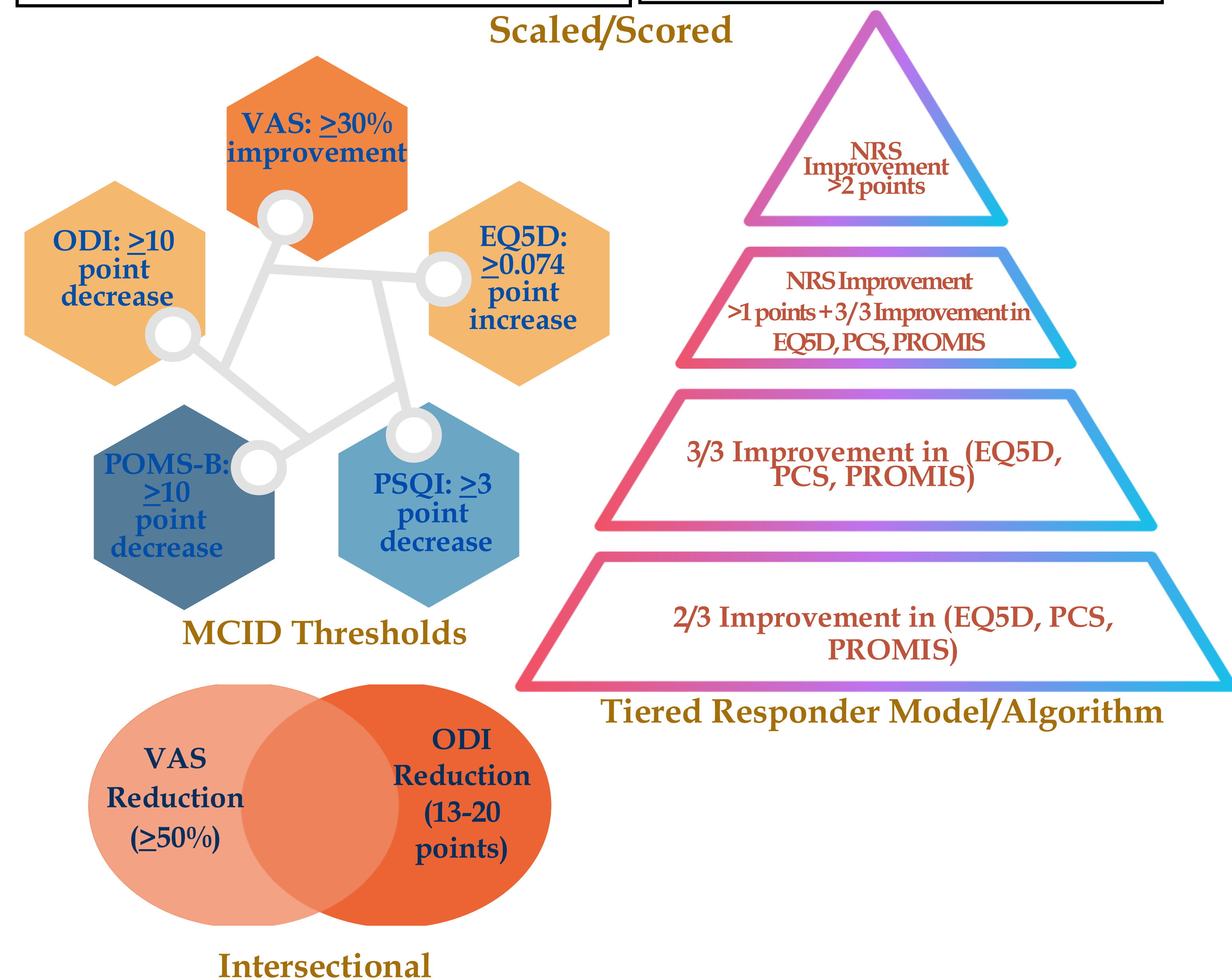
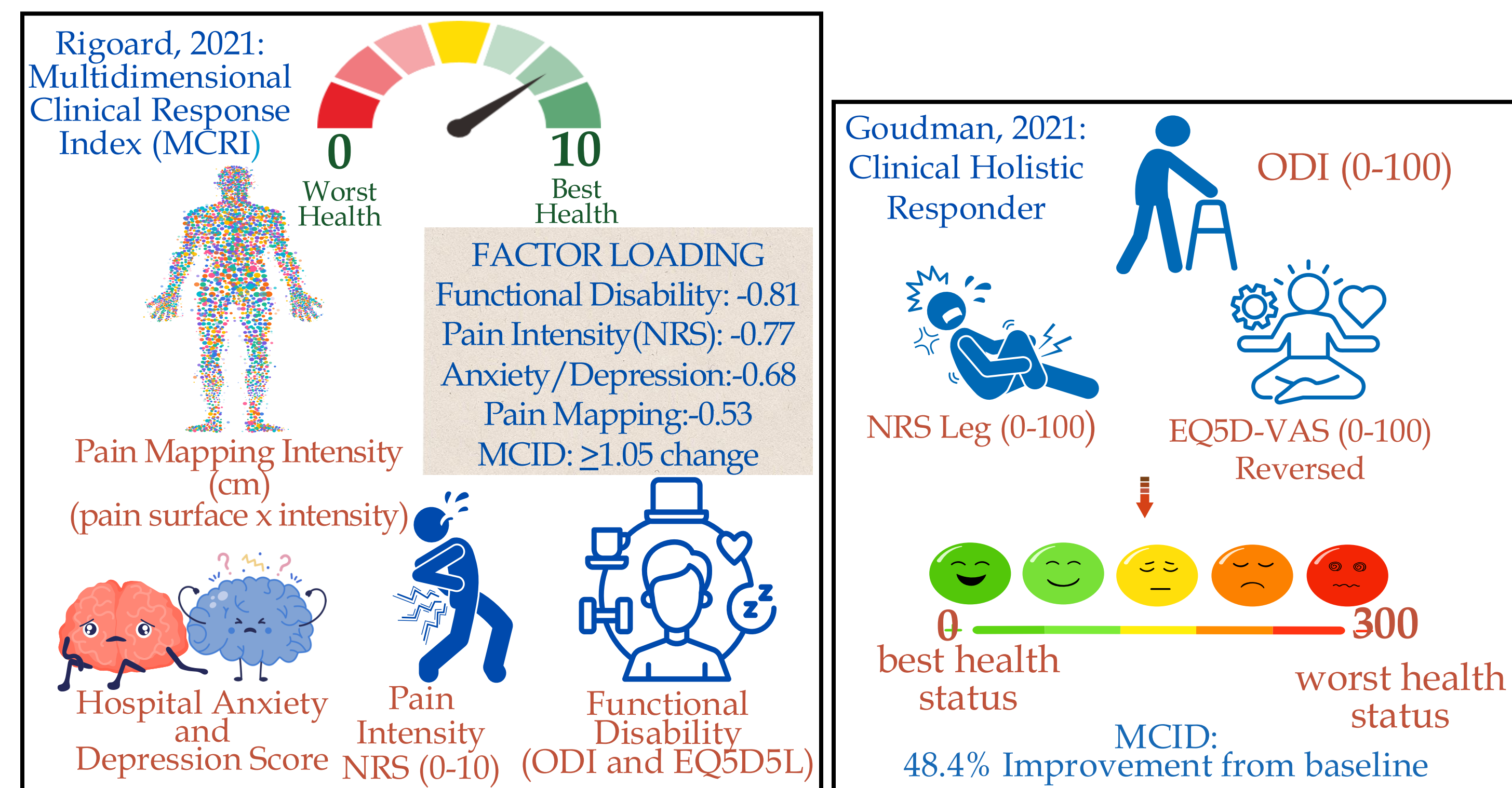


Table 1: Summary of outcome measures evaluated in the studies reviewed

First Author/ Year of Publication	Pain Intensity	Functional capacity	Cognitive/ Affective	HRQOL/ Adverse Event
Rigoard, 2023	VAS, Pain Surface Intensity	ODI	HADS	EQ-5D-5L
Rigoard, 2024	VAS, Pain Surface Intensity	ODI	HADS	EQ-5D-5L
Rigoard, 2025	VAS, Pain Surface Intensity	ODI	HADS	EQ-5D-5L
Ounajim, 2025	VAS, Pain Surface Intensity	ODI	HADS	EQ-5D-5L
Bouche, 2025	VAS, Pain Surface Intensity	ODI	HADS	EQ-5D-5L
Goudman 2023	NRS	ODI		EQ-5DVAS
Pilitsis, 2021	NRS		PCS	EQ-5D-5L PROMIS-PF EQ-5D-5L
Kallewaard 2024	VAS	ODI		
Quintero, 2024	NRS, MPQ	ODI	PCS, BDI	
Kapural 2024#	VAS	ODI	POMS-B	EQ-5D-5L
Mekhail 2024#	VAS	ODI	POMS-B	EQ-5D-5L
Levy, 2024#	VAS	ODI	POMS	EQ-5D-5L
Goudman 2021*	NRS	ODI		
Tabatabaei 2024##	NRS	Physical Activity (PROMIS)	GAD-7, PHQ 9; PCS	PROMIS
Hollingworth, 2011 **	NRS	RMDQ		
Deer, 2017	VAS			Neurologic Deficit
Gilligan 2021	VAS	ODI		
Deer, 2023	NRS	ODI		
Whittle, 2024	NRS	ODI		
Al-Kaisy 2019^	NRS			
Russo 2020	NRS	Walking tolerance time		

*Medication Quantification Scale; **Opioid use; #Pittsburg Sleep Quality Index; ##Insomnia Sleep index; ^Patient Global Impression of Change (included in outcome measures used in the studies)

BDI: Beck Depression Inventory; EQ5D5L: 5 domain measure of health related quality of life(mobility, self care, usual activity, pain/discomfort, anxiety/depression) GAD: Generalized Anxiety Disorder 7; HADS: Hospital Anxiety Scale; ISI: Insomnia Severity Index; MPQ: McGill Pain Questionnaire; MQS: Medication Quantification Scale; NRS: Numeric Rating Scale; ODI: Oswestry Disability Index; PCS: Pain Catastrophizing Scale; PGIC: Patient Global Impression of Change; PHQ9: Patient Health Questionnaire 9; POMS-B: Profile of Mood States-Brief; PROMIS: Patient Reported Outcome Measurement Information System; PSQI: Pittsburg Sleep Quality Index; RDQ: Roland Morris Disability Questionnaire

Results

21 studies with 1666 patients
Diagnoses: PSPS, CRPS, Mechanical back pain

Interventions: Spinal cord (n=1355 patients)
Dorsal root ganglion (n=149 patients)
Peripheral nerve (n=6 patients)
Paraspinal muscle (n= 156 patients) stimulation.

Key Findings:

- Multiple outcome measures used in defining composite outcomes
- Heterogeneity of composite outcome models or algorithms currently utilized (Fig 2)
- Composite outcomes provide more comprehensive picture of treatment but use of pain intensity metrics still an integral part of composite measure
- Composite outcomes highlight multidimensional outcome measures, function, and patient satisfaction in defining treatment outcomes in implanted neuromodulation therapies
- More studies needed to validate composite outcome measures

References

- Goudman L, et al. Neuromodulation. 2023;26(1):139-146. doi:10.1016/j.neurom.2021.10.020
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- Pilitsis JG, et al. Neuromodulation. 2021;24(1):68-75. doi:10.1111/ner.13212