Psychological factors as predictors of outcomes in Spinal Cord Stimulation

Evidence-based review

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Important note

- *The purpose of this report is to outline and interpret the best current evidence about the role of psychological factors in the outcomes of spinal cord stimulation procedures.*
- *It is not intended to replace clinical judgement or be used as a clinical protocol.*
- *A reasonable attempt has been made to find and review papers relevant to the focus of this report; however, it does not claim to be exhaustive.*
- *This document has been prepared by the staff of the Evidence Based Healthcare Team, ACC Research. The content does not necessarily represent the official view of ACC or represent ACC policy.*
- *This report is based upon information supplied up to March 2016.*

Abbreviations

ACC	Accident Compensation Corporation
BDI	Beck Depression Inventory
CRPS	Complex Regional Pain Syndrome
CSD	Clinical Services Directorate
FBSS	Failed Back Surgery Syndrome
HADS	Hospital Anxiety and Depression Scale
IPG	Implant Pulse Generator
Kessler-10	Kessler Psychological Distress Scale
MMPI	Minnesota Multiphasic Personality Inventory
MMPI-2-RF	Minnesota Multiphasic Personality Inventory 2 Revised Form
NRS	Numerical Rating Scale
ODI	Oswestry Disability Index
OR	Odds Ratio
PCS	Pain Catastrophizing Scale
PCSQ	Pain Coping Strategies Questionnaire
PSEQ	Pain Self-Efficacy Questionnaire
r	correlation coefficient
RR	Relative Risk
SCS	Spinal Cord Stimulation
SF-36	Short Form Health Survey
VAS	Visual Analogue Scale

1 Executive Summary

1.1 Background

The main purpose of this evidence-based review is to provide the Clinical Services Directorate clinical advisory team with an overview of the most recent evidence on the role of psychological factors in assessing patient suitability for treatment with spinal cord stimulation (SCS). Spinal cord stimulation (SCS) is an interventional pain management procedure used to manage persistent, chronic pain that has not responded to conventional pain management methods[1,2]. It involves the implantation of an electrode array and pulse generator, which delivers low-voltage electrical stimulation to the spinal cord to modulate pain pathways. The patient controls the level of stimulation through an external controller. SCS has been evaluated as an effective and cost-effective pain intervention[2], however some patients experience a decline in pain reduction in the intermediate to long-term (two to five years). Psychological status is considered an important factor in the success of SCS. It is recommended in almost all guidelines that patients undergo a psychological examination prior to selection for SCS but little information is provided regarding the structure of the evaluation, what characteristics are important and which measures should be used[15]. Currently, patients with major psychological conditions, for example, psychosis, mania or untreated major depression, are excluded from treatment with SCS but little is known about the importance of other psychological factors. Given the high cost and variable effectiveness of SCS, ACC is interested in ways to identify the best candidates for this procedure. The purpose of the current review is to summarise the most recent evidence regarding the role of patient psychological factors in predicting outcomes from SCS.

1.2 Methodology

A search was conducted of Ovid Medline, Embase, PsychInfo and Google Scholar from January 2000 to February 2016. Systematic reviews, meta-analyses, cohort, case-control and cross-sectional studies which compared SCS outcomes in people with and without various psychological variables (e.g. depression, catastrophising) were included. The search identified 50 papers from which two systematic reviews and seven cohort studies met inclusion criteria. Included studies were appraised for quality and the findings summarized.

1.3 Main results

While the evidence base for the role of psychological factors in outcomes from SCS has expanded significantly since 2000, there is still a lack of high quality studies with long-term follow-up. Two systematic reviews, four prospective and three retrospective cohort studies were included in the current report. Studies were graded low to moderate quality based on their study design and the likelihood of bias. All of the studies were set within clinical practices, so patients with major psychological disorders were excluded as part of initial screening prior to SCS. Only one low quality study followed patients up for longer than 12-months after SCS implantation, although two large studies[8,9] are ongoing.

In patients who received a SCS implant, there was consistent evidence of an association between pre-implant depression scores, low self-efficacy and high catastrophising, and poorer outcomes following SCS. The presence of symptoms of depression was associated with poorer function and disability outcomes, but no significant difference in pain scores, at 12-months post-implant. Low self-efficacy and high catastrophising were often measured together and were associated with poorer pain and satisfaction outcomes in the short to intermediate term. In the included studies, anxiety was not significantly associated with poorer outcomes and the evidence was conflicting for high somatization or bodily concern.

Commonly used measures were single factor measures e.g. Hospital Anxiety and Depression Scale, Beck Depression Inventory, Pain Self-efficacy Questionnaire, and multifactorial measures such as the Minnesota Multiphasic Personality Inventory. These two types of measures serve different functions and both were useful in assessing psychological status prior to SCS.

1.4 Conclusions

This review confirms that psychological factors should be an essential component of assessment prior to SCS. The current review identified consistent evidence of an association between pre-implant psychological factors such as depression and poor coping strategies, and poorer pain and disability outcomes following SCS. This evidence

suggests that, in addition to screening for major psychological disorders, the selection of suitable candidates for SCS should also include an assessment of psychological factors such as depression and coping strategies. Psychological factors such as these may potentially be good targets for improving outcomes by providing a comprehensive pain management follow-up, but this requires further research.

Some studies measured multiple factors and these studies indicated that the combination of several factors increased the risk of poorer outcomes following SCS. This suggests that it is probably important to measure a broad range of characteristics and to consider the cumulative effect of poor coping styles and strategies as well as clinical conditions. To make a fully informed decision about the suitability of a candidate for SCS, ACC clinical advisors need to be informed of the person's psychological symptoms and coping strategies and how these will be managed as part of their comprehensive pain management strategy.

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2 Background

2.1 Objective of this report

The main purpose of this evidence-based review is to provide the Clinical Services Directorate clinical advisory team with an overview of the most recent evidence on the role of psychological factors in assessing patient suitability for treatment with spinal cord stimulation (SCS). ACC developed clinical guidelines for treatment with SCS (Neuromodulation Treatment with Spinal Cord Stimulators[1]) in conjunction with an expert working group in 2012. The guidelines cover the process for requesting SCS and endorse a rigorous approach to patient selection, including the importance of the psychological assessment and psychological exclusion criteria. Currently, exclusion is based on having a major psychological, cognitive, or substance abuse disorder. Evidence regarding other psychological factors, such as moderate symptoms of depression, anxiety and coping strategies, was not clear at the time the guidelines were developed. Since this time, several studies have been published which may provide more specific information. The clinical advisory team requested a review of recent evidence to ensure that the patient selection criteria applied by both ACC and providers of SCS services reflects the most up-to-date evidence. The current report provides further guidance about the importance of psychological factors in SCS and how best to measure them. The information will be used to help ACC staff and SCS providers identify the best candidates for SCS, and to reinforce the importance of a multidisciplinary approach to pain management, including assessing psychological factors as part of the person's comprehensive pain management strategy.

2.2 Description of Neuromodulation Treatment Using Spinal Cord Stimulation

Spinal cord stimulation is an interventional pain management procedure used to manage persistent, chronic pain that has not responded to conventional pain management methods[1,2]. It involves the delivery of low-voltage electrical stimulation to the spinal cord to modulate pain pathways. The composition and function of a SCS system is described in the ACC Guidelines for Neuromodulation Treatment with Spinal Cord Stimulators (2012)[1], so only a brief description follows in the current report. Essentially, an SCS system is comprised of three parts: an implant pulse generator (IPG), an extradural electrode array, which is implanted in the patient's spinal cord, and a patient-controlled programmer. The IPG and the electrode array are both surgically implanted in the patient's body and connected via a lead (implanted under the skin). The programmer is a remote control, used by the patient to control the level of stimulation generated by the IPG with different settings for different activities and levels of pain[1].

2.3 Effectiveness of Spinal Cord Stimulation and the role of patient selection

A number of previous systematic reviews[3,4], including an ACC evidence review (ACC 2009)[2], concluded that SCS is effective in ***carefully selected patients*** for the management of neuropathic pain originating from Failed Back Surgery Syndrome (FBSS) and Complex Regional Pain Syndrome (CRPS-1), compared with reoperation or continuing conventional pain management. However, there is considerable individual variation in long-term outcomes from SCS. Approximately 50% of the patients who receive a SCS implant experience a 50% or greater reduction in pre-implant pain scores[2]. A proportion of those patients will experience a decline in the effectiveness of the implant, with some studies suggesting effectiveness declines over the intermediate to long term (two years +)[2,5,7]. It has been proposed that patient psychological factors may play a role in the long-term effectiveness of SCS[6,7,15]. Almost all guidelines for SCS, including the ACC guidelines (2012)[1], agree that a psychological evaluation is an essential part of consideration for SCS, but there is little information regarding the structure of the evaluation, what characteristics are important and which measures should be used[15]. A small set of studies have investigated the effectiveness of cognitive interventions alongside SCS to improve outcomes. Molloy et al (2006)[21] reported that cognitive pain management training provided sequentially with SCS was more effective than either treatment alone. Roditi and Robinson (2011)[22] suggested that psychologists might be able to help patients become active participants in their pain management and feel more in command of their pain control through psychological interventions.

The purpose of the current review is to assess the most recent evidence regarding the role of patient psychological characteristics as predictors of outcomes from SCS.

2.3.1 *Indications for Spinal Cord Stimulation*

Currently ACC funds SCS for chronic neuropathic pain related to Failed Back Surgery Syndrome (FBSS) and Complex Regional Pain Syndrome (CRPS-1) as a result of an ACC-covered injury. Purchasing recommendations for spinal cord stimulation were developed by ACCs Purchasing Guidance Advisory Group in 2009, and weigh up the effectiveness and cost-effectiveness of spinal cord stimulation. The recommendations can be found here http://www.acc.co.nz/for-providers/clinical-best-practice/interventional-pain-management/interventions/body-map/DIS_CTRB094010.

2.4 Rationale for the current review

Given the high cost and variable effectiveness of SCS, ACC is very interested in ways to identify the best candidates for this procedure. The current ACC guidelines for SCS[1] include detailed guidance about patient selection criteria and the importance of psychological suitability prior to spinal cord stimulation (see Appendix A for a summary), but evidence regarding the role of specific psychological factors was not available at the time the guidelines were developed. Since then, several studies have been published which may provide more information. The current report focuses on recent studies that investigate the effect of specific psychological factors and coping strategies on outcomes from spinal cord stimulation, in order to provide further guidance about the importance of psychological factors and how to measure them. The information will be used to help ACC staff and providers identify the best candidates for spinal cord stimulation and what psychological approaches to pain management should be offered in conjunction with SCS approaches.

To this end, this report utilizes EBH tools and methodologies to:

- Identify best available evidence using standard EBH research methods (described in methods section below) and appraise articles found in peer-reviewed medical journals, guided by the Scottish Intercollegiate Guideline Network (SIGN) criteria (section 3.3 below),
- clearly outline the quality and consistency of evidence for and against the most commonly considered psychological risk factors, and
- clearly outline the caveats within the included evidence that need to be taken into consideration by the clinical advisory team when using this report as a guide for decisions about the role of psychological factors in outcomes from spinal cord stimulation.

3 Methods

3.1 Search Strategy

An initial search was conducted by two EBH researchers within ACC Research using the following databases from 2000 to 20 February 2016:

- Ovid MEDLINE In-Process & Other Non-Indexed Citations
- Ovid MEDLINE <1946 to Present>
- Embase
- PsychINFO

Google scholar was also searched using keywords: patient selection criteria, spinal cord stimulation, psych$, neuromodulation, and the references of key publications were handsearched for additional relevant papers.

Full search strategies are presented in Appendix B.

3.1.1 Final inclusion criteria for primary studies

The search identified 50 publications. Two recent high quality systematic reviews (Celestin et al 2009[6]; Sparkes et al 2010[7]) were identified in the search. As these reviews included primary studies up to 2009, the current report included any additional primary studies published between 2009 and 2016 that were not included in either of the systematic reviews.

3.2 Inclusion and Exclusion Criteria

3.2.1 Inclusion Criteria

- *Study design*: Systematic reviews, meta-analyses, prospective and retrospective cohort studies, cross-sectional studies, case control studies published from January 2000 – February 2016
- *Types of participant:* People with identified psychological factors, or unhelpful coping strategies related to pain". who have received spinal cord stimulation
- *Types of comparison:* People without psychological factors or unhelpful coping strategies related to pain who have received spinal cord stimulation
- *Types of outcome measures:* Levels of pain, coping and disability following spinal cord stimulation implantation

3.2.2 Exclusion Criteria

- *Study design:* Studies with no control group, case series and grey (non-peer reviewed) literature, literature reviews
- Studies that did not investigate one or more psychological risk factors for outcomes from spinal cord stimulation implantation
- Non-English studies

3.3 Level of Evidence

Studies meeting the criteria for inclusion in this report were assessed for their methodological quality using the Scottish Intercollegiate Guideline Network (SIGN) level of evidence system (See table 1 below). Evidence tables summarising the methodology and findings of each included study and a brief outline of any limitations are presented in Appendix D.

Table 1. Levels of evidence based on the Scottish Intercollegiate Guideline Network (SIGN) level of evidence system

Levels of evidence	
1++	High quality meta analyses, systematic reviews of randomised controlled trials (RCTs), or RCTs with a very low risk of bias
1+	Well conducted meta analyses, systematic reviews of RCTs, or RCTs with a low risk of bias
1-	Meta analyses, systematic reviews of RCTs, or RCTs with a high risk of bias
2++	High quality systematic reviews of case-control or cohort studies High quality case-control or cohort studies with a very low risk of confounding, bias, or chance and a high probability that the relationship is causal
2+	Well conducted case control or cohort studies with a low risk of confounding, bias, or chance and a moderate probability that the relationship is causal
2-	Case control or cohort studies with a high risk of confounding, bias, or chance and a significant risk that the relationship is not causal
3	Non-analytic studies, e.g. case reports, case series
4	Expert opinion

4 Results

4.1 Overview of Studies

Seven primary studies and two systematic reviews[6,7] met inclusion criteria for this review. Four prospective cohort studies[8,9,10,14] were identified with the remaining three studies being retrospective cohort studies[11,12,13]; these were generally retrospective reviews of medical records. Retrospective studies such as these can be open to information bias in that they rely on the accuracy and completeness of any case notes taken during patient consultations. Measures of psychological status and pain outcomes may have been administered by several different people, creating the potential for interviewer bias. Prospective, planned cohort studies eliminate some of these sources of bias by being able to train and therefore standardize the way interviewers administer the study measures. Evidence tables summarizing the study characteristics and any potential sources of bias are presented in Appendix D.

The included studies were graded as having low to moderate quality of evidence based on their design and susceptibility to bias. Participants were predominantly recruited through pain services and clinics. Indications for spinal cord stimulation were most commonly neuropathic back and leg pain as a result of Failed Back Surgery Syndrome (FBSS) and Complex Regional Pain Syndrome (CRPS I and II) but small numbers of patients with refractory radiculopathy or peripheral neuropathy, and refractory angina were also included in some studies.

In most of the studies participants had already been screened for major psychological disorders, substance abuse, and cognitive impairment. Any people with major psychological difficulties were excluded from eligibility for SCS and the remaining cohort represented group of people who did not meet diagnostic criteria for any of these conditions. This may have reduced the ability of studies to detect the effect of psychological factors on outcomes as the range of scores on the psychological scales would be smaller, and differences between the two groups (failures and successes) may have been subtle.

All of the cohort studies used well-validated and appropriate measures of psychological factors e.g. the Hospital Anxiety Depression Scale (HADS)[16], Minnesota Multiphasic Personality Inventory (MMPI-2-RF)[17] and Beck Depression Inventory (BDI)[18]. The study by Block and colleagues[8] was funded by the publishers of the MMPI and written by the developers of the MMPI, who may have a vested interest in promoting the performance of their measure. The remaining studies had no funding issues or other conflicts of interest. The studies consistently focused on similar psychological factors, such as coping strategies, pain self-efficacy, catastrophising, depression and anxiety. While semi-structured clinical interviews were also used by several studies as part of their assessment, they did not report the findings of these interviews in the published studies, but focused on the more quantifiable measures of psychological well-being. In some studies, mainly retrospective cohorts, the questionnaire findings were used to determine who would have a full clinical interview by a psychologist or psychiatrist[11].

The outcome of spinal cord stimulation implantation was most often measured using patient self-reports of pain relief, such as numerical rating scales and visual analogue scales. These types of measures have been criticized as being subjective, but they have been used extensively in the measure of pain and are widely accepted as robust and valid tools[19] (see ACC Persistent Pain Measures Compendium). Three studies grouped participants into ‘successes’ and ‘failures’ based on their level of pain reduction, with participants who reported a fifty percent or more reduction in pre-implantation pain scores considered successes[11,13,14]. The remaining studies[8,9,10,12] compared mean scores for measures of post-implantation pain, disability, quality of life, satisfaction and pain-related impacts on daily living. Follow-up varied from 2 months[12] to an average of 4.8 years[13] after receiving an SCS implant. Four out of the six studies followed patients for at least six months post-implant.

Table 2 below provides a brief outline of the main findings and participants included within the primary studies. The evidence provided by these studies was graded as moderate to low based on study design and the likelihood of potential bias (see evidence tables in Appendix D for more details). The included systematic reviews are discussed in section 4.3 and Table 8.

Table 2. Overview of primary studies of psychological factors included in report

Reference and study design	Participants	Pre-implant psychological screening	Assessment of psychological factors	Main findings	Quality of evidence
Block et al (2015)[8] Prospective cohort	N = 345 patients referred for a pre-surgical psychological screening prior to undergoing SCS Recruited through a back clinic and a pain management centre 50% participation rate for 3-6 month questionnaires – expected to change with later assessments	All patients were referred for a pre-surgical psychological screening Three follow-up assessments planned following implantation: 3-6 months; 12 months; 24 months Current paper reports 3-6 month findings 26 excluded due to invalid MMPI-2-RF	Minnesota Multiphasic Personality Inventory- 2 – Revised Form Oswestry Disability Index Self-reported pain levels, pain interference with lifestyle, implant outcome expectations, current emotional state Post-implant pain level Dissatisfaction	High pre-implant Emotional/Internalisation Dysfunction scores were significantly associated with all post-operative scores High pre-implant Thought Dysfunction scores were significantly associated with higher post-implant negative affect only High pre-implant Behavioural/Externalising Dysfunction scores were not significantly associated with any post-operative measures	Moderate: 2+
Lame et al (2009)[14] Prospective cohort	N = 58 patients with chronic CRPS-I recruited through a pain clinic in the Netherlands 26 excluded due to unsuccessful SCS trial 32 proceeded to full SCS implant	All patients were referred for a presurgical psychological screening. Those who had a successful trial SCS proceeded to full implant and were included in analyses 9-month follow-up questionnaires sent to 32 patients who received SCS implant	Preoperative Questionnaires: Pain Intensity VAS Global Perceived Effect Quality of Life SF-36 Pain Catastrophising Scale Post-operative Questionnaires: Pain Intensity VAS Global Perceived Effect Quality of Life SF-36	Patients divided into two groups based on outcomes from SCS at 9 months. Pre-surgical variables compared for those with successful (at least 50% pain reduction) and unsuccessful SCS outcomes. Pain catastrophising was not significantly associated with any of the outcome variables	Moderate: 2+
Rosenberg et al (2015)[9] Prospective cohort	N = 386 patients enrolled from 45 different centres in the US who had a successful SCS trial Patients were 18 years and over with chronic intractable pain and baseline pain intensity of at least 6/10	45 different centres were involved in the study. The paper reports that screening and baseline evaluations were completed prior to SCS trial. 3-,6- and 12- month follow-up planned Follow-up data available for 242 participants as the study is on-going	Standardised measures were used at pre- and post- surgical assessments: Pain Catastrophising Scale State-Trait Anxiety Index Quality of Life Satisfaction	Patients were divided into two subgroups based on their PCS scores. Clinically catastrophising patients had significantly lower levels of pain relief and higher intensity of pain at 6 months and 12 months follow-up compared with non-catastrophising patients.	Moderate: 2+
Sparkes et al (2015)[10] Prospective cohort	N = 68 patients who had a successful SCS trial Recruited through a pain clinic Patients were aged 18 years or over with chronic neuropathic pain 12 patients lost to follow-up	Pre-surgical assessment by a multidisciplinary team including clinical psychologist Exclusion criteria: • Unrealistic expectations • Lack of comprehension • Unrealistic beliefs about their pain 6- and 12-month follow-up	Pre- and post-surgical measures: Oswestry Disability Index Hospital Anxiety and Depression Scale Pain Coping Strategies Questionnaire Autonomous Coping component was comprised of items 'control over pain', 'ability to decrease pain', and 'catastrophising'	Significant predictors of pain reduction at 12 months: Age at time of implant Autonomous Coping component of the PCSQ Significant predictors of disability at 12 months: Duration of pain prior to implant HADS Depression	Moderate: 2+
Bendinger et al (2015)[11] Retrospective	N = 92 patients who received a full SCS implant in the Sheffield Chronic Pain Service	Multidisciplinary team approval including psychological assessment where appropriate	Pre-surgical measures: Hospital Anxiety and Depression Scale	Predictor variables were compared for successful (>50% pain reduction) versus unsuccessful outcomes	Moderate: 2+

cohort	between 2005 and 2013 Recruited through a pain clinic 176 patients screened for SCS implant 113 patients had a trial implant 92 patients had a successful trial and proceeded to receiving a full SCS implant 9 patients lost to follow-up	Exclusion criteria: • History of substance abuse • Major depressive disorder or history of suicidal behaviour • Serious cognitive impairment • Significant psychiatric disorder 12 month follow-up	Pain Catastrophising Scale Pain Self-Efficacy Questionnaire Sleep Quality Distress during daily activities – numerical rating scale	Significant predictors or pain reduction at 12 months: Sleep interference Depression Lack of confidence in performing physical activities No significant difference for anxiety, catastrophising, or level of distress	
Sumner and Lofland (2014)[12] Retrospective cohort	N = 84 patients who had received a permanent SCS implant at a US pain clinic Patients were aged 18 years and over with a diagnosis of chronic intractable pain and a successful SCS trial 26 patients lost-to-follow-up	Semi-structured interview Self-report measures Medical chart review Exclusion criteria: Significant psychopathology Patterns of non-adherence (missed appointments) Actively abusing drugs or alcohol Two month follow-up	Pre- and post-surgical measures: Minnesota Multiphasic Personality Inventory – 2 – Revised Form Pain Coping Strategies Questionnaire: catastrophising subscale Pain VAS	Majority of the patients reported elevated pre-surgical psychological factors. Post-SCS pain scores at 8 weeks follow-up were correlated with hysteria scores. Post-SCS pain scores were not significantly correlated with depression, hypochondriasis or catastrophising	Low: 2-
Wolter et al (2013)[13] Retrospective cohort	N=46 consecutive patients treated with lumbar, thoracic or cervical neurostimulators who had a successful SCS trial Recruited through a hospital-based interdisciplinary pain centre 9 patients lost to follow-up	Psychological assessment completed prior to trial SCS for all patients. Patient records were used to access the results of these assessments. Follow-up questionnaire sent to patients to collect post-operative information Variable length of follow-up from 1 month to 14.5years post-implant. Mean = 4.8 years follow-up	<u>Pre-surgical measures::</u> Hospital Anxiety and Depression Scale Pain Disability Index <u>Post-surgical measures:</u> Treatment satisfaction Hospital Anxiety and Depression Scale Beck Depression Inventory Pain Disability Index Pain Self-Efficacy Questionnaire	Successful = 50% or greater pain reduction (n=24) Not successful = <50% pain reduction (n=13) No significant differences in pre-operative psychological scores between successful and not successful SCS patients. No statistically significant difference in pre-operative HADS scores between those with successful and unsuccessful SCS trials	Low: 2-

4.2 Associations between psychological risk factors and outcomes from SCS

4.2.1 Depression

Five studies examined the role of depression in outcomes from SCS[8,10,11,12,13]. In three studies the Hospital Anxiety and Depression Scale was used[10,11,13], with the remaining two studies using the emotional dysfunction and low positive emotion scales from the Minnesota Multiphasic Personality Inventory-2-Revised Form[8,12]. The HADS-Depression tool is based on diagnostic criteria for depression while the MMPI-2-RF includes measures of low mood (anhedonia) and demoralization, which incorporates feelings of being overwhelmed, helplessness, hopelessness and a sense of inefficacy[8]. Sparkes et al (2015)[10] reported a significant association between HADS-depression scores and 12-month disability scores but no association with 12-month pain scores. Bendinger et al (2015)[11] used regression analysis and reported that a HADS-Depression cut-off score of greater than 10 predicted less than 50% pain reduction following SCS. Wolter et al (2013)[13] completed a long-term follow-up of SCS patients (mean follow-

up 4.8 years) and found no significant difference in pre-operative depression scores for those with successful and unsuccessful outcomes. Block et al (2015)[8] reported increased relative risk of disability, dissatisfaction, expectations not met, but not pain, when participants scored highly on the overall emotional/internalization dysfunction scale. Low positive emotions (including anhedonia) were also associated with increased relative risk of post-implant disability but not pain.

Table 3 summarises the findings of studies of the role of depression in SCS. Overall, it appears that depression scores may be a significant predictor of disability outcomes (primarily measured using the Oswestry Disability Index) when measured between 2 and 12-months after SCS implantation. The association between depression scores and pain reduction following SCS was less consistent. The study by Block and colleagues is on-going and 12- and 24-month follow-up data will be reported in due course.

Table 3. Primary studies which examined the association between depression and outcomes from SCS

Reference	Measure of Depression	Main findings
Bendinger et al (2015)[11]	Hospital Anxiety and Depression Scale *12 month follow-up*	*Compared pre-implant scores for those who achieved at least 50% reduction in pain(Group A) and those who did not (Group B)* *Regression analyses showed that depression scores were a significant predictor of unsuccessful pain outcomes at 1 year follow-up:* *OR (SCS failure) if HADS-Depression >10 = 2.99 (95% CI 11.16 – 7.68)*
Sparkes et al (2015)[10]	Hospital Anxiety and Depression Scale *12 month follow-up*	*Regression analyses showed that HAD depression was a significant predictor of 12 month disability outcomes* *HAD depression was not a significant predictor of 12 month pain reduction*
Wolter et al (2013)[13]	Hospital Anxiety and Depression Scale *Mean follow-up = 4.8 years*	*No significant difference in pre-operative depression scores between those with successful (Mean = 10.2) and not successful (Mean = 9.2) outcomes (based on pain reduction scores).*
Block et al (2015)[8]	Minnesota Multiphasic Personality Inventory- 2 – Revised Format *3-6 month follow-up*	*Pre-implant Emotional/Internalisation Dysfunction showed increased relative risk for higher post-implant disability and satisfaction but not pain post-implant* *RR (elevated ODI) = 1.48 (95% CI 1.17 – 1.88)* *RR (elevated dissatisfaction) = 1.80 (95% CI 1.41 – 2.3)* *RR (expectations not met) = 1.74 (95% CI 1.38 – 2.4)* *Low positive emotions (including anhedonia)showed increased relative risk for higher post-implant disability but not pain* *RR (elevated ODI) = 1.57 (95% CI 1.25 – 1.96)*
Sumner and Loflund (2014)[12]	Minnesota Multiphasic Personality Inventory- 2 – Revised Format Scale 2 – morale, hopelessness, depressive symptoms *8 week follow-up*	*Pre-SCS Depression not significantly associated with post-implant VAS pain score (r=0.08)*

4.2.2 Anxiety

Four studies[8,10,11,13] assessed the role of anxiety in post-SCS outcomes and did not find any significant association between pre-implant anxiety levels and pain or disability outcomes. It is important to note that all the included studies utilized measures of generalized anxiety, rather than measures of pain-related anxiety. Three studies utilized the HADS and one used scales from the MMPI-2-RF. Length of follow-up varied widely from a mean of five months (Block et al 2015[8]) to almost five years (Wolter et al 2013[13]). Block and colleagues reported an increased relative risk of post-implant dissatisfaction at 3-6 months when patients scored higher on pre-implant Dysfunctional Negative Emotions (generalized anxiety, fear and anger), and an increased relative risk of higher post-implant pain levels when pre-implant demoralization scores (global anxiety, depression, inefficacy) were higher. This study is still in progress and publications of longer-term outcomes are expected in the future.

Table 4 summarises the main findings of studies which examined generalized anxiety as a predictor of SCS outcomes.

Table 4. Primary studies which examined the association between anxiety and outcomes from SCS

Reference	Measure of Anxiety	Main findings
Bendinger et al (2015)[11]	Hospital Anxiety and Depression Scale *12 month follow-up*	*Compared pre-implant scores for those who achieved at least 50% reduction in pain(Group A) and those who did not (Group B)* *No significant difference in HADS-Anxiety scores for the two groups* *Group A Median = 7.5, Group B Median = 9, p=0.21*
Sparkes et al (2015)[10]	Hospital Anxiety and Depression Scale *12 month follow-up*	*Regression analyses showed HADS - Anxiety was not a significant predictor of 12 month pain reduction or disability score*
Wolter et al (2013)[13]	Hospital Anxiety and Depression Scale *Mean follow-up = 4.8 years*	*No significant difference in pre-operative anxiety scores for those with successful and not successful outcomes (based on pain reduction scores).*
Block et al (2015)[8]	Minnesota Multiphasic Personality Inventory- 2 – Revised Format *3-6 month follow-up*	*Pre-implant Dysfunctional Negative Emotions (including anxiety, fear and anger) showed significantly increased relative risk for post-implant satisfaction, but not post-implant pain or disability.* *RR (expectations not met) = 1.56 (95% CI 1.19 – 2.06)* *RR (elevated dissatisfaction) = 1.70 (95% CI 1.28 – 2.26)* *Pre-implant Negative Emotionality/Neuroticism Revised showed increased relative risk for post-implant disability but not pain, dissatisfaction or expectations not met* *RR (elevated ODI) = 1.63 (95% CI 1.32 – 2.00)* *Pre-implant Demoralisation (global anxiety, depression, inefficacy) showed increased relative risk for higher post implant pain levels* *RR (pain level) = 1.47 (95% CI 1.11 – 1.95)*

4.2.3 Coping strategies/pain self-efficacy

Pain self-efficacy can be described as a belief or confidence in one's ability to manage or control pain, or confidence in one's ability to perform daily activities[10,11]. Pain self-efficacy measures assess beliefs and attitudes about coping with pain and controlling pain.

Three studies assessed the relationship between pre-SCS levels of self-efficacy and post-SCS outcomes[8,10,11]. Three different measures of self-efficacy were employed. The Pain Self-Efficacy Questionnaire utilized by Bendinger et al (2015) and Wolter et al (2013) is specifically designed to assess self-efficacy in the presence of persistent pain, while the other two measures include self-efficacy amongst measures of broader coping strategies (PCSQ) or personality constructs (MMPI-2-RF). For this reason it is difficult to separate out the individual effect of pain self-efficacy and it is considered alongside catastrophising (exaggerated negative thinking during pain), anxiety and depression in this and the following section. Table 5 summarises the measures used and main findings of the three included studies.

One study indicated that pain self-efficacy and catastrophising as a combined factor was a strong predictor of post-implant pain but not disability[10]. A further study[8] considered self-efficacy, anxiety and depression as part of a Demoralisation factor in the MMPI. This study indicated that these three factors together increased the relative risk of poorer pain, disability and satisfaction outcomes following SCS (RRs 1.42 – 1.86). Bendinger et al (2015[11]) looked specifically at pain self-efficacy as a single factor and reported significantly increased odds of SCS failure at 12 months follow-up if PSEQ scores were 18 or under (OR (SCS failure) = 2.84, 95% CI 1.13 – 7.14).

One further study by Wolter and colleagues (2013)[13] examined post-SCS levels of pain self-efficacy using the PSEQ and reported a significant association between post-implant self-efficacy and mean post-implant pain reduction levels during stimulation from the implant (r=0.53, p<0.0009). There were also strong associations between post-SCS pain self-efficacy scores and depression, suggesting these factors may be inter-related.

Table 5. Primary studies which examined the association between coping strategies and self-efficacy and outcomes from SCS

Reference	Measure of coping strategies/pain self-efficacy	Main findings
Bendinger et al (2015)[11]	Pain Self-Efficacy Questionnaire *12 month follow-up*	*Compared pre-implant scores for those who achieved at least 50% reduction in pain(Group A) and those who did not (Group B)* *Group A Median =21, Group B Median = 16, p=0.03* *Regression analysis suggested a cut-off score of ≤18 was a risk factor for failure of SCS at 12 months.* *OR (SCS failure) if PSEQ≤ 18 = 2.84 (95% CI 1.13 – 7.14)*
Sparkes et al (2015)[10]	Pain Coping Strategies Questionnaire *PCSQ is comprised of two factors: Cognitive and Behavioural Coping Strategies, and Autonomous Coping* *12 month follow-up*	*Regression analyses showed that Autonomous Coping was a significant predictor of 12-month pain outcomes but not disability.* *Autonomous Coping = control over pain, ability to decrease pain and catastrophising.* *Cognitive and Behavioural Coping Strategies was not a significant predictor of either pain or disability at 12 months follow-up.*
Block et al (2015)[8]	Minnesota Multiphasic Personality Inventory-2-Revised Form *3-6 month follow-up*	*Pre-implant Demoralisation (including anxiety, depression and low self-efficacy) showed significantly increased relative risk for all post-implant outcomes.* *RR (post-implant pain) = 1.47 (95% CI 1.11 – 1.95)* *RR (pain-related interference) = 1.39 (95% CI 1.04 – 1.86)* *RR (post-implant ODI) = 1.42 (95% CI 1.11 – 1.81)* *RR (expectations not met) = 1.78 (95% CI 1.44 – 2.20)* *RR (elevated dissatisfaction) = 1.86 (95% CI 1.46 – 2.36)*

4.2.4 Catastrophising

High levels of pain-related catastrophising, which is defined as exaggerated negative thinking during, or in anticipation of pain, have been associated with poor recovery from spinal surgery and persistent pain[9]. It is comprised of components such as rumination, magnification of complaints and feelings of helplessness[9].

Five studies investigated the relationship between catastrophising and SCS outcomes. Three studies utilized the Pain Catastrophising Scale (PCS)[9,11,14] and two used the Pain Coping Strategies Questionnaire (PCSQ)[10,12] which incorporates aspects of self-efficacy and catastrophising as part of an Autonomous Coping factor. Follow-up varied from two months to 12 months following SCS.

Bendinger et al (2015)[11] and Sparkes et al (2015)[10] reported a significant association between high levels of catastrophising and pain scores, but not disability, at 12-months follow-up. A PCS cut-off score of 26 was identified through regression analyses, but did not significantly predict outcomes when reapplied to the sample (OR (SCS failure) = 2.84, 95% CI 0.89 – 5.8). Lame et al (2009)[14] reported no significant association between outcomes from SCS and high catastrophising in a prospective cohort study of patients with CRPS-I. The remaining two studies[9,12] reported a significant association between concurrent measures of catastrophising and pain before SCS implantation and at 6-months post-implant.

Taken together, the findings from studies of self-efficacy and catastrophising suggest that it is the combination of these factors which may affect outcomes from SCS. A combination of low self-efficacy, or a belief that one cannot control or decrease the pain, and high levels of catastrophising increased the likelihood of poor intermediate outcomes from SCS in two studies[8,10]. This also suggests that patients with high self-efficacy and low levels of catastrophising may make ideal candidates for SCS, as they may be more able to optimise their outcomes from the procedure. Some studies also reported a significant association between depression scores and catastrophising[13]. Table 6 outlines the main findings of studies of pain catastrophising and outcomes from SCS.

Table 6. Primary studies which examined the association between pain catastrophising and outcomes from SCS

Reference	Measure of Catastrophising	Main findings
Bendinger et al (2015)[11]	Pain Catastrophising Scale *12-month follow-up*	*Compared pre-implant scores for those who achieved at least 50% reduction in pain (Group A) and those who did not (Group B)* *Significant difference in PCS between Group A and B* *Group A Median = 20.5, Group B Median = 31, p=0.04* *OR (SCS failure) if PCS ≤ 26 = 2.84 (95% CI 0.89 – 5.8)*
Sparkes et al (2015)[10]	Pain Coping Strategies Questionnaire *PCSQ is comprised of two factors: Cognitive and Behavioural Coping Strategies, and Autonomous Coping factor* *12-month follow-up*	*Regression analyses showed that Autonomous Coping was a significant predictor of pain outcomes but not disability. Autonomous Coping = control over pain, ability to decrease pain and catastrophising.* *Cognitive and Behavioural Coping Strategies was not a significant predictor of either pain or disability at 12 months follow-up.*
Rosenberg et al (2015)[9]	Pain Catastrophising Scale *6-month follow-up*	*Regression analyses showed that catastrophising at 6-months post-implant predicted pain scores, suggested that controlling catastrophising may improve pain scores post-SCS. Study was unable to say whether catastrophising at baseline predicted later pain scores post-SCS, and so could not be used for screening.*

Lame et al (2009)[14]	Pain Catastrophising Scale *9 month follow-up*	*Regression analyses showed that catastrophising was not a significant predictor of pain or quality of life outcomes 9 months post-SCS in patients with CRPS-I.*
Sumner and Loflund (2014)[12]	Pain Coping Strategies Questionnaire – catastrophising subscale *2 months follow-up*	*Significant association between pre-SCS catastrophising and pre-SCS pain scores* *No significant association between pre-SCS catastrophising and post-SCS pain scores*

4.2.5 *Somatisation/Pain sensitivity/Bodily concern/Hypochondriasis*

Somatisation has been described as being overly concerned or preoccupied with bodily complaints and levels of pain[30]. Some studies measure this as bodily concern or pain sensitivity. The MMPI has a specific scale called somatic complaints, which measures the tendency of a person to report medically unexplainable physical symptoms. In previous versions of the MMPI this was called Hypochondriasis[8].

Two studies[8,12] investigated the effect of high somatization on short term (up to 6-month) outcomes from SCS with mixed findings (see Table 7). Both utilized the MMPI-2-RF. Sumner and Loflund (2014)[12] reported a significant correlation between pre-SCS bodily concern and higher post-SCS pain scores two months after receiving the implant ($r=0.22$, $p<0.05$). Block et al (2015)[8] reported that overall pre-implant somatic complaints were not associated with an increased relative risk of poor SCS outcomes at 3-6 months follow-up. However, they did report a significantly increased risk of post-implant disability with high malaise or cognitive complaint scores (RRs 1.61). Pain scores were not associated with any of the somatic complaint subscales. Neither study has followed participants up long enough to report on intermediate outcomes although the study by Block and colleagues plans to report on 12-month and 24-month outcomes in the future.

Table 7. Primary studies which examined the association between somatisation and outcomes from SCS

Reference	Measure of Somatisation	Main findings
Sumner and Loflund (2014)[12]	MMPI-2-RF Bodily concern, somatic response to stressful situations, pain sensitivity subscales *2 months follow-up*	*Significant correlation between pre-SCS bodily concern and post-SCS pain scores:* *r=0.22 (p<0.05)* *No significant association between somatic response or pain sensitivity subscales and pain scores*
Block et al (2015)[8]	MMPI-2-RF Somatic Complaints factor made up of Malaise, Gastrointestinal, Head Pain, Neurological, Cognitive Complaints *3-6 month follow-up*	*Overall Pre-implant Somatic Complaints (diffuse somatic symptoms) did not show a significantly increased relative risk for post-implant failure.* *Two components of the Somatic Complaints factor showed an increased relative risk for elevated post-implant disability but not pain:* *RR (SCS disability) if Malaise ≥ 80 = 1.61, 95% CI 1.29 – 2.01* *RR (SCS disability) if Cognitive Complaints ≥ 75 = 1.61, 95% CI 1.3 – 1.99*

4.3 Findings from systematic reviews

Two recent systematic reviews were identified that examined the role of psychological factors in outcomes from SCS (see Table 8). In a well-conducted review, Sparkes et al (2010)[7] included nine prospective studies overall, with evidence from six studies that depression may impact on outcomes from SCS. There were with less conclusive results for mania, hysteria and hypochondriasis. Sparkes and colleagues suggested that depression

may be a useful target for treatment alongside SCS, given studies have shown that depression scores can improve with SCS and other treatments, however, this hypothesis has yet to be tested in intervention studies. Celestin et al (2009)[6] identified four prospective studies of the relationship between psychological variables and outcomes of SCS. The inclusion criteria were not well reported in this review, and the included studies varied considerably in follow-up time, design and measurement of psychosocial variables. Some evidence was reported of an association between pre-implant depression and anxiety scores and poor outcomes from SCS, however, the authors were unable to make any firm conclusions.

Table 8. Overview of secondary studies of psychological factors

Reference	Study design	Inclusion criteria	Included studies	Main findings	Quality of evidence
Celestin et al 2009[6]	Systematic review Search dates: up to August 2008 Prospective studies	Prospective studies which examined the relationship between pre-surgical psychosocial variables and outcomes from SCS. Unclear how studies were critically appraised	N=4 studies (an additional 21 studies looked at psychosocial predictors of outcomes following lumbar surgery) Described as prospective designs but unclear what the specific designs were. Follow-up varied from 3 months to 7 years	Psychological variables were predictive of outcome in 3 out of 4 studies. Depression and anxiety were both correlated with the success of outcomes. Suggests a possible association between pre-surgical psychological variables and outcomes from SCS. Most common measures used were: MMPI California Personality Inventory McGill Pain Questionnaire Derogatis Affects Balance Scale	Moderate: 2++
Sparkes et al (2010)[7]	Systematic review Search dates: up to July 2009 Case series, case-control, cohort studies	Prospective studies investigating the influence of psychological variables on outcomes from SCS	N = 9 studies (prospective cohort, case control, case series) Follow-up varied from 3 months to 3.5 years	Some evidence that depression may influence outcomes from SCS and may be good target for treatment alongside SCS, rather than used to exclude patients. Results inconclusive for mania, hysteria, hypochondriasis. Most common measures used were: MMPI and MMPI-2-RF Hospital Anxiety Depression Scale Beck Depression Inventory Hamilton Psychiatric Rating Scale	Moderate: 2++

4.3.1 Guidelines and other jurisdictions

Appendix C summarises the guidance regarding psychological assessments prior to SCS from key pain specialist organisations and insurers in Australasia and overseas[23-29]. While several guidelines are available regarding the clinical and cost-effectiveness of spinal cord stimulation for chronic pain, few include detailed information on psychological assessment. Most provide general recommendations of the importance of psychological screening, and the exclusion of patients with major psychological disturbances. Very little guidance is available regarding the composition of psychological screening, which measures should be used, or which psychological factors are important beyond major psychological conditions and substance disorders[15].

4.4 Measures of psychological risk factors

The included studies utilized either measures of single psychological factors, such as depression, anxiety or catastrophising, or multifactorial measures of personality constructs and coping strategies. Each measure has its advantages and disadvantages. Single factor measures, such as the HADS and the BDI, are often quick to administer and may link directly to diagnostic criteria, but they do not provide a complete picture on their own of a

person's psychological status and ways of coping. Multifactorial measures, such as the MMPI and PCSQ, are not generally designed around diagnostic criteria, and can be longer and more time-consuming, but measure a broader range of psychological factors. Some studies have also suggested that candidates for SCS may minimize their psychological symptoms of depression, anxiety and ability to cope to avoid exclusion[20]. The MMPI includes questions designed to detect false or unlikely clusters of responses, which may make it more difficult to manipulate the results[8,17] than with single factor tools. This measure requires extensive training and clinical qualifications in order to receive permission to administer it, and these requirements in addition to its cost may make it a less feasible option to use in clinical practice.

A previous ACC report evaluated the psychometric performance and utility of a large range of measures related to persistent pain[19]. This report assessed the validity and usability of measures of pain severity, functional impairment, quality of life and psychological constructs. In reviewing measures of psychological components of pain, the authors identified the BDI, HADS, and the PSEQ as having good validity and internal and external consistency. For a discussion of the advantages and disadvantages of different psychological measures for people with chronic pain, please refer to the ACC Persistent Pain Measures Compendium[19].

5 Discussion

5.1 Nature and quality of the evidence

While the evidence base for the role of psychological factors in outcomes from SCS has expanded significantly since 2010, there is still a lack of high quality studies with long-term follow-up. Most of the studies included in the current report followed patients for a maximum of 12 months post-SCS. There is evidence of a decline in pain reduction for some people two to five years after SCS implantation[2,10], so extending follow-up to at least two years would be beneficial. Block et al (2015)[8] plan to continue following patients up to two years post-surgery and these findings may shed some light on the role of psychological factors in longer-term outcomes.

All of the primary studies utilised patient cohorts who had been referred for treatment with SCS. The reasons for referral were not well reported and in some studies less than half of those originally referred for SCS progressed through to receiving the implant. Patients were also screened for major psychological risk factors (e.g. major, untreated psychological disorders, substance disorders), with further exclusions of patients considered unsuitable for psychological reasons. Excluded patients were not followed-up so no data is available comparing the outcomes of those who received and did not receive treatment with SCS. This means that the included studies were comparing psychological risk factors in cohorts that had already screened and excluded potentially high-risk individuals, and are likely to underestimate the overall effect of psychological factors on outcomes. In addition, none of the studies reported whether participants received any psychological support or therapy for any of their identified difficulties. While these limitations certainly affect the quality and strength of the findings, an advantage of this methodology is that the cohorts reflect current clinical practice, and the analyses are representative of the association between psychological risk factors and outcomes in carefully selected patient groups.

Two different kinds of measures were commonly used as part of the assessment of psychological factors. Single factor measures, for example of depression, catastrophising and pain self-efficacy, were commonly used to examine the association between individual psychological factors and SCS. These types of measures include validated diagnostic tools, such as the Beck Depression Index and the Hospital Anxiety and Depression Scale. These are reasonably simple to administer and are useful for identifying the presence of symptoms of common psychological factors, and assessing the effects of any treatment. Multifactorial measures of key characteristics, such as Minnesota Multiphasic Personality Inventory-2-Revised Form and the Pain Coping Strategies Questionnaire, have also been used widely in studies of SCS, particularly in studies that attempted to examine the inter-relationship of different psychological factors. These are useful for identifying subclinical levels of conditions and personality characteristics which might impair a person's ability to fully benefit from SCS e.g. self-efficacy, coping strategies, neuroticism, low mood. It is important to note however, that some of these measures require extensive training and clinical qualifications in order to purchase and administer the tests. Each type of measure serves a different function and it would seem that, in order to gain a full picture of the factors that might affect

outcomes from SCS, inclusion of a range of measures would be useful. The advantages and disadvantages of different pain measures are discussed in detail in the ACC compendium of pain measures[19].

5.2 Summary of findings

There is evidence of an association between several psychological factors and outcomes from SCS, even after other confounding factors such as age and duration of pain have been accounted for. There was consistent evidence of a relationship between higher pre-SCS depression scores and worse disability scores following SCS, although there was not a significant relationship with post-SCS pain scores. Disability was measured in most studies using the Oswestry Disability Index, which assesses the impact of illness or pain on the tasks of daily living. There was also consistent evidence of a relationship between self-efficacy and catastrophising and pain-related outcomes from SCS. People with high self-efficacy, or a belief in their ability to manage and control the pain, and low levels of catastrophising prior to receiving SCS had significantly better pain scores at 12-months follow-up than those with low self-efficacy and high catastrophising. One study also reported a relationship between self-efficacy and post-SCS levels of disability and satisfaction but these were measured only 3-6 months following SCS. There was also an association between psychological factors and pain or disability scores at the same time-point. Self-efficacy and catastrophising were also strongly related to depression scores. None of the studies identified a significant association between pre-SCS levels of anxiety and post-SCS outcomes. Findings for somatisation were inconsistent.

Two studies[8,11] used regression analyses to identify cut-off scores for measures which were significantly associated with outcomes from SCS. A HADS – Depression score ≤ 10 and a PSEQ >18 were both predictive of SCS failure (less than 50% pain reduction) 12 months following SCS. Block et al (2015)[8] identified predictive cut-off levels for several factors of the MMPI-2-RF. These cut-off levels may need confirming through other studies but could provide some guidance for the use of these tools in clinical practice for SCS.

Taken together, these findings suggest high levels of depression and poor coping strategies, such as low self-efficacy and a tendency to catastrophise when experiencing or thinking about one's pain, are associated with worse outcomes from SCS. They may not necessarily exclude people from eligibility for SCS, but the evidence suggests they should be part of the psychological assessment prior to and following SCS and may be useful red flags to identify candidates at risk of poorer outcomes. The included studies were unable to assess whether psychological interventions to target these psychological factors might improve SCS outcomes. The small number of studies which have examined the effect of psychological interventions on SCS outcomes[21,22] suggest they may potentially be good targets for improving outcomes, but further research is needed.

6 Conclusion

6.1 Evidence statement

There is some evidence that moderate levels of specific psychological variables mitigate the effectiveness of spinal cord stimulation in some patients. The included evidence shows that symptoms of depression, and poor coping strategies, such as low self-efficacy and high catastrophising, are associated with poorer outcomes six to twelve months after SCS. Further follow-up is required concerning long-term outcomes (2 years +).

Some studies measured multiple factors and these studies indicated that the combination of several factors increased the risk of poorer outcomes following SCS. This suggests that it is probably important to measure a broad range of characteristics and to consider the cumulative effect of poor coping styles and strategies as well as clinical symptoms. Given the comorbidity of mental health conditions, it is likely that many people will have multiple risk factors present. Poor coping strategies and the presence of symptoms of depression may not necessarily exclude people from having SCS, but they should be included as part of psychological assessment prior to SCS, and inform the development of a comprehensive pain management strategy for each patient.

6.2 Recommendations

This review confirms that the assessment and ongoing management of psychological factors and coping strategies is an essential component of treatment with SCS. Psychological status is linked with outcomes from SCS and should be a key consideration in determining who is a good candidate for SCS. Patients are currently excluded based on having a major, uncontrolled psychological, substance abuse, or cognitive disorder. The current review identified consistent evidence of an association between pre-SCS levels of depression, low self-efficacy and high catastrophising, and poorer pain and disability outcomes. Patients without the presence of these psychological factors had significantly better pain and disability scores at six to twelve month follow-up after SCS.

This evidence suggests that, in addition to screening for major psychological disorders, the selection of suitable candidates for SCS should also include an assessment of psychological factors such as depression and coping strategies. These psychological factors are potentially good targets for improving outcomes by providing a comprehensive pain management follow up, and this should be the focus of future research. To make a fully informed decision about the suitability of a candidate for SCS, ACC clinical advisors need to be informed of the person's psychological symptoms and coping strategies and how these will be managed as part of their comprehensive pain management strategy.

The recommendations of this review are:

- In addition to screening for major psychological, cognitive and substance disorders, psychological factors such as depression, coping strategies, self-efficacy and catastrophising, should be assessed as part of consideration for SCS using validated assessment tools. The client's comprehensive pain management strategy should include the management of these types of factors in both the short, and intermediate to long term.
- In order to make a robust decision about the suitability of a candidate for SCS, ACC clinical advisors need to be fully informed of any psychological factors and coping strategies that may potentially impact on outcomes.
- On their own, any single characteristic might not have a great effect on outcomes, but given the comorbid nature of psychological distress, it is likely that the cumulative effect of multiple factors will have greater impact on a client's post-SCS levels of pain and disability.
- A range of validated assessment tools, including single and multifactorial measures, is recommended as each type of measure serves a different function. For a discussion of the advantages and disadvantages of different psychological measures for people with chronic pain, please refer to the ACC Persistent Pain Measures Compendium[19].
- Some psychological factors were associated with worse pain levels and some were associated with the way a person's pain affected their daily life (disability). Future studies should include a measure of function or impact on daily living, not just pain. Other useful measures are the use of supplementary pain medication and the ability of people to return to work and other activities.

7 References

1. Accident Compensation Corporation (2012). Neuromodulation treatment with spinal cord stimulators for pain management. Clinical Guidelines. ACC: Wellington, New Zealand.

2. Accident Compensation Corporation (2009). Effectiveness of spinal cord stimulation for the management of neuropathic pain. ACC: Wellington, New Zealand.

3. National Institute for Health and Care Excellence (NICE) (2008). Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin. NICE Technology Appraisal Guidance [TA159]. https://www.nice.org.uk/guidance/ta159

4. Simpson, E.L., Duenas, A. et al (2009). Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin: systematic review and economic evaluation. Health Technol Assess. 2009 Mar;13(17):iii, ix-x, 1-154.

5. Sparkes E., Duarte, R.V. et al (2011). Qualitative exploration of psychological factors associated with spinal cord stimulation outcome. Chronic Illness, 1: 1-13.

6. Celestin, J., Edwards, R.R. et al (2009). Pretreatment psychosocial variables as predictors of outcomes following lumbar surgery and spinal cord stimulation: A systematic review and literature synthesis. Pain Medicine, 10 (4): 639-653.

7. Sparkes, E. Duarte, R.V. et al (2010). A systematic literature review of psychological characteristics as determinants of outcome for spinal cord stimulation therapy. Pain, 150: 284 – 289.

8. Block A.R., Marek, R.J. et al (2015). Associations between pre-implant psychosocial factors and spinal cord stimulation outcome: Evaluation using the MMPI-2-RF. Assessment, 1-11.

9. Rosenberg, J.C., Schultz, D.M. et al (2015). Increased pain catastrophisation associated with lower pain relief during spinal cord stimulation: Results from a large post-market study. Neuromodulation, 18: 277-284.

10. Sparkes, E., Duarte, R.V. et al (2015). Analysis of psychological characteristics impacting spinal cord stimulation treatment outcomes: A prospective assessment. Pain Physician, 18: E369 – 377.

11. Bendinger T., Plunkett N., et al (2015). Psychological factors as outcome predictors for spinal cord stimulation. Neuromodulation 2015; 18: 465–471.

12. Sumner, L.A. and Loflund, K. (2014). Spinal cord stimulation: Subjective pain intensity and presurgical correlates in chronic pain patients. Chronic Illness, 10 (3): 157-166.

13. Wolter, T., Fauler, I. et al (2013). The impact of psychological factors on outcomes for spinal cord stimulation: An analysis with long-term follow-up. Pain Physician 16: 265 – 275.

14. Lame, I., Peters, M.L. et al (2009). Can the outcome of spinal cord stimulation in chronic complex regional pain syndrome type I patients be predicted by catastrophizing thoughts? Anesthesia and Analgesia, 109(2): 592-599.

15. Campbell, C.M., R.N. Jamieson et al. (2013). Psychological screening/phenotyping as predictors for spinal cord stimulation. Curr Pain Headache Rep 17(1): 307

16. Zigmond AS, Snaith RP. The hospital anxiety and depression scale. Acta Psychiatr Scand 1983; 67: 361-370.

17. Ben-Porath, Y. S., & Tellegen, A. (2008/2011). The Minnesota Multiphasic Personality Inventory-2 Restructured Form (MMPI-2-RF): Manual for administration, scoring, and interpretation. Minneapolis, MN: University of Minnesota Press.

18. Beck, A. T., Ward, C. H., Mendelson, M., Mock, J., & Erbaugh, J. (1961). An Inventory for Measuring Depression. Archives of General Psychiatry, 4, 561.

19. Grimmer-Somers K, Vipond N, et al (2009). A review and critique of assessment instruments for patients with persistent pain. Journal of Pain Research;2:21–47.

20. Davis, C.E., Kyle B.N. et al (2015). Comparison of pain, functioning, coping and psychological distress in patients with chronic low back pain evaluated for spinal cord stimulator implant or behavioural pain management. Pain Medicine, 16 (4): 753-760.

21. Molloy A.R., Nicholas, M.K. et al (2006). Does a combination of intensive cognitive behavioural pain management and a spinal implantable device confer any advantage? A preliminary examination. Pain Practice, 6(2): 96-103.

22. Roditi D. and Robinson, M.E. (2011). The role of psychological interventions in the management of patients with chronic pain. Psychology Research and Behaviour Management, 4: 41-49.

23. Australian and New Zealand College of Anaesthetists, Faculty of Pain Medicine (2011). Neuromodulation (spinal cord stimulation) in the management of patients with chronic pain. Guidelines. http://www.fpm.anzca.edu.au/resources/professional-documents/documents/PM9%202011.pdf

24. Atkinson L., Sundaraj, S.R. et al (2011). Recommendations for patient selection in spinal cord stimulation. Journal of Clinical Neuroscience, 18(10):1295 – 1302. [Australasian Neurostimulation Working Group guidance].

25. British Pain Society (2009). Spinal cord stimulation for the management of pain: Recommendations for best clinical practice. Consensus document. British Pain Society: UK.

26. Raff M., Melvill, R. et al (2013). Spinal cord stimulation for the management of pain: Recommendations for best clinical practice. [South African Pain Society]. South African Medical Journal, 103 (6): 423-430.

27. North R. et al (2007). Practice parameters for the use of spinal cord stimulation in the treatment of chronic neuropathic pain. Pain Medicine, 8 (S4), S199-S275.

28. AETNA Insurance (2015) Dorsal column stimulation policy 0194. http://www.aetna.com/cpb/medical/data/100_199/0194.html

29. CIGNA Insurance (2012). Spinal cord stimulation policy 0380. https://cignaforhcp.cigna.com/public/content/pdf/coveragePolicies/medical/mm_0380_coveragepositioncriteria_spinal_cord_stimulation.pdf

30. Block A.R., Ben-Porath, Y.S. et al (2013). Psychological risk factors for poor outcome of spine surgery and spinal cord stimulator implant: A review of the literature and their assessment with the MMPI-2-RF. The Clinical Neuropsychologist, 27:1, 81-107.

8 Appendices

8.1 Appendix A: Summary of ACC guidance regarding psychological assessment prior to SCS

Psychological assessment and recommendations
Psychometric tests must have well-recognised reliability and validity and be suitable for repeated measurements including symptom reporting **The psychological assessment must provide a diagnostic summary and make recommendations that address:** • Factors to maximise current pain modulation/perception • The patient's ability to participate in further rehabilitation • Interventions for identified issues to be aware of when implementing an SCS trial e.g. an escalating analgesic dose, unresolved compensation status, unrealistic expectations, inadequate support from spouse, family or others, a history of compliance problems or a history of substance abuse.
The psychological assessment must include a clinical evaluation of the patients: • History of psychological function • History of psychological/psychiatric diagnoses • Perception of their pain problem • Past pain management strategies and how they responded • Current pain management strategies • Thought content and symptoms, including mood, anxiety, cognitive function, and memory • Response to their pain condition in the context of their domestic and social environment • Current level of activity and function, quality of life, level of spousal, family or social support, and participation (in work and society) • Approach to previous and current medication • Use of drugs, alcohol, tobacco and caffeine • Behavioural habits including sleep and hygiene • Motivational factors, goals, and influencing factors such as a perceived locus of control • Attitude to therapeutic interventions and the perceived risks and benefits of long-term association with the SCS and pain services

Psychological exclusion factors

- History of escalating medical reliance
- Objective signs on the psychometric tests e.g. DASS-21
- Poorly controlled psychosis
- Impulsivity, poor mood regulation, poor anxiety management
- Major uncontrolled depression or anxiety
- Active suicidal behaviour, untreated self-harm behaviour
- Alcohol or drug dependence or abuse
- Serious cognitive deficits
- Overt secondary gain issues

8.2 Appendix B: Search Strategy

Medline	Embase	Medline In-Process & PsycINFO (free text)
1. spinal cord stimulation/	1. spinal cord stimulation/	1. (spinal cord stimulat$ or spinal neuromodulat$).ti,sh.
2. (spinal cord stimulat$ or spinal neuromodulat$).ti,sh.	2. (spinal cord stimulat$ or spinal neuromodulat$).ti,sh.	2. limit 1 to (english language and yr="2000 -Current")
3. 1 or 2	3. 1 or 2	3. 2 and (psych$ or mental$ or patient selection).mp.
4. remove duplicates from 3	4. remove duplicates from 3	*4. limit 3 to all journals [option only available in PsycINFO]*
5. limit 4 to (english language and yr="2000 -Current")	5. limit 4 to (english language and yr="2000 -Current")	
6. exp psychology/ or exp psychopathology/ or exp psychological tests/	6. exp psychology/ or exp psychopathology/ or exp psychological tests/	
7. Patient Selection/	7. Patient Selection/	
8. exp personality assessment/ or exp psychiatric status rating scales/ or neuropsychological tests/ or exp psychotherapy/	8. exp personality assessment/ or exp psychiatric status rating scales/ or neuropsychological tests/ or exp psychotherapy/	
9. exp personality/ or exp psychology, social/ or exp mental disorders/	9. exp personality/ or exp psychology, social/ or exp mental disorders/	
10. *risk factors/	10. *risk factors/	
11. *prognosis/ or treatment failure/	11. *prognosis/ or treatment failure/	
12. mental health/ or pain threshold/ or exp psychology, applied/ or exp psychophysiology/ or exp resilience, psychological/	12. mental health/ or pain threshold/ or exp psychology, applied/ or exp psychophysiology/ or exp resilience, psychological/	
13. Disease Susceptibility/	13. Disease Susceptibility/	
14. px.fs.	14. psychological well being/	
15. or/6-14	15. psychological aspect/	
16. 5 and 15	16. or/6-15	
17. limit 16 to humans	17. 5 and 16	
	18. limit 17 to humans	

8.3 Appendix C: Recommendations of other jurisdictions and guidelines

Organisation	Absolute Psychological Contraindications	Relative psychological contraindications	Require amelioration prior to SCS	Psychological criteria	Components of a psychological evaluation
ANZCA FPM guidance[23]	Usage of illicit drugs Unsuccessful trial of SCS	Cognitive impairment may preclude SCS if the patient is unable to understand the treatment, unless adequate support from carer or community services is available	Psychiatric disorders such as: Active psychosis Major mood disorder Inappropriate use of alcohol or prescription medication Unstable social or environmental circumstances	SCS should be part of an ongoing multimodal management plan with a prominent psychosocial component All patients being considered for SCS should undergo comprehensive multidisciplinary assessment of physical, psychological and social functioning. At least two experienced pain specialists should assess a patient for consideration for SCS	Goals of SCS should be discussed, including improvement in quality of life (physical and psychosocial), reduction (not elimination) of pain, return to work, reduced requirement for medication
Australasian Neurostimulation Working Group guidance[24]	Cognitive impairment will preclude SCS if the patient is unable to understand the therapy, unless adequate support from carer or community services is available Active psychosis Major untreated mood disorder Somatization disorder		Active or untreated abuse of alcohol, drugs or medication (e.g. opioids) would require other appropriate management before consideration	All patients being considered for SCS should undergo appropriate multidisciplinary assessment of physical, psychological and social functioning. This may include interviews with the patient and their family/carer and psychological testing	Example of a psychological test battery: Beck Depression Inventory Depression Anxiety Stress Scales McGill Pain Questionnaire State Trait Anxiety Inventory Pain Coping Strategies Questionnaire Pain Locus of Control Scale Pain Self-Efficacy Questionnaire Short-form 36 medical outcomes (SF-36) Personality Assessment Inventory
British Pain Society[25]		Cognitive impairment, communication problems, or learning difficulty resulting in failure to understand the therapy is not a reason to exclude patients from SCS, but these patients must have a cognisant caregiver and adequate		All patients being considered for SCS must be assessed with regard to physical, psychological, and social functioning.	Qualitative psychological testing does not predict outcome, but assessment by a psychologist is desirable to assess the patient's beliefs, expectations, and understanding of the treatment in relation to the condition. It is also an important opportunity to discuss pain management strategies, including activity pacing, both before and after the procedure

		social support.			
South African Spine Society, Neurological Society of South Africa, South African Society of Anesthesiologists [26]		Cognitive impairment, communication problems or learning difficulty resulting in failure to understand the therapy are not reasons to exclude patients from SCS, but these patients must have a cognizant caregiver and adequate social support	Patients with concurrent physical or mental illness should be assessed in close conjunction with relevant clinical teams If there is significant psychological distress identified at the assessment, such patients may benefit from individual psychological therapy (e.g. CBT) before proceeding to SCS	All patients being considered for SCS must be assessed with regard to physical, psychological, and social functioning	Assessment by a psychologist is desirable to assess the patient's beliefs, expectations, and understanding of the treatment in relation to the condition
Neuromodulation Therapy Access Coalition (North et al 2007) [27]	Inability to control the device	An unresolved major psychiatric comorbidity The unresolved possibility of secondary gain An active and untreated substance abuse disorder Inconsistency among the patient's history, pain description, physical examination, diagnostic studies Abnormal or inconsistent pain ratings			Psychological evaluation must be carried out prior to undergoing a screening trial with a surgically placed electrode
AETNA [28]		Serious mental disabilities, psychiatric disturbances, or poor personality factors that are associated with poor outcomes.			
Cigna [29]	Inadequately controlled mental health problem			Purpose of the assessment is to evaluate the potential role that psychological factors	Evaluation by a mental health provider (e.g., a face-to-face assessment with or without

	(e.g., alcohol or drug dependence, depression, psychosis) that would negatively impact the success of a SCS or contraindicate its placement		(e.g., depression, anxiety, emotional state, underlying mental illness, drug and/or alcohol abuse) may play in mediating the pain response, and to offer appropriate recommendations with regard to psychological management before and after surgery.	psychological questionnaires and/or psychological testing). The assessment of readiness for change, coping skills, pain perception, expectations for pain alleviation, perceived disability, and acceptance of the disability may be useful in predicting the success of SCS.

8.4 Appendix D: Evidence tables

Prospective Cohort Studies

Study	Methodology	Outcomes & results	Paper grading *[Y – yes; N – No; CS – Can't say; NA – Not applicable]*		Reviewer comments & evidence level
Block et al (2015)[8] Assessment, 1-11 **Study design** Prospective cohort **Research question** To identify psychological factors associated with SCS outcomes **Funding** University of Minnesota Press (publisher of the MMPI-2-RF) **Conflicts of interest**	N = 414 patients referred for a presurgical psychological screening prior to undergoing SCS, of whom N = 345 (83%) consented to participate N= 201 women and N = 118 men Mean age = 53.4 years (SD = 13.9 years) Recruited through two pain centres – a back clinic and a pain management centre *Exclusions* 26 patients who returned invalid MMPI-2-RF protocols **Baseline Measures** MMPI-2-RF: Measures emotional, thought, behavioural, somatoform,	50% of participants had not completed the follow-up questionnaires at the time of data analysis. This may change with subsequent follow-up assessments. **Findings (3 – 6 month follow-up)** <u>Correlations between pre-operative MMPI scales and post-operative pain and disability scores</u> Pre-implant Emotional/Internalisation Dysfunction was significantly associated with all post-operative scores. Correlations from 0.24 (post-op pain level) to 0.52 (post-implant negative affect) Pre-implant Thought Dysfunction was significantly associated with higher post-implant negative affect only (r=0.24) Pre-implant Behavioural/Externalising Dysfunction was not significantly	Appropriate and focused question?	Y	Robust method but presents just short-term follow-up data at this point. 50% of participants did not complete the follow-up questionnaires for the 3-6 month follow-up period. No information on the responders vs non-responders and the findings may not be representative of the cohort. Study presents findings from first follow-up (3-6 months). Twelve and 24-month follow-up findings will be reported in due course Various MMPI scales seem to predict pain and disability
			Two groups sourced from comparable source populations	Y	
			Indicates how many people asked to took part in study	Y	
			Likelihood that some eligible subjects may have the outcome at the time of enrolment assessed and taken into account in analysis	N	
			% of individuals or clusters recruited dropped out	Y	
			Comparison made between full participants and those lost to follow-up	N	
			Outcomes clearly defined	Y	
			Assessment of outcome blind to exposure status	CS	

One of the authors is co-author of the MMPI-2-RF and receives royalties on the sales of this test	and interpersonal dysfunction Oswestry Disability Index: 10 item, self-report questionnaire that measures the impact of pain on patients functional ability Patient self-reported survey data: Self-report measure of pain levels, pain interference with lifestyle, implant outcome expectations, current emotional state **Follow-up Measures** Oswestry Disability Index Patient self-reported survey data: post-implant pain level; interference with lifestyle; did not meet expectations; dissatisfaction Three follow-up assessments following implantation: 3-6 months; 12 months; 24 months **Indications** Not reported	associated with any post-operative measures. Items which contributed to Emotional/Internalising Dysfunction scores were the strongest pre-implant predictors of negative outcomes. Specifically these were Demoralisation and Dysfunctional Negative Emotions. <u>Relative risk for post-implant pain, interference with lifestyle, dissatisfaction, expectations not met using MMPI-2-RF scales as predictors:</u> Participants with High Demoralisation scores had a higher relative risk for poor scores on all post-implant measures of pain and satisfaction (RR range 1.39 – 1.86) Participants with high Emotional Dysfunction scale scores had a higher relative risk of reporting poorer functional ability, negative affect and dissatisfaction (RR range 1.48 – 1.80) Participants with higher Malaise and Cognitive Complaints had a higher relative risk of reporting more functional impairment (RR 1.61) Participants with elevated substance abuse scores had an increased relative risk of dissatisfaction/expectations not met (RR 1.70) Participants with Low positive emotionality had an increased relative risk post-implant disability (RR 1.57), expectations not met (RR 1.56) and dissatisfaction (RR 1.70) Participants with elevated Negative emotionality/Neuroticism scores had an increased relative risk of post-implant	Recognition knowledge of outcome could have affected assessment	CS	outcomes post-implant. Cut-off scores were calculated for the different scales which could be used to identify patients who might be at an increased risk of negative outcomes. **Grade: 2+**
			Assessment method reliable	Y	
			Evidence from other sources used to demonstrate method of outcome assessment is valid and reliable	Y	
			Exposure level measured more than once	N	
			Main confounders identified and taken into account	Y	
			Confidence intervals provided	Y	
			Are results directly applicable to ACC claims for SCS?	Y	

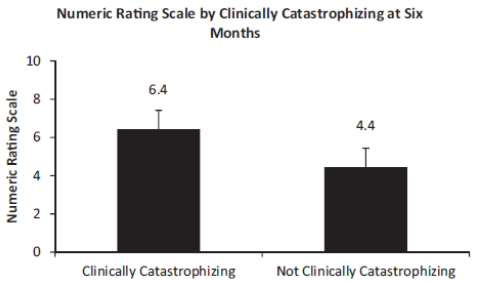
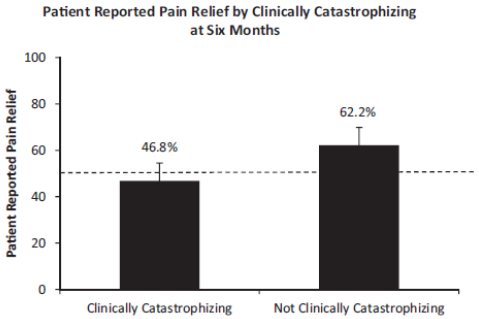
		disability (RR 1.63) **Authors conclusions** Emotional Dysfunction scales of the MMPI-2-RF were associated with poorer outcomes post-implant. These scales assess feelings of being overwhelmed, highly distressed, dissatisfied with life, inability to experience positive emotions, higher levels of anxiety and anger, and lack of self-confidence. "It appears that emotional dysfunction can affect cognition, motivation, compliance, and pain perception in ways that bode poorly for the outcome of SCS."			

Study	Methodology	Outcomes & results	Paper grading		Reviewer comments & evidence level
Lame et al (2009)[14] Anesthesia and Analgesia, 109(2): 592 - 599 **Study design:** Prospective cohort **Research question:** To examine the influence of catastrophising on the outcome of SCS **Funding** Not stated	**Participants** N=32 patients with CRPS-I treated spinal cord stimulation An additional 26 patients had an unsuccessful trial and did not proceed to the full implant. 3 patients did not complete follow-up questionnaires and so were excluded from analyses. 21% males, 79% females Mean age = 38.9 yrs (sd =10.5) Patients recruited through an outpatient pain clinic at the University Hospital, Maastricht, Netherlands	**Pre vs. Post-operative pain scores** 38% achieved at least 50% pain reduction following SCS 53% reported much improved or total pain relief 31% slightly improved 9% no improvement 6% worse **Pre- vs. post-operative HADS scores** None of the variables included in analyses, including catastrophising, were significantly different for those with successful outcomes compared with unsuccessful outcomes.	Appropriate and focused question?	Y	Relies on the accuracy of questionnaire data. Post-SCS pain levels were reported on the follow-up questionnaire. High return rate for questionnaire (90%) but 45% of participants did not progress to a full implant, so the final participants with SCS implants may not represent the initial sample very well. Patients were classified as successful or not successful based on their post-operative pain scores. There was quite a large standard deviation in PCS scores prior to SCS and
			Two groups sourced from comparable source populations	Y	
			Indicates how many people asked to took part in study	Y	
			Likelihood that some eligible subjects may have the outcome at the time of enrolment assessed and taken into account in analysis	N	
			% of individuals or clusters recruited dropped out	Y	
			Comparison made between full participants and those lost to follow-up	N	
			Outcomes clearly defined	Y	

No conflicts of interest declared	Patients were recruited between January 2000 and September 2006. Participants were sent a follow-up questionnaire to complete 9 months after SCS implantation. **Preoperative Questionnaire Package** Demographic Variables Disease Variables Pain Intensity VAS Global Perceived Effect (7-point scale from 1 'worst ever' to 7 'total pain relief' Quality of Life SF-36 Pain Catastrophising Scale **Post-operative Questionnaire Package** Pain Intensity VAS Global Perceived Effect Quality of Life SF-36 **Indications** CRPS-I 100%	Pain catastrophising scores: Mean (successful) = 34.4 (SD = 4.9) Mean (unsuccessful) = 29.0 (SD = 12.0), t = 1.50, p=0.15 **Authors conclusions** "We found no evidence for the predictive value of pain catastrophizing for SCS outcome in terms of pain intensity, GPE, and QOL in patients with CRPS-I."	Assessment of outcome blind to exposure status	CS	the small sample size may have reduced the power of the study to detect any differences in outcomes. Power calculations for a recommended sample size were not reported. **Grade: 2-**
			Recognition knowledge of outcome could have affected assessment	CS	
			Assessment method reliable	Y	
			Evidence from other sources used to demonstrate method of outcome assessment is valid and reliable	Y	
			Exposure level measured more than once	Y	
			Main confounders identified and taken into account	Y	
			Confidence intervals provided	Y	
			Are results directly applicable to ACC claims for SCS?	Y	

Study	Methodology	Outcomes & results	Paper grading		Reviewer comments & evidence level
Rosenberg et al (2015)[9] Neuromodulation,	Total patients enrolled = 620 across 45 different centres in the U.S. **N = 386** patients had a successful	**Findings** 6-month follow-up data available for 242 participants as the study is on-going	Appropriate and focused question?	Y	Tests the relationship between catastrophising and outcomes from SCS.
			Two groups sourced from comparable source populations	Y	

18: 277-284 **Study design:** Multi-centre Prospective cohort study **Research question:** To investigate the role of catastrophising in outcomes from SCS **Funding** EMPOWER study (Eon Mini Product Options, Wellness, Effectiveness and Relief)	trial and were implanted with the SCS device. Average age = 55.8 years (SD = 14.5 years) Mean Pain Duration = 10.5 years Mean Pain intensity = 7.3 (SD = 1.6) **Intervention** EonMini™ permanent IPG and leads **Inclusion criteria** Chronic intractable pain of the trunk and/or limbs Were at least 18 years of age Had a baseline pain intensity of at least 6 on the NRS **Pre-implant trial** Those who experienced greater than 50% pain relief at the end of a 5 day trial of SCS progressed to the full implant **Follow-up** 3, 6, and 12 month follow-up assessments. Patient demographics were collected at baseline. Questionnaires were administered at baseline (pre-implant) and during 3-, 6-, and 12-month follow-up visits (post-implant). **Data Collection** Pain Intensity: Numeric Rating Scale from 0 to 10 Patient-reported pain relief – greater than 50% relief considered clinically significant	Correlations were classified as follows: Weak: less than 0.3 Moderate: between 0.3 and 0.5 Strong: 0.5 and above **Correlations between pain intensity NRS scores and all other measures for each timepoint** PCS scores and anxiety scores at baseline were weakly correlated with pain intensity at baseline. PCS and anxiety scores at 6 months were moderately to strongly correlated with pain intensity at 6 months. This persisted after controlling for confounders. **Logistic Regression for clinically v non-clinically catastrophising patients** Participants were divided into two groups based on their catastrophising scores. PCS ≥30 was considered clinically significant PCS<30 non-clinical catastrophising Pain scores at each timepoint were compared for those above and below the cut-off. At baseline 56.9% of participants were considered to be clinically catastrophising. Patients who were clinically catastrophising had significantly lower patient-reported pain relief at 6 months follow-up ($F(1, 237) = 10.67$, $p<0.001$) and 12 months follow-up ($F(1,149) = 21.16$, $p<0.001$). The same pattern occurred for pain intensity at 6 and 12-months follow-up.	Indicates how many people asked to took part in study	Y	Study is ongoing so 6 and 12 month follow-up includes only those patients who have completed assessments so far. Focusses on catastrophising as one element of the Fear Avoidance Model (FAM), which explains how psychosocial factors can lead to pain-related fear, hypervigilance and avoidance, thereby increasing disability and subjective experiences of pain. Moderate to strong associations between concurrent catastrophising and pain intensity and pain relief outcomes were found at 6 month and 12 months follow-up. However, pre-implant catastrophising was not predictive of post-implant outcomes. **Grade: 2+**
			Likelihood that some eligible subjects may have the outcome at the time of enrolment assessed and taken into account in analysis	N	
			% of individuals or clusters recruited dropped out	CS	
			Comparison made between full participants and those lost to follow-up	N	
			Outcomes clearly defined	Y	
			Assessment of outcome blind to exposure status	Y	
			Recognition knowledge of outcome could have affected assessment	N	
			Assessment method reliable	Y	
			Evidence from other sources used to demonstrate method of outcome assessment is valid and reliable	Y	
			Exposure level measured more than once	Y	
			Main confounders identified and taken into account	Y	
			Confidence intervals provided	Y	
			Are results directly applicable to ACC claims for SCS?	Y	

	Pain Catastrophising Scale: 13 item questionnaire. Includes scores of magnification, rumination and helplessness. State-Trait Anxiety Index: 40 item questionnaire measuring both state anxiety (a temporary product of perceived threats) and trait anxiety (more permanent product of personality and beliefs). Quality of Life: 5-point Likert scale Satisfaction: 5-point Likert scale **Primary indication** CRPS I and II 5.1% Failed back surgery syndrome 42.8% Radiculopathies 32.4% Other 19.7%	  **Author conclusion:** Patients reporting higher levels of catastrophising reported higher levels of pain intensity and lower levels of pain relief, satisfaction and quality of life at 6-months and 12-months post-implant. This suggests that levels of catastrophising should be monitored prior to and following SCS implantation. Improving patients' catastrophising may improve outcomes from SCS.			

Study	Methodology	Outcomes & results	Paper grading		Reviewer comments & evidence level
Sparkes et al,	**Participants**	7 patients failed trial with SCS and 12 were	Appropriate and focused question?	Y	Suggests that it is not

(2015)[10] Pain Physician, 18: E369 - E377 **Study design:** Prospective cohort **Research question:** To identify psychological characteristics that may impact upon the efficacy of SCS **Funding** Faculty of Health, Birmingham City University No conflicts of interest declared	N = 68 patients who received a full SCS implant Mean age = 47.4 ± 1.5 yrs Mean duration of pain = 8.2 ± 0.8 yrs **Source population** N = 75 consecutive patients recruited from a pain clinic (7 patients failed trial implant and did not proceed to the full SCS implant) Eligible participants were patients aged 18 years and over with chronic neuropathic pain **Pre-SCS trial assessment** Assessment by a multidisciplinary team prior to referral for an SCS trial – pain consultant, clinical psychologist, physiotherapist Successful trial = more than 50% pain relief consistently reported at the end of the trial week **Exclusion criteria** - Medically unfit for implant surgery - Unrealistic expectations of treatment - Lack of comprehension - Unrealistic beliefs surrounding their pain **Assessment of psychological variables and pain and disability outcomes** Baseline, 6 months and 12 months after SCS implantation Pain intensity - Visual Analogue	lost-to-follow up N = 56 patients included in final analysis **Findings** Repeated measures ANOVA compared all outcomes at baseline, 6 months and 12 months follow-up and multivariate regression analyses were used to identify significant relationships between baseline factors and follow-up outcomes **Predictors of pain reduction at 12 months:** Gender, duration of pain prior to implant, HAD anxiety, HAD depression, Cognitive and Behavioural Strategies component of the PCSQ were not significant predictors of 12 month pain reduction. Age at time of implant ($p<0.013$) and the Autonomous Coping Component of the PCSQ ($p<0.032$) were significant predictors of 12 month pain reduction. **Predictors of improvement in ODI scores at 12 months:** Gender, age at time of implant, HAD anxiety and both components of the PCSQ were not significant predictors of 12 month ODI scores. Duration of pain prior to implant ($p<0.013$) and HAD depression ($p<0.009$) were significant predictors of ODI improvement at 12 months. Autonomous Coping component was comprised of items 'control over pain', 'ability to decrease pain', and 'catastrophising' **Author conclusion** "Suggests patients with increased	Two groups sourced from comparable source populations	Y	catastrophising alone but a combination of control over pain, ability to control pain and low levels of catastrophising that create optimal pain reduction outcomes (see discussion) 12/68 (17.6%) patients were lost to follow-up – may have been more severe/less favourable or more favourable outcomes – no information about those patients available Patients with unrealistic expectations and beliefs about the treatment were excluded from the study. While it would be useful to follow these patients it would be unethical to proceed with SCS implants. The consistent ethical concerns of health professionals about treating patients with unrealistic expectations and beliefs with SCS, suggests that unrealistic expectations and beliefs may be important psychosocial factors in outcomes of SCS **Grade: 2+**
			Indicates how many people asked to took part in study	Y	
			Likelihood that some eligible subjects may have the outcome at the time of enrolment assessed and taken into account in analysis	N	
			% of individuals or clusters recruited dropped out	Y	
			Comparison made between full participants and those lost to follow-up	N	
			Outcomes clearly defined	Y	
			Assessment of outcome blind to exposure status	CS	
			Recognition knowledge of outcome could have affected assessment	N	
			Assessment method reliable	Y	
			Evidence from other sources used to demonstrate method of outcome assessment is valid and reliable	Y	
			Exposure level measured more than once	N	
			Main confounders identified and taken into account	Y	
			Confidence intervals provided	Y	
			Are results directly applicable to ACC claims for SCS?	Y	

	Scale Oswestry Disability Index (ODI) Hospital Anxiety and Depression Scale (HADS) Pain Coping Strategies Questionnaire (PCSQ) – factor analysis created two scores from this measure: Autonomous Coping component and Cognitive and Behavioural Strategies component **Indications:** FBSS = 42.6% CRPS = 33.3% Other = 24.1% (e.g. arachnoidoitis, coccydynia)	perceived control over pain and the ability to decrease pain, alongside lower levels of catastrophising at baseline, achieve greater reductions in pain at 12 months." "Psychological characteristics such as depression and autonomous coping strategies may influence and predict the long-term efficacy of SCS. Also, age at time of implant and duration of pain prior to implant were found to impact SCS outcome. Support for patients with low autonomous coping strategies and long-standing depression prior to implant may prove efficacious to longterm SCS outcome."			

Retrospective Cohort Studies

Study	Methodology	Outcomes & results	Paper grading		Reviewer comments & evidence level
Bendinger et al (2015)[11] Neuromodulation, 18: 465 - 471 **Study design:** Retrospective cohort – review of patient records **Research question:** To identify pre-SCS implantation psychological variables which	**Participants** N = 92 patients who underwent SCS between 2005 and 2013 in the Sheffield Chronic Pain Service 9 patients lost-to-follow up because of SCS failure, infection, lack of documentation N = 83 with 1 year follow-up data **Source population** A total of 176 patients were referred as possible candidates for SCS. 113 were approved for SCS trial following MDT assessment,	**Classification of successful outcome from SCS** Successful outcome defined as at least 50% pain reduction from pre-implantation pain at 1 year follow-up using validated NRS Successful outcome: N= 39 patients Not successful outcome: N = 44 patients ~61% in each group had a formal psychological assessment **Analyses** Possible predictor variables were then	Appropriate and focused question? Two groups sourced from comparable source populations Indicates how many people asked to took part in study Likelihood that some eligible subjects may have the outcome at the time of enrolment assessed and taken into account in analysis % of individuals or clusters recruited dropped out Comparison made between full participants and those lost to	Y Y N N Y N	Study compared psychological risk factors in a group of 83 patients who had received a permanent SCS implant and had follow-up data available 1 year post-implant. The group were divided in to successful and not successful outcomes based on their levels of pain reduction at 1 year follow-up. Patients with major psychiatric disorders, major depression or drug or alcohol addiction were already excluded from this

might predict outcome **Funding** Clinical Effectiveness Department, Sheffield Teaching Hospital	with 92 patients receiving a permanent implant. **Criteria for full SCS implantation** Conventional medical management and CBT unsuccessful in treating pain Multidisciplinary team approval (including psychological assessment where appropriate). MDT: pain medicine consultants, SCS specialist nurse, clinical psychologist, consultant functional neurosurgeon All candidates completed self-report questionnaires. These were assessed by a specialist nurse who referred patients to a clinical psychologist if needed. Successful trial – 2-7 days, at least 50% pain reduction + significant return of physical functioning + adequate paraesthesia coverage of the index pain topography **Exclusion criteria for SCS** Medical conditions which prevent implantation of SCS, short life expectancy, presence of another significant pain condition, inconsistent pain scoring, lack of compliance with current pain therapies, history of substance abuse, major depressive or suicidal behaviour, serious cognitive impairment, and any other significant psychiatric comorbidities **Self-report measures of pre-implantation variables** Hospital Anxiety and Depression	compared for the two groups **Univariate analyses** No significant differences in indications for SCS between the two groups. **Preimplantation scores for 'successful' versus 'not successful' outcome groups** No significant differences in age, gender, or length of pain prior to implantation for the two groups. Successful Not successful Median pain: 8 8, NS Sleep interference: 7 8, p <0.05 Pain catastrophising: 20.5 31, p <0.05 HADS Depression: 8 11, p <0.05 Pain Self-Efficacy: 21 16, p<0.05 HADS Anxiety 7.5 9, p=0.21 Distress level: 8 8, p=0.54 **Receiver Operating Characteristic (ROC) curves** Cut-off thresholds were calculated using ROC curves for measures where there were significant differences in initial analyses (sleep interference, HADS depression, catastrophising, pain self-efficacy). Patients were then subdivided again into groups based on whether they were above or below these thresholds and outcomes for these groups were compared. HADS depression score >10 and PSEQ score ≤ 18 found to be dependent risk factors for failure of SCS treatment. Strong	follow-up		group so the analyses compare outcomes in a relatively psychologically sound group of people. The differences between the two groups could therefore be subtle. Used validated questionnaires to assess psychological factors, however only a proportion of patients had a full assessment with a clinical psychologist. A NRS was used to measure sleep interference which may not be as reliable as using a dedicated sleep interference scale. SCS procedures were performed over an 8-year period between 2005 and 2013, however the authors stated that patient selection criteria and trial methodology remained stable during this time. **Grade: 2+**
			Outcomes clearly defined	Y	
			Assessment of outcome blind to exposure status	CS	
			Recognition knowledge of outcome could have affected assessment	N	
			Assessment method reliable	Y	
			Evidence from other sources used to demonstrate method of outcome assessment is valid and reliable	Y	
			Exposure level measured more than once	N	
			Main confounders identified and taken into account	Y	
			Confidence intervals provided	Y	
			Are results directly applicable to ACC claims for SCS?	Y	

	Scale Pain Catastrophising Scale Pain Self-Efficacy Questionnaire – beliefs and attitudes in reporting pain, confidence in coping with pain Intensity of Pain – Numerical Rating Scale Sleep quality - Numerical Rating Scale Distress during daily activities – Numerical Rating Scale **Indications:** FBSS = 48.2% Refractory radiculopathy or peripheral neuropathy = 21.7% CRPS = 22.9% Refractory angina = 4.8%	correlation between HADS depression score and PSEQ score. Sleep interference score >7 found to be an independent risk factor. OR (HADS depression score >10) = 2.99, 95% CI = 1.16 – 7.68 OR (PSEQ ≤ 18) = 2.84, 95% CI 1.13 – 7.14 OR (sleep interference >7) = 6.38, 95% CI 1.69 – 24.03 **Author conclusion** Out of six evaluated psychological factors—distress, risk of anxiety, risk of depression, catastrophising, sleep interference, and lack of confidence in performing physical activities—only measures of sleep interference, depression, and lack of confidence in performing physical activities were found, in this study, to be risk factors for a suboptimal outcome after SCS implantation.			

Study	Methodology	Outcomes & results	Paper grading		Reviewer comments & evidence level
Sumner and Lofland (2014)[12] Chronic Illness, 10(3), 157-166 **Study design** Retrospective cohort **Research question**	N = 58 patients who had received a permanent SCS implant at a US pain clinic 84 patients were initially recruited but only 58 were included in the final analyses due to missing data points **Inclusion criteria**	**Findings** **Pre-SCS pain scores** Medical diagnosis, marital status and catastrophising all significantly associated with pre-surgical VAS scores Catastrophising and pre-SCS VAS (r = -0.03, p<0.05) **Post-SCS surgery pain scores**	Appropriate and focused question? Two groups sourced from comparable source populations Indicates how many people asked to took part in study Likelihood that some eligible subjects may have the outcome at the time of enrolment assessed and taken into account in analysis	Y Y N N	Retrospective study based on chart review 84 patients recruited but only 58 (69%) included in final analyses due to missing data. No functional measure of pain Most of the correlations

To evaluate the association between presurgical factors and pain intensity following SCS **Funding** No specific grant – no conflicts of interest	18 years and older Diagnosis of a chronic, intractable pain Successful response to trial stimulation (≥ 50% pain relief) **Methods** Outcomes based on chart review – only patients with eight VAS scores pre-surgery and eight VAS scores post-surgery were included in analyses **Psychological screening prior to selection for trial implant** Semi-structured interview Self-report measures Medical chart review **Exclusions prior to full implant:** Significant psychopathology Patterns of non-adherence (missed appointments) Actively abusing drugs or alcohol **Pre-surgical Measures** <u>MMPI-2: 3 subscales</u> Hysteria – awareness of problems and vulnerabilities Hypochondriasis - concern with bodily symptoms Depression <u>Coping Strategies Questionnaire:</u> Catastrophising subscale (6 items) <u>VAS</u> (0 = no pain to 10 – worst pain imaginable) Subjective pain	BMI, medical diagnosis, employment, ethnicity, marital status all significantly associated with post-SCS VAS scores Bodily concern scale of the MMPI-2 ($r=0.22$, $p<0.05$) significantly associated with post-SCS pain scores. Depression and catastrophising not significantly associated with post-SCS pain scores. **Author conclusion** The majority of the sample reported elevations on some of the presurgical psychological factors, particularly pain sensitivity and somatic preoccupation. Bodily concern was significantly associated with post-SCS pain scores.	% of individuals or clusters recruited dropped out	Y	with pre- and post-VAS measures of pain were very weak even though some of them were statistically significant. **Grade: 2-**
			Comparison made between full participants and those lost to follow-up	N	
			Outcomes clearly defined	Y	
			Assessment of outcome blind to exposure status	CS	
			Recognition knowledge of outcome could have affected assessment	N	
			Assessment method reliable	Y	
			Evidence from other sources used to demonstrate method of outcome assessment is valid and reliable	Y	
			Exposure level measured more than once	N	
			Main confounders identified and taken into account	Y	
			Confidence intervals provided	Y	
			Are results directly applicable to ACC claims for SCS?	Y	

	intensity **Indications** CRPS = 51.9% Non-CRPS low back pain = 33.3% Other = 7.4% Cervical pain = 3.7% Possible CRPS = 3.7%				

Study	Methodology	Outcomes & results	Paper grading		Reviewer comments & evidence level
Wolter et al (2013)[13] Pain Physician, 16: 265-275 **Study design:** Retrospective cohort - chart review **Research question:** To examine the influence of psychological factors on the outcome of SCS **Funding** Not stated No conflicts of interest declared	**Participants** N=46 consecutive patients treated with lumbar, thoracic or cervical neurostimulators An additional 6 patients had an unsuccessful trial and did not proceed to the full implant. Patients recruited through the University Hospital Freiburg Interdisciplinary Pain Center Patients were treated between July 2008 and July 2012. Patient records were reviewed and all participants were sent a follow-up questionnaire to complete (mean 4.8 years after implantation). **Preoperative Assessments – based on retrospective review of records** Diagnosis	N=37/46 patients (80.4%) completed the questionnaire **Characteristics of completers** Mean age at time of implant = 52.7 years (range 33.4 – 74.7 years) Mean duration of pain = 7.5 ± 6.2 years Mean time elapsed since implant = 4.8 years ± 4.3 years (range 0.1 – 14.5 years) **Pre vs. Post-operative pain scores** Preoperative pain score, mean = 7, SD = 1.7 Follow-up Pain Scores: Without stimulation = 6.5, SD = 1.9 With stimulation = 3.3, SD = 1.5 Preoperative Pain-related Disability = 44.2, SD = 13.9 **Pre- vs. post-operative HADS scores** Pre Post p-value	Appropriate and focused question?	Y	Post-SCS pain levels were reported on the follow-up questionnaire. An average of 4.8 years had elapsed since the patients had the SCS procedure, ranging from 0.1 to 14.5 years. Would have been better if patients had completed follow-up questionnaires at standard post-operative intervals, e.g. 12 months, 2 years. Patients were classified as successful or not successful based on their post-operative pain scores at this time. It is possible though that some may have initially had a successful response but by 4 years post-procedure they were no longer experiencing good results and were classified as not successful.
			Two groups sourced from comparable source populations	CS	
			Indicates how many people asked to took part in study	Y	
			Likelihood that some eligible subjects may have the outcome at the time of enrolment assessed and taken into account in analysis	N	
			% of individuals or clusters recruited dropped out	N	
			Comparison made between full participants and those lost to follow-up	N	
			Outcomes clearly defined	Y	
			Assessment of outcome blind to exposure status	CS	
			Recognition knowledge of outcome could have affected assessment	NA	

	Duration of disease Pre- and post-operative pain scores: 11 point NRS Preoperative duration of disease Preoperative depression and anxiety: HADS Preoperative Pain Disability Index **Follow-up questionnaire post-surgery** Pain Scores with and without stimulation: 11 point NRS Time intervals of stimulation Paresthesia coverage Treatment satisfaction Medication intake Anxiety/depression: HADS; BDI Pain Disability Index Self efficacy: Pain Self-efficacy Questionnaire **Indications** FBSS = 43.2% Peripheral neuropathic pain = 21.6% Peripheral arterial occlusive disease = 13.5% CRPS = 10.8% Chronic cluster headache = 8.1% Angina pectoris = 2.7%	HADS Anxiety 8.6 7.1 0.1365 HADS Depression 9.8 7.4 0.0053 HADS total 18.5 14.5 0.0375 **Successful v Unsuccessful Outcomes from SCS** <u>Pain</u> Patients were grouped based on level of post-operative pain reduction compared with pre-operative scores: Successful = 50% or greater pain reduction (n=24) Not successful = <50% pain reduction (n=13) There were no significant differences in pre-operative psychological scores between successful and not successful SCS patients. <u>Anxiety/Depression</u> No statistically significant difference in pre-operative HADS scores between those with successful and unsuccessful SCS trials. **Authors conclusions** Pre-operative depression/anxiety and pain-related disability did not predict outcome from SCS in the current study.	Assessment method reliable Evidence from other sources used to demonstrate method of outcome assessment is valid and reliable Exposure level measured more than once Main confounders identified and taken into account Confidence intervals provided Are results directly applicable to ACC claims for SCS?	N Y N Y Y Y	This misclassification may have impacted on the detection of significant associations between pre-operative assessments and post-operative pain scores. No pre-operative self-efficacy scores were collected. **Grade: 2-**

Systematic Reviews

Study	Methodology	Outcomes & results	Paper Grading		Reviewer comments & evidence level
Sparkes et al (2010)[7] Pain, 150: 284 - 289 **Study design:** Systematic review **Research Question** To investigate psychological characteristics as determinants of outcome for spinal cord stimulation **Funding** Not stated No conflicts of interest declared	**Search strategy** Cochrane, CINAHL, Medline, PsychInfo, PsychArticles searched up to July 2009 Handsearched references of reviews for additional studies Two authors retrieved and selected references for inclusion **Inclusion criteria** Prospective cohort studies, case control, case series Studies of the influence of psychological variables on outcomes from SCS Assessment of psychological variables through questionnaires, psychological tests, interviews, algorithms Subjects were chronic pain patients **Exclusion criteria** Single case studies Reviews or guidance papers that didn't include original research **Quality Assessment** Studies quality assessed using the Public Health Critical Appraisal Skills	**Included Studies** N=95 studies identified N= 9 studies met inclusion criteria Patients were generally sourced through pain clinics Mainly low back and leg pain due to FBSS Five prospective trials, follow-up varied from 3 months to 3.5 years **Efficacy of SCS** Measured in different ways and varied from reduction in pain of 30-50%, to return of previously painful activities and in one study, rating SCS as 'slightly helpful' or above Main indications for SCS were neuropathic leg and back pain **Psychological Characteristics** MMPI and MMPI-2 were most common measures, followed by the Hospital Anxiety Depression Scale, Beck Depression Inventory and Hamilton Psychiatric Rating Scale **Depression** 6 studies: 3 studies with more than 6 months follow-up None of the studies reported whether depression scores reflected depression before or after the onset of chronic pain – may be important given depression can improve with SCS or be treated	Clearly defined research question Two people selected studies and extract data Comprehensive literature search carried out Authors clearly state how limited review by publication type Included and excluded studies listed Characteristics of included studies are provided Scientific quality of included studies assessed and documented Scientific quality of included studies assessed appropriately Appropriate methods used to combine	**Y** **Y** **Y** **Y** **N** **Y** **?** **?** **Y**	A thorough search strategy and synthesis of the evidence Not clear what the results of the quality appraisal of included studies were. Difficult to judge the impact of the individual studies without details of the quality appraisal High variability in the way psychological variables were measured and efficacy of SCS meant that the authors were unable to perform a meta-analysis **Grade: 2++**

	Programme for Cohort Studies	prior to implantation with SCS and may not be a complete contra-indication **Mania** Two studies – both suggested mania may impact on the efficacy of SCS however one study investigated only the trial period and 1 study included only 11 participants **Hysteria** As above for mania **Hypochondriasis** Disparity in the findings. Two studies reported higher scores associated with a positive outcome and two studies that higher hypochondriasis was associated with less positive outcomes from SCS **Interviews** One study compared the results of a psychiatric interview to that of standardised questionnaires and found agreement for all but one patient. **Authors conclusions** Depression may not be an exclusion criteria for SCS but could be considered an additional target for treatment alongside SCS. Results were inconclusive for mania, hysteria and hypochondriasis.	individual study findings Likelihood of publication bias assessed Conflicts of interest declared Are results of study directly applicable to patient group targeted by guideline?	**N** **Y** **Y**	

Study	Methodology	Outcomes & results	Paper Grading		Reviewer comments & evidence level
Celestin et al (2009)[6] Pain Medicine, 10 (4): 639 - 653	**Search strategy** PubMed, Cochrane Central, Embase, PsycInfo and Web of Science searched to August 2008	**Included studies** N=753 studies identified of which 25 eligible articles were included	Clearly defined research question Two people selected studies and extract	**Y** **Y**	A thorough search strategy. Included only prospective studies so the number of included studies is small. Study characteristics and

Study design: Systematic review **Research question:** To examine the relationship between presurgical psychosocial predictor variables and outcomes from SCS **Funding** Not stated	Handsearched references of reviews for additional studies Two authors retrieved and selected references for inclusion **Inclusion criteria** Prospective study design Back pain as primary complaint Undergone lumbar spine surgery or implantation of an SCS device Follow-up 3 weeks or longer Identified pre-treatment psychological variables to predict treatment outcome **Exclusion criteria** No statistical analysis of predictor variables Non-English language Letters, conference proceedings **Quality Assessment** Studies quality assessed by two reviewers – unclear whether standardised checklist was used	N=4 studies of SCS **Findings** <u>Study Diagnosis</u> Burchiel et al (1995) CLBP/or leg pain North et al (1996) CLBP Dumoulin et al (1995) FBSS Long et al (1981) Mixed <u>Psychological factors</u> Baseline Psychological Measures: Minnesota Multiphasic Personality Inventory, California Personality Inventory, 24-item questionnaire (not named, possibly not a validated tool), McGill Pain Questionnaire, Derogatis Affects Balance Scale Found to be predictive of outcome in 3 out of 4 studies. Psychological variables varied between studies but included: Burchiel et al (1995) MMPI depression scores correlated with poor outcome, 3-6 month follow-up North et al (1996) Low DABS anxiety score predicted a successful trial, 2 years follow-up Dumoulin et al (1995) 'psychological themes' from a 24-item psychodynamic questionnaire predicted outcome, 6 month follow-up Long et al (1981) Not well reported – referred to as 'psychological factors', up to 7 years follow-up **Authors conclusions** The findings suggest the possibility of an	data Comprehensive literature search carried out Authors clearly state how limited review by publication type Included and excluded studies listed Characteristics of included studies are provided Scientific quality of included studies assessed and documented Scientific quality of included studies assessed appropriately Appropriate methods used to combine individual study findings Likelihood of publication bias assessed Conflicts of interest declared Are results of study directly applicable to patient group targeted	**Y** **N** **N** **Y** **Y** **?** **Y** **N** **N** **Y**	methodologies were not reported well in this review, it is unclear whether one study was truly prospective in design, and the studies were not critically appraised. Studies varied widely in the psychological factors they investigated so synthesis of the findings was difficult. While 3 out of 4 studies indicated an association between pre-SCS variables and post-SCS outcomes, the authors were unable to make any firm conclusions. **Grade: 2++**

		association between pre-treatment psychological variables and outcomes from SCS but it cannot be clearly determined by the current evidence. There have been no trials comparing outcomes of SCS after having or not having pre-treatment psychological screening. MMPI was the most common tool used to assess psychological variables but this may in part reflect the era in which many of the studies were carried out (1980s)	by guideline?		